National Institute for Health and Care Excellence

Medicines Optimisation
Scope Consultation Table
Consultation 9th September – 4th October 2013

Unique comment ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
1	SH	Leonard Cheshire disability	1	4.1.1 a)	Should include people moving in or out of supported care environments ie care homes, nursing homes, supported living, domiciliary care – any environment where health or personal care is provided which might include support with medicines management or administration	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
2	SH	Leonard Cheshire disability	2	4.1.1	Include non professional carers of people receiving care – they can be instrumental in medicines compliance	Thank you for your comment. Carers have been added to the population section of the scope.
3	SH	Cambridge university hospitals NHS Trust	1		 65167.pdf	Thank you for your comment. The key issues section of the scope has been amended. The population section of the scope has been amended to reflect your comment.
4	SH	Steve Turner Innovations	1	4.1.1 a)	Could this include a point on patients who are seen by a variety of different prescribers simultaneously? Rationale: It is commonplace, in paediatric community care, for children with complex conditions and at the end of life to have medicines prescribed concurrently by 5 or more prescribers. This does happen for other groups too, for example those who move between primary and secondary care with mental illness.	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
5	SH	Steve Turner Innovations	2	3 f	Not sure if this adequately describes the situation. To me this implies that people are	Thank you for your comment.

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					always transferred from provider to provider in a planed and measured way. In some cases (paediatrics) patients are seen by different providers on the same day e.g. special school in the morning; short break house in the afternoon; home care team at night; Community Pead .Nurse in the morning. I don't think there's anything to add to the document, just wanted to point out that for some, multiple medicines reconciliations can happen in a day.	
6	SH	Swansea University	1	General	This work addresses an important gap in health care delivery. The text is clearly set out.	Thank you for your comment.
7	SH	Swansea University	2	4.1.1 a)	The list of patient groups should be expanded to include pregnant and lactating women, and women in labour.	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
8	SH	Swansea University	3	4.3.1	There is no mention of service user engagement with medication monitoring or regular systematic checks for any of the known adverse effects of medicines. Examples are available[1-3].	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
9	SH	Swansea University	4		It would be helpful to acknowledge that multidisciplinary team-working extends beyond sub-optimal use of medicines to monitoring any adverse effects of medicines.	Thank you for your comment.
10	SH	Swansea University	5		Monitoring errors fall within the scope of accepted definitions of medication errors[4], but are poorly defined in the literature. The guideline development group offers an opportunity for this. There is relatively little work in this area, other than monitoring venous blood samples.	Thank you for your comment.
11	SH	Swansea University	6		Reviewing and monitoring patient outcomes is a key aspect of medicines optimisation, and	Thank you for your comment. The detail of your comments may be

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					should be given greater prominence in the scoping document. Interventions directed at medication monitoring should be explored in relation to the goal to reduce preventable medicines-related hospital admissions.	considered in the review protocols to answer the finalised review questions when signed off by the GDG.
12	SH	Swansea University	7		There is no mention of the roles of nurses. Nurses usually spend more time with patients and know them better than other practitioners. They are ideally placed to undertake medicines monitoring, and our studies indicate direct patient benfits[1,5,6,7].	Thank you for your comment. The 'need for the guideline' has been amended to reflect your comment.
13	SH	Swansea University	8		The importance of monitoring and interpreting vital signs in relation to medicines administered should be included in the scope of the guideline.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
14	SH	Swansea University	9	4.4	Monitoring errors will need to be closely defined, as above.	Thank you for your comment.
15	SH	Swansea University	10		Global outcomes, such as quality of life, are poorly suited to examining the impact of strategies to optimise medications, such as medication reviews[8,9].	Thank you for your comment.
16	SH	Swansea University	11	4.6	Our work indicates that medicines optimisation results in improvements in care which are unlikely to be reflected in economic costs[1,5,6,7]. Existing instruments are insufficiently sensitive to record important aspects of patient welfare, such as improved management of xerostomia or urinary tract infections, and improved use of services, such as dentists and opticians.	Thank you for your comment.
17	SH	Swansea University	12	5.2	There are no existing NICE guidelines on medicines monitoring. A NICE guideline in this area would benefit both practitioners and service users.	Thank you for your comment.
18	SH	Association for	1	4.1.1.	We would particularly ask that pregnant and	Thank you for your comment. The

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		Improvements in the Maternity Services			breast-feeding women and neonates should be included as special categories. We receive many queries and problems on our national help line. These include (a) women who are already on medication when they become pregnant – eg for epilepsy, mental illness, etc., (b) women who feel that GPs, health visitors and midwives with whom they have most contact, are not well informed and they do not feel reassured by their advice (c|) women who wish to continue breast-feeding but are doubtful about using prescribed medication (d) parents of neonates in special care baby units who are worried or unhappy about the quantity and type of medication they are being given. Sometimes women on medication give up breast-feeding unnecessarily for fear of effects of drugs on the infant, or are wrongly advised by health visitors that they need to give up. We would especially ask for more involvement of paediatric and neonatal pharmacists, and for parents to have direct access to them. A further problem is that available data on safety seems to be based on only short-term research, and not on longer term follow- up of exposed foetuses or neonates. Thoughtful parents know very well that longer term problems may exist. In Recommendations for Research we hope that follow-up studies of exposed and control children will be recommended. .	population section of the scope has been amended to reflect your comment.
19	SH	Association for Improvements in the Maternity	2	3 (g) 4.3.1.	*The right to be involved in discussions about care.* We are seeing a number of complaints from	Thank you for your comment. The key issues section of the scope has been amended.

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		Services			parents of babies both in and out of hospital, that their queries as parents trying to take seriously the responsibility for this new life, are met not with information but with threats to report them to social services if they do not "comply". Questions are thereby silenced, and thoughtful, learning, responsible parenting with shared decision-making is discouraged. Could you please emphasise that the right to have information and ask questions also extends to parents responsible for children who are minors, even babies? We are in touch with a number of families sometimes for years after initial contact, and cannot emphasise too strongly how damaging such authoritarian responses are. They lead to long-term distrust of health care services, reduction in sharing information, reluctance to consult in any future incident where parents fear criticism, more use of alternative practitioners…… All these points and more we have already stressed to Chief Medical Officers in the UK.	
20	SH	Association for Improvements in the Maternity Services	3	General	See NICE guideline PH11 on maternal and child nutrition, http://publications.nice.org.uk/maternal-and-child-nutrition-ph11/recommendations#breastfeeding-3 Recommendation 15.	Thank you for your comment. We are unable to include all related NICE guidance.
21	SH	NHS North Somerset CCG	1	4.1.1(a)	Are patients approaching end of life worthy of specific mention or are they sufficiently included in the existing categories?	Thank you for your comment. The population section of the scope has been amended.
22	SH	NHS North Somerset CCG	2	4.2 (a)	Should care homes be specifically mentioned?	Thank you for your comment. NICE are developing good practice

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						guidance for managing medicine in care homes.
23	SH	NHS North Somerset CCG	3	4.3.1 (b)	Should electronic prescribing be specifically mentioned and addressed?	Thank you for your comment. Electronic prescription service (EPS) is an area that will not be covered in the guideline.
24	SH	University of Bolton		4.1.1	Also include all practitioners who prescribe medicines.	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
25	SH	NHS Dorset CCG	1	General	Some issues such as repeat dispensing are part of the community pharmacy contract, may need some experience in community pharmacy commissioning in the group that reviews this guidance.	Thank you for your comment.
26	SH	NHS Dorset CCG	2	General	Some issues with general practice and community pharmacy may require contractual changes to successfully implement, or other levers. For example QoF has removed the medicines points, which were good levers for getting medicines initiatives implemented. How to incentivise and deliver recommendations for medicines optimisation may be a challenge without contractual levers. Similarly the monitoring of some drugs and their outcomes is associated with directed Enhanced services, such as Near patient testing and osteoporosis in general practice and whilst such schemes may be outside of the scope of this guidance, the method of implementation would need to take them into account.	Thank you for your comment.
27	SH	NHS Dorset CCG	3	3 i)	May be difficult to consider decision making, which will influence adherence whilst excluding CG76	Thank you for your comment. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this

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						subject).
28	SH	NHS Dorset CCG	4	General	Since this will be all NHS funded care, may need to link to the care homes medicines advice as this will be a more challenging environment when it comes to implementation.	Thank you for your comment.
29	SH	NHS Dorset CCG	5	General	Need to remember dispensing practice patients when considering the advice, review and support for new medicines etc, as they will not have access to a pharmacist.	Thank you for your comment.
30	SH	NHS Dorset CCG	6	General	The scope is very broad, bringing in the whole decision making process, medicines management processes such as repeat dispensing and prescribing and trying to look at uptake of NICE TAs as well as all of the interfaces of care and medicines reconciliation across all settings. May end up being more of a medicines management process guidance rather than a making sure individual patient care is optimised around medicines, with monitoring review and personalisation around the individual.	Thank you for your comment. The scope has amended to reflect your comment.
31	SH	Multiple Sclerosis Trust	1	General	The MS Trust is very happy with the draft scope.	Thank you for your comment.
32	SH	Multiple Sclerosis Trust	2	4.3.1	We are particularly pleased to see that shared decision making and decision aids are considered 'in scope' at 4.3.1 *Patient and carer engagement in shared decision making* point d) and *Evidence-informed decision making* at point f)	Thank you for your comment.
33	SH	Multiple Sclerosis Trust	3	General	Is there any clarification on how the Guideline will inform the work of the Medicines Optimisation Clinical Reference Group that is part of NHS England?	Thank you for your comment. The NICE short clinical guideline methodology will be used to develop the guidance. Organisations are able to contribute to guidance development at the draft consultation stage.

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34	SH	British Society for Rheumatology			Thank you for the reminder of the deadline for comments on this scope. This was circulated to the members of our Clinical Affairs Committee, but I have not received any specific comments on the various sections of the scope. However, BSR fully recognises the importance – especially to a speciality such as Rheumatology, with its focus on long term conditions - of ensuring that patients get the best medicine, in the optimum dose, for the correct length of time, with appropriate monitoring and that the patient is involved in decisions about prescribing. Therefore we would like to endorse the scope and look forward to being kept in the picture as this Guideline progresses.	Thank you for your comment.
35	SH	Royal College of Pathologists	1	4.3.1 (c)	There is no mention of choice in the document	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
36	SH	Royal College of Pathologists	2	4.1.1 (a)	No mention of mental illness or drug use and abuse	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
37	SH	Royal College of Pathologists	3	4.3.1 (a)	The guideline will not be exclusively for patients, and might better refer to "people". Not all who take medicines regard themselves as patients (eg oral contraceptives)	Thank you for your comment. Terminology for' patients' or 'people' will be determined by NICE publishing team.
38	SH	Public Health England	1	General	The following comments have been requested: Do you think this scope could be changed to better promote equality of opportunity relating to age, disability, gender, gender identity, ethnicity, religion and belief, sexual orientation or socio-economic status? In answering this question, please include details of: • Which particular parts of the scope you think	Thank you for your comment.

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					affect equality of opportunity. • Why and how you think equality of opportunity is affected PHE endorses the scope as laid out in the consultation as it includes all patient groups using medicines	
39	SH	Public Health England	2	3a and 3b	NICE has asked the question: For the purpose of this guideline, we have outlined a definition of medicines optimisation (see section 3a). Do you agree with this definition? PHE endorses this definition as it lays out clearly the differences between medicines optimisation and medicines management	Thank you for your comment.
40	SH	Public Health England	3	General	NICE has stated it is interested in knowing whether there are any specific areas throughout the patient journey that particularly need to improve in relation to medicines optimisation. Transfers of care are mentioned and PHE endorses this part of the patient journey which could be improved. The introduction to the consultation specifies the financial costs of waste medicines not taken and the costs of adverse effects of medicines. It would be useful to include a dialogue on medicines not taken as intended in terms of both financial costs and the detrimental results for patients. It would be useful to include information about medication errors in addition to adverse drugs	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.

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					reactions and potential steps to reduce the incidence of medication errors. It would be useful to have clear guidance on the responsibilities of all involved in medicines optimisation. Mention should be made with regard to withholding medicines requested by patients with an explanation of the reasons	
41	SH	Public Health England	4	General	NICE has asked: What are the key priority areas for the guideline to focus on? PHE is an organisation which supports evidence-based decision making and endorses this approach.	Thank you for your comment.
42	SH	Public Health England	5	4.1.1	NICE has asked: Are there any groups that should be covered within the guideline that have not been listed? 4.1.1. b states the scope will cover all practitioners who administer medicines. PHE considers this should be extended to cover all practitioners who prescribe, supply, dispense and/or give advice about medicines, whether directly to the public or to other health and social care practitioners.	Thank you for your comment. The scope has been amended to reflect your comment.
43	SH	Public Health England	6	4.3.1	This section mentions intra- and inter-professional collaboration and transfer of medicines information across care settings. PHE would like to point out this extends not just across traditional interfaces, such as primary and secondary care, but also includes a number of potential agencies such as local authorities, social care, mental health and public health	Thank you for your comment. The scope has been amended to reflect your comment.

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					services.	
44	SH	Public Health England	7	General	PHE endorses all the other items proposed for the scope of the guidance.	Thank you for your comment.
45	SH	NHS Greater Manchester Commissioning Support Unit	1	3 f)	"30% to 70% of patients have an error or unintentional change to their medicines when their care is transferred" This seems like a wide range to quote. Is this statistic and others in section 3 referenced in the main document?	Thank you for your comment. NICE style indicates that referencing is not required in the scope.
46	SH	NHS Greater Manchester Commissioning Support Unit	2	4.1.1 b)	I think the scope should include "all practitioners who prescribe and administer medicines"	Thank you for your comment. The scope has been amended to reflect your comment.
47	SH	NHS Greater Manchester Commissioning Support Unit	3	4.3.1 evidence informed decision making g)	Pharmacists ordering prescriptions on behalf of a patient to fulfil a free- non NHS - collection and/ or delivery service should be included in the scope as this is where many items are given incorrectly to a patient. This especially occurs when, without confirming what is required with the patient, the pharmacy may order items which have been stopped or reduced in frequency or may not order a new item if they do not have up to date patient records.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
48	SH	NHS Greater Manchester Commissioning Support Unit	4	4.3.1 reducing medicines-related patient safety incidents i)	"sub- optimal" use may be due to patient choice rather than poor communication or explanation	Thank you for your comment.
50	SH	Arrhythmia Alliance	1	4.1.1	Other groups to consider: (1) People with a chronic condition and (2) people who should have their medications reviewed for optimal therapy.	Thank you for your comment.
51	SH	Arrhythmia Alliance	2	4.3.1	Working with patient organisations for patient and clinician education and awareness of medicine optimisation. In terms of transferring information across the care system, it is important to focus on how this	Thank you for your comment.

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					will be done.	
52	SH	Arrhythmia Alliance	3	4.3.2	We feel that (j) Education and training of health and social care practitioners relating to medicines should both be considered in the scope. This is so that the best patient outcomes for medicine optimisation can be reached.	Thank you for your comment. Health Education England (HEE) was established as a special health authority in June 2012 and assumed full responsibilities from April 2013. HEE now hold responsibility for providing leadership, planning and development of the whole healthcare and public health workforce, in relation to education and training.
53	SH	The Christie NHS Foundation Trust	1	General.	The Christie is very supportive of this initiative and this guidance.	Thank you for your comment.
54	SH	The Christie NHS Foundation Trust	2	General.	The Christie feels that specific reference may need to be made to cancer patients and the difficulties they may encounter with Medicines management and optimisation. Our experience (currently anecdotal, but we will be looking to undertake research in this area) is that we have an aging demographic of patients being placed on very expensive, relatively new, chemotherapy drugs. Often these patients will already be on a number of chronic medications. This therefore presents real challenges in terms of medicines optimisation. Should these patients be taken off their existing drug regimen, should it be simplified, while they are on chemotherapy? However the outcome may be that while their cancer is treated their other conditions deteriorate. Possible advice / guidance should therefore be that prior to patients being placed on oral chemotherapy a review should be undertaken of their existing chronic medication and an assessment made as to what should	Thank you for your comment.

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					continue and what should stop.	
55	SH	East & South East England Specialist Pharmacy Service	1	3a)	We support this definition in principle but consider the wording is still HCP centred rather than patient centred. There needs to be greater emphasis on the need to respect patient's views and health beliefs. Perhaps add 'which respects the patient's opinions and wishes' after 'involving patient engagement'. This also clearly moves the concept on from medicines management.	Thank you for your comment. The definition of medicines optimisation has been amended to reflect your comment.
56	SH	East & South East England Specialist Pharmacy Service	2	4.1	We are pleased to see the prison population mentioned specifically in this guideline	Thank you for your comment. The scope has been amended although this detail may be considered in the review protocols.
57	SH	East & South East England Specialist Pharmacy Service	3	4.1.1 b)	It is unclear to us why practitioners who administer medicines are targeted as a group, but not practitioners who prescribe and supply medicines	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
58	SH	East & South East England Specialist Pharmacy Service	4	4.3.2	The overall scope for the CG is very comprehensive. We cannot see any gaps. However, while recognising there is a NICE CG on adherence, supporting adherence is also a fundamental component of MO. The two guidelines will need to be closely linked. It may be counter productive to describe adherence as an area that will not be covered in this CG	Thank you for your comment. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). NICE have separate processes for reviewing existing NICE guidance.
59	SH	East & South East England Specialist Pharmacy Service	5	4.4	Laudable but not very measurable in the context of MO!	Thank you for your comment.
60	SH	East & South East England Specialist	6	4.5	The provision of an evidence base will be key to persuading uptake of the more difficult aspects of MO, such as shared decision making.	Thank you for your comment.

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		Pharmacy Service				
61	SH	East & South East England Specialist Pharmacy Service	7	General	We commend the broad scope of this CG which has the potential to deliver improved patient outcomes and better use of NHS resource wherever medicines are used.	Thank you for your comment.
62	SH	UK Medicines Information	1	3a	Rather than re-define the concept of medicines optimisation we would prefer NICE to base the guideline on a definition more aligned with that already developed by the RPS and endorsed by a number of royal colleges. We feel that this better captures the concept of this being a patient-focussed, outcome orientated activity rather than a medicines- focussed series of processes and thus helps differentiate it from concepts like medicines management (albeit accepting that that is a critical component). Similarly we would like to see some attempt to explain medicines optimisation in the context of pharmaceutical care which has international acceptance and continues to be the terminology of choice in Scotland. We are not sure about the helpfulness of including proviso "within existing resources". For that to be helpful NICE would need to provide some indication of what level of resource is likely to be needed to achieve any recommendations made to avoid variation in provision/ uptake.	Thank you for your comment. The scope has been amended to reflect your comment.
63	SH	UK Medicines Information	2	3g	We feel the NHS Constitution and the rights of patients to be involved in decision making should have much greater prominence in setting the scene as well as the ability to 'delegate' such decisions to the health care professionals involved.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.

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64	SH	UK Medicines Information	3	3l	We feel that there are two distinct issues here - one is QIPP savings and the other is inexplicably high levels of variation in practice. Left as worded it implies that QIPP savings realised thus far are due reductions in variations in medicines use and prescribing when for the period in question they largely reflect the impact of the introduction of a few key generic medicines. Variation in practice would be better addressed under 3k. We feel it would also be helpful to go further into variation in practice by highlighting examples of over-prescribing in some patient groups (eg recent work on statins in primary prevention) and of under-prescribing in other groups (eg use of oral anticoagulants in AF).	Thank you for your comment, the scope has been amended to reflect your comment.
65	SH	UK Medicines Information	4	3 - general	We also feel there should be some acknowledgement that an informed decision not to take a medicine is appropriate in some circumstances - although for vaccinations there is also an element of societal responsibility involved (so perhaps vaccination programmes might be regarded as being out of scope?) . Recognition that patient choice is key needs to underline any guideline recommendations	Thank you for your comment.
66	SH	UK Medicines Information	5	4	Groups that will be covered - there is a tension between defining groups to aid searching for evidence and producing a guideline which is helpful to practitioners- for the latter we feel this needs to cover anyone taking a medicine or having responsibility for another person taking a medicine. However whilst self-medication with OTC and P medicines maybe relevant it is perhaps not such a high priority.	Thank you for your comment. The population section of the scope has been amended to reflect your comment.

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67	SH	UK Medicines Information	6	4	The phrase "practitioners who administer medicines" needs to be revisited to include any practitioner that is involved in prescribing, administering, dispensing or counselling a patient or carer about medicines.	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
68	SH	UK Medicines Information	7	4	Setting: we are not clear on the nuances of prisons, remand centres etc and with what type of setting is covered by the term "in the community" but basically scope should be such that it does not exempt any groups of people taking medicines just because of their setting. Limiting to 'all publicly-funded health and social care' may be enough.	Thank you for your comment. The settings section of the scope has been amended to reflect your comment.
69	SH	UK Medicines Information	8	4.3.1: **Patient and carer engagement**	3b/d/e/g: We feel this should also look at information for people for whom English is not their first language and also information requirements for supporting people taking medicines with specific religious restrictions. We would also like to see some focus on the impact of the presence or absence of some excipients (eg. gelatin, lactose) on decision-making.	Thank you for your comment. The NICE project team have already identified during the scoping phase the needs of this group as important to consider. This has been highlighted on the NICE equality impact assessment. The GDG will consider this during the development of the guidance and formation of the recommendations.
70	SH	UK Medicines Information	9	4.3.1 - **Evidence-informed decision making**	a/d/e/f: needs to include measures of recording informed decisions not to take a medicine.	Thank you for your comment. The key issues section of the scope has been amended.
71	SH	UK Medicines Information	10	4.3.1 - **Evidence-informed decision making**	Also needs to reflect the different stages at which information is needed and how it might be elicited. In the decision about whether to take a medicine or not - there is a need to access unbiased information outlining the benefits, risks and life style issues in a suitably accessible format. After starting a medicine it is more likely to be the availability of an "interactive" resource	Thank you for your comment.

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					that can be used to discuss individual concerns about side effects, tips for compliance, impact on OTC choices etc.	
72	SH	UK Medicines Information	11	4.3.1: **Reducing medicines-related patient safety incidents**	a: should be extended to include lapses in continuity of supply due to shortages (whilst accepting cause of shortages is outside scope), use of specials, breakdown in communication between providers.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
73	SH	UK Medicines Information	12	**4.4 main outcomes**	Outcomes need to be realistic and measurable and we are unclear that shifts in morbidity and/or mortality could be attributable to the intervention(s). Furthermore they need to include or at least be sensitive to impact of informed decision not to take a medicine.	Thank you for your comment. Outcomes of mortality relating to medicines may be captured in evidence.
74	SH	Virgin Care	1	4.1.1	Specific consideration should be made for patients living in their own home requiring external support (e.g. community services, private care agencies) to take their medicines	Thank you for your comment. The settings section of the scope has been amended to reflect your comment.
75	SH	Virgin Care	2	4.3.1	The role and use of 'Self-management plans' should be specifically covered in 'Patient and carer engagement…' section	Thank you for your comment. The scope has been amended to reflect your comment.
76	SH	Virgin Care	3	4.3.1	Specific consideration should be given to simplification and rationalisation of a patient's medicine regime in the 'Evidence-informed decision making' section	Thank you for your comment.
77	SH	Virgin Care	4	4.3.1	Specific consideration should be given to the impact of medication switch programmes (e.g. QIPP-led statin changes) in part (g) of the 'Evidence-informed decision making' section	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review.
78	SH	Virgin Care	5	4.3.1	Practitioners with a medicines optimisation remit exist beyond traditional pharmacy models (e.g. Community Matrons) and should be explicitly mentioned in part (g) of the 'Transferring medicines information across care settings' section	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review. questions when signed off by the GDG.

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79	SH	Virgin Care	6	4.3.1	Following the Royal Pharmaceutical Society's guidance on multi-compartment compliance aids, should there be specific consideration of the use of such compliance aids under the 'Reducing medicines-related patient safety incidents' section.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review.
80	SH	Virgin Care	7	4.3.1	Part (f) under 'Reducing preventable medicines-related hospital admissions and re-admissions' section: this is not an important enough point to be a standalone area, and particularly not one that fits under such a negative heading.	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
81	SH	City Healthcare Partnership Hull	1	3a	Optimisation definition too long. 1st sentence sufficient.	Thank you for your comment. The definition of medicines optimisation has been amended to reflect your comment.
82	SH	City Healthcare Partnership Hull	2	4.1.1a	Groups that will be covered – include all people who will be using medicines and people who are not receiving medicines when they should or could benefit from medicines – not necessary to pick out particular groups	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
83	SH	City Healthcare Partnership Hull	3	4.1.1b	All practitioners who prescribe, supply or administer medicines	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
84	SH	City Healthcare Partnership Hull	4	4.2a	No mention of tertiary care – suggest either include or remove all an so reads all publicly funded health and social care	Thank you for your comment. The settings section of the scope has been amended to reflect your comment.
85	SH	City Healthcare Partnership Hull	4	4.3.1	Not sure why separate sections for patient and carer engagement and evidence-informed decision making as seem to be the same thing and repetition in both. The shared decision making should be evidence based and involve patient choice. Intra- and inter- professional collaboration. Needs to mention cross sector pharmacy	Thank you for your comment. The setting section and key issues section of the scope have been amended to reflect your comment.

Unique comment ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					working. Clear introduction so audience this guideline is aimed at are clear that this involves them. Leadership – how do we engage all professionals to have this communication Reducing medicines-related safety incidents. d – not just about learning from incidents but patient experience as well, concern that in the new healthcare world post 1st April 2013 learnings aren't shared as effectively to improve pt experience and outcomes as not aware who is responsible in organisations	
86	SH	City Healthcare Partnership Hull	5	4.5 d	What is the most effective process for transferring medicines information but also medicines supply across care settings	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
87	SH	City Healthcare Partnership Hull	6	General	Need to market opitmisation and highlight the difference between medicines management. Although optimisation like management should be have leadership by pharmacy all professionals and contacts with patients need to take ownership of optimisation – not sure if enough emphasis on this in the guideline. Key areas for optimisation are when a new medicine (i.e new to the patient) is commenced regarding pt choice and understanding and also during transfer of care.	Thank you for your comment. The definition of medicines optimisation has been amended to reflect your comment.
88	SH	Merck Serono	1	4.3.1 (a-g) *Patient and carer engagement in shared decision making*	Merck Serono welcomes the principles of patient engagement and believes that patient involvement is paramount in maximising the benefits of their medicines and treatments. We support the subtopics that NICE has outlined here, but would like "Patient Choice" to be considered as a specific issue. We perceive patient empowerment in choosing their medicines-administration device or their treatment options, as a key component in their	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.

Unique comment ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					engagement.	
89	SH	Merck Serono	2	4.3.1 (b) *Patient and carer engagement in shared decision making, Evidence-informed decision making, Intra- and inter-professional collaboration*	With the advancements in technology improving patients access to information. We would like to propose that the guidelines include the use of technology in its assessment. Patient apps, internet access, electronic patient records are becoming more evident in informing the patient or healthcare professional and can have an impact on their decision making process. Merck Serono is presently developing apps which we perceive supports the patient through information and education. We note that that technology such as "*computerised decision support*" is mentioned in the scoping document, but we suggest that it should be considered as a 'stand alone' topic.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
90	SH	Merck Serono	3	4.3.1 (g) *Intra- and inter-professional collaboration*	We welcome the collaborative approach in seeking solutions in medicines optimisation. We particularly welcome the recognition that the pharmaceutical industry can contribute to this. We would like to suggest that industry led patient support services, such as homecare, nursing and education services should be consider within the scope, to assess their impact and benefit in this area. Merck Serono is financially committed to supporting patients with chronic conditions, such as multiple sclerosis, with nurse led support services. From our own preliminary results, we do observe that this can improve patient's management of medication and possibly outcomes.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
91	SH	Merck Serono	4	4.3.1 (c) *Intra- and inter-professional collaboration*	Merck Serono supports the principle of responsibility of "practitioners with a medicines optimisation remit" to delivering the outcomes. However, we believe that ownership of this issue	Thank you for your comment. The need for the guideline section has been amended to reflect your comment.

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				4.3.1 (h) Reducing preventable medicines-related hospital admissions and re-admissions	should not be limited to the few. We suggest that It should be made clear through the introduction of Quality Standards from these guidelines that thisis the responsibility of the entire multi-disciplinary team, across primary and secondary care. Sharing of this interest could be the most appropriate method in driving the cultural uptake required to maximise the outcomes and prevent adverse events from medicines.	
92	SH	Merck Serono	5	*3 (d) Need for the guideline 4.3.2 (a) Areas that will not be covered*	Merck Serono appreciates that "Medicines optimisation" is a difficult topic to scope and there is the need to limit focus of the guidelines. We also understand that there are already guidelines available in terms of adherence (CG76). However, as one of the major needs for the guidelines is the "cost of waste prescription medicines" we suggest that the scope will need to be expanded. Our understanding is that one of the most recognisable ways that outcomes from a medication can be optimised is through patient's adherence and persistence with their treatment. The correct uptake and usage of medication for the appropriate treatment period. Hence we do believe that the topics of adherence and persistence should be included in the scope and developed within the guidelines. The clinical guideline on adherence (CG76) was published in 2009. It may also require review at this time. Would it not be appropriate to amalgamate both guidelines under the remit of Medicines optimisation?	Thank you for your comment. Medicines waste is considered an outcome of failures in other aspects of the medicines optimisation system, therefore by addressing these problems the consequence of waste medicines is likely to reduce. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). NICE have separate processes for reviewing existing NICE guidance.
93	SH	Merck Serono	6	General	Merck Serono considers that an important method for optimising medicines, is the prescribing of the right medication for the right patient. Patient stratification is becoming more	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions

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					prevalent, maximising a medicines benefit in the most receptive patient cohort (e.g. biomarker testing). Within oncology, the introduction of KRAS testing is targeting the patients that would benefit the most from a medication, which would not have its optimum effect on the larger metastatic colorectal cancer population. We have noted that patient stratification has not been mentioned in the draft scope. On implementation, Quality standards on stratification from these guidelines, could have a considerable impact on increasing the treatment benefits to patients and minimising adverse events.	when signed off by the GDG.
94	SH	UK Clinical Pharmacy Association	1	The definition of medicines optimization (section 3a)	• The definition of medicines optimisation is direct. It is crucial that a distinction is made between medicines management and medicines optimisation. • The definition needs to be simple enough for all staff to remember what it is all about – patient outcome. • This seems reasonable. For me there may be something about concordance that perhaps has not been incorporated. It needs to be something about coming to an agreement with the patient including taking into account the patient's condition **and** the way they live their lives. Medicines taking has to fit in to the way a patient lives their life otherwise there will be non-adherence to the treatment regimen. Need to recognise not just intentional non-	Thank you for your comment. The need for the guideline section has been amended to reflect your comment. The definition of medicines optimisation has been amended to reflect your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.

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					adherence but also unintentional non-adherence because the regimen is not practical or suit their daily living. E.g. patient having Homecare assists with medicines there is no point in prescribing a medicine at a time of day when home care can't assist the patient.	
95	SH	UK Clinical Pharmacy Association	2	The definition of medicines optimization (section 3f)	• There also needs to be emphasis of potential for errors occurring as patients are transferred **INTO** hospital rather than emphasis on discharge.	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
96	SH	UK Clinical Pharmacy Association	3	What are the key priorities for the guideline to focus on? (Are there any specific areas throughout the patient journey that particularly need to improve in relation to medicines optimization?)	• This scope need to also include evidence based prescribing decisions upon which optimising the patient outcome is key. Prescribing decisions define (or limits) the potential to meet the best possible outcome for a patient. Prescribing decisions are influenced by guidelines/ interests which are often financial. • The Scope mentions transfer of care and emphasises discharge from hospital. I think this ignores the problem of other areas of transfer of care. Transfer into hospital is just as poor, with incorrect or incomplete information coming into secondary care from primary care. The communication between GP and community pharmacists and vice versa also hinders medicines optimisation	Thank you for your comments. The key issues section of the scope has been amended to reflect your comments.
97	SH	UK Clinical Pharmacy Association	4	Are there any groups that should be covered within the	• Transplant or Critical care Patients • Should the scope of medicines optimisation cover OTC / purchased	Thank you for your comment. The population section of the scope has been amended to reflect your

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				guideline that have not been listed (section 4.1.1)?	medicines???	comment. The term 'medicines' has been clarified to include over-the-counter medicines in the population section.
98	SH	UK Clinical Pharmacy Association	5	Page 6, g) Specific responsibilities of practitioners with a medicines optimisation remit, such as practice-based pharmacists and medicines management discharge technicians	• All healthcare practitioners who prescribe or manage medicines have specific responsibilities. Singling out one or two roles runs the risk of unfairly placing the expectation to deliver on a few rather than a whole systems approach.	Thank you for your comment. The population section of the scope, the term 'medicines' has been clarified to include over-the-counter medicines.
99	SH	Baxter Healthcare Ltd	1		We welcome the production of a new clinical guideline for medicines optimisation and would like to thank NICE for this opportunity to comment on this draft scope.	Thank you for your comment.
100	SH	Baxter Healthcare Ltd	2	4.1.1	In the list of groups that will be covered in the scope of the guideline, please could NICE clarify the 6th bullet point "people who are prescribed a new medicine"? Does this refer to a medicine which is new to the patient or a medicine which is new to market?	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
101	SH	Baxter Healthcare Ltd	3	4.1.1	Would NICE consider adding "patients receiving intravenous infusions of medicines including bespoke compounded chemotherapy regimens" to this list? This can be a major source of waste and result in significant costs to the NHS. For example, where drugs have to be discarded because the patient is unfit to receive treatment.	Thank you for your comment. 'Areas that will not be covered' are listed in the scope. Medicines waste is considered an outcome of failures in other aspects of the medicines optimisation system, therefore by addressing these problems the consequence of waste medicines is likely to reduce.
102	SH	Baxter	4	4.3.1	We agree that the groups covered in "Patient	Thank you for your comment. The key

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		Healthcare Ltd			and carer engagement in shared decision making" are appropriate and relevant; however, an increasing number of patients are now managing the administration of non-oral medicines in their own homes. This approach can provide many social and economic benefits, but can be complex and patients therefore require training and support. Would NICE therefore consider also adding home patients into this section?	issues section of the scope has been amended to reflect your comment.
103	SH	Baxter Healthcare Ltd	5	4.3.1	In the "Evidence based informed decision making section" would NICE consider adding that information should be made available to empower patients to understand how access to medicines is open to unexplained regional variation in order to enable them to be able to negotiate treatment options more effectively with their clinicians? Would NICE also consider highlighting the Information Standard kite mark as a trusted assurance of the quality of information? The Information Standard is a certification scheme for all organisations producing evidence-based health and care information for the public. Any organisation achieving The Information Standard has undergone a rigorous assessment to check that the information they produce is clear, accurate, balanced, evidence-based and up-to-date.	Thank you for your comment. Access to medicines is considered in the NICE good practice guidance on developing and updating local formularies. This will not be considered as part of this guideline.
104	SH	Baxter Healthcare Ltd	6	4.3.1	In the section entitled "Intra- and inter-professional collaboration", working with the pharmaceutical industry is highlighted as one of the areas within this scope. The Home Care industry is also an important stakeholder and	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.

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					often has direct contact with patients, provides assistance to enable treatment at home and can access information about medicines usage, wastage and other issues that may not otherwise be monitored. In fact, organisations involved in home care services can have an impact on many areas that affect medicines optimisation from safety, to the transfer of information, to reducing hospital admissions. Would NICE therefore consider adding the role of home care companies into the scope?	
105	SH	Baxter Healthcare Ltd	7	4.4	In point b) please could NICE clarify that "Hospitalisation and health care utilisation" also includes length of hospital stay?	Thank you for your comment. This outcome would include length of hospital stay.
106	SH	Baxter Healthcare Ltd	8	General	One aspect of medicines optimisation that has not been included in this scope is that of nutritional status. Would NICE consider including the requirement for nutritional status to be assessed regularly to maximise the effectiveness of interventions? Patients who are undernourished are less likely to respond to treatment. Consideration should therefore be given to the evidence to support supplementing patients with oral or parenteral nutrition.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
107	SH	Baxter Healthcare Ltd	9	Review question a	**For all patients using medicines what is the effect of patient and carer engagement in improving shared decision making between patients, carers and health practitioners compared to usual care?** The recent report from the Health Foundation states that "*Strategies to enhance shared decision making can improve:*	Thank you for your comment.

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					– people's knowledge about their condition and treatment options *– people's involvement in their care* *– people's satisfaction with care* *– people's self-confidence in their own knowledge and self-care skills* *– professionals' communication with patients.* *There is also emerging evidence, from mainly observational and small scale studies, that supporting people to share in decision making can improve their satisfaction with care and the extent to which they concord with treatment."* The report also states *"Interventions to improve shared decision making have been found to enhance knowledge, involvement in decisions and patient satisfaction and in some cases to improve adherence to treatment."* Moumjid N, Carrère MO, Charavel M, Brémond A. Clinical issues in shared decision-making applied to breast cancer. *Health Expect* 2003;6(3):222-7. Whelan T, Levine M, Willan A et al. Effect of a decision aid on knowledge and treatment decision making for breast cancer surgery: a randomized trial. *JAMA* 2004;292(4):435-41.	
108	SH	Baxter Healthcare Ltd	10	Review question b	**For all patients using medicines what is the effect of evidence-informed decision making processes in improving patient outcomes from medicines compared to usual care?** We would agree that using an evidence base to make a decision is certainly preferred. However there are some areas where there may not be sufficient or any evidence available for a	Thank you for your comment.

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					particular medicine. For example a patient who has a rare disease where currently there is no established medical intervention available but where there are emerging technologies which could extend the patient's life but the strength of evidence is not yet available due to the small number of patients and short length of time the medicine has been on the market. Another example may be where a patient may be prescribed off licence medication in the absence of any life saving alternatives.	
109	SH	Baxter Healthcare Ltd	11	Review question c	**For all practitioners involved with medicines what is the effect of intra- and inter-professional collaboration on improving patient outcomes from medicines compared to usual care?** Intra and Inter professional collaboration is critical to ensure all patient capabilities and needs are taken in to account, thus ensuring optimal medication. The pharmaceutical industry can also provide major resources such as clinical information, cost effectiveness data and medicines usage. The clinical information that this industry can provide is not just limited to clinical trial data and evidence, but also includes in depth understanding of the disease area and accumulated experience of medicines usage from across the globe. The other professional group that should be included in such collaboration are health service payers. This professional group have the knowledge and expertise to enable the optimisation of health gains across a whole population and ensure best use of allocated	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.

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					resource.	
110	SH	Baxter Healthcare Ltd	12	Review question d	**For all patients using medicines what is the most effective system and process for transferring medicines information across care settings to reduce medicines related patient safety incidents compared to usual care?** The use of telemedicine can support safe and effective care for patients, particularly those that are managing their own condition and/or being treated at home. Remote patient monitoring can support the early detection of issues (such as fluid overload in dialysis patients) and allow optimisation of prescription to prevent complications and avoid hospital admissions. There are various systems in use across the NHS that can do this, for example http://www.uhb.nhs.uk/birmingham-systems-pics.htm We would propose that systems such as this that are already available and validated should be shared, rather than reinvented across the NHS.	**Thank you for your comment. The key issues section of the scope has been amended.**
111	SH	Baxter Healthcare Ltd	13	Review question e	**For all patients using medicines what is the most effective and cost-effective system and process for safe and appropriate prescribing, at reducing medicines related patient safety incidents compared to usual care?** Electronic prescribing and electronic patient records accessible by all appropriate personal immediately at point of need.	Thank you for your comment. The key issues section of the scope has been amended.
112	SH	Baxter Healthcare Ltd	14	Review question f	**For all patients using medicines what is the effect and cost-effectiveness of current systems and processes for safe and**	Thank you for your comment. The key issues section of the scope has been amended.

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					appropriate prescribing for reducing medicines-related hospital admissions and re-admissions compared to usual care? The use of a more tailored dosing prescribing system can have many positive effects on patients and the wider health system. For example, individualising the dose of a particular medicine through routine monitoring of drug half life (for example with Factor VIII in haemophilia patients) will enable the identification those patients who have been either under or over treated. This can then ensure that future prescriptions are tailored to individual patients needs and limited drug budgets can better utilised. Using the example of haemophilia, tailored dosing regimens could prevent avoidable bleeds and joint damage which is associated with high cost interventions and unquantifiable patient quality of life outcomes.	
113	SH	Astellas Pharma Ltd	1	General	Astellas Pharma Ltd (Astellas) welcomes the development of the medicines optimisation clinical guideline and is pleased to be able to respond to the consultation on the draft scope. Our response draws on our knowledge and experience of supporting high quality medicines use in urology, including the treatment of overactive bladder (OAB) and lower urinary tract symptoms (LUTS) (including urinary incontinence) associated with benign prostatic hyperplasia (BPH)[i]. We recognise that the ultimate goal of medicines optimisation is to secure the greatest possible health gain from investment in medicine and the	Thank you for your comment.

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					field of urology provides an instructive case in point. For example, effective medicines use in the management of LUTS has the potential to transform patient outcomes and maximise value. It can be achieved by: • adopting a proactive approach to shared decision-making based on timely medication review • ensuring that patients are offered the full range of NICE approved treatments • supporting adherence and reducing morbidity relating to treatment cessation • managing issues relating to polypharmacy	
114	SH	Astellas Pharma Ltd	2	4.3.1	Astellas welcomes the inclusion of medication review within the draft scope. However we do not believe that reviews should focus solely on mitigating the harms associated with medicines use but should also address wider effects in relation to symptom reduction, tolerability, satisfaction and quality of life. Medication reviews should allow patients and clinicians to reflect on treatment goals, to identify whether the choice of treatment is most appropriate and to tailor the personal care management plan to reflect current needs and expectations. A timely review can also improve patient experience by ensuring that patients are involved and engaged in decisions about their care[ii]. To address this, Astellas recommends that the scope explicitly includes medication review in the sections 'patient and carer engagement in shared decision-making' and 'evidence informed decision-making' as well as the section on	Thank you for your comment. The key issues section of the scope has been amended.

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					'reducing medicines-related patient safety incidents'. This change would echo evidence-based practice set out in other NICE guidance, such as: • CG171 *The management of urinary incontinence in women* (1.7.11 'offer a face-to-face or telephone review four weeks after the start of each new OAB drug treatment...ask the woman if she is satisfied with the therapy') • QS45 *Lower urinary tract symptoms in men* (quality statement 6: 'It is important that men with LUTS who are taking drug treatments for their symptoms have a medication review initiated promptly after their treatment has been prescribed eg 4-6 weeks...the review of drugs will inform decisions about their continued use, taking into account the effect of these drugs on symptoms and quality of life, as well as any adverse effects')	
115	SH	Astellas Pharma Ltd	3	4.3.1	Astellas recommends that the section on 'patient and carer engagement in shared decision-making' includes a specific reference to the development of a personalised management plan. Part 'e' refers to 'individualised care and personalised care' but these are clinical approaches based on a set of behaviours that may be difficult to monitor and evaluate. Personalised care management plans are recommended throughout NICE guidance and are endorsed by the National collaboration for integrated care and support[iii]. The use of a care plan is a positive way to document and measure the extent to which patient-centred care and	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.

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					supported self-management are taking place in practice.	
116	SH	Astellas Pharma Ltd	4	4.3.1	Astellas welcomes the focus on information provision and shared-decision-making in the scope. Both are critical to supporting patient engagement in their treatment and in helping to underpin safe and effective medicines use. Information and shared decision-making are also important precursors to patient choice. Evidence based choice of medicines has been identified as one of four principles of medicines optimisation by the Royal Pharmaceutical Society[iv], but is absent from the scope. Choice of treatment supports medicines optimisation in two main ways: • by ensuring that medicines are selected using the best available evidence • by supporting patient engagement and increasing patient ownership and control over their treatment To address this, Astellas recommends that the section on 'evidence-informed decision making' should cover treatment choice and the right to treatments that have been recommended by NICE for use in the NHS[v].	Thank you for your comment. The NICE guidance development process follows methodology based on evidence. Access to medicines is considered in the NICE good practice guidance on developing and updating local formularies. This will not be considered as part of this guideline. The key issues section of the scope has been amended to reflect your comment.
117	SH	Astellas Pharma Ltd	5	4.3.1	Astellas notes that the scope covers 'people using multiple medicines (polypharmacy)'. This is an area that could be further strengthened within the scope by including a specific reference to polypharmacy within the section on 'reducing medicines-related patient safety incidents'. Evidence suggests that multimorbidity is strongly associated with the occurrence of adverse events, given that it	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.

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					requires the input of a range of specialities and more extensive medicines usage[vi].	
118	SH	Astellas Pharma Ltd	6	4.3.1	Astellas notes that the section on 'reducing preventable medicines-related hospital admissions and re-admissions' focuses primarily on admissions that are caused by adverse events. It overlooks increased healthcare utilisation and cost that is caused by discontinuation of treatment, which is an important aspect of medicines optimisation. For example, failure to manage LUTS effectively can lead to increased morbidity and can result in: • acute hospitalisations due to urinary tract infection and unnecessary catheterisation • higher risk of falls and fractures • increased risk of pressure ulcers related to incontinence[vii,viii] The scope would therefore be strengthened by addressing admissions that are caused by poor adherence as well as through medicines usage.	Thank you for your comment. The main outcomes section includes 'health and social care related quality of life' which would include morbidity, and 'patient-related outcomes' which will include medicines adherence as an outcome, where appropriate cross-reference will be made.
119	SH	Astellas Pharma Ltd	7	4.3.2	Astellas notes that the draft scope does not cover medicines adherence because this is addressed by a separate guideline (CG76). However, given that medicines adherence is integral to medicines optimisation, these issues should be reflected in the scope. NICE should consider including a section in the scope specifically addressing adherence with the intention of providing a summary along with clear links through to CG76 within the full guideline. Much of the detail of the scope, such as information and shared decision-making, underpin adherence. For example, timely	Thank you for your comment. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). NICE have separate processes for reviewing existing NICE guidance. The main outcomes section includes 'patient-related outcomes' which will include medicines adherence as an outcome, where appropriate cross-reference will be made.

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					treatment review can help to ensure that unacceptable side effects are identified and patients are offered an appropriate alternative at the earliest opportunity before they decide to discontinue treatment. Ensuring that the guideline presents a complete picture of best practice across the breadth of medicines optimisation, including adherence, will increase its utility.	
120	SH	Department of Health			I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you for your comment.
121	SH	Royal College of Paediatrics and Child Health	1	General	Good that children and adolescents are included at the various stages.	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
122	SH	Royal College of Paediatrics and Child Health	2	4.1.1	'Groups that will be targeted' makes more sense than 'Groups that will be covered' as a header, as next section entitled 'Groups not covered' states none.	Thank you for your comment. The guidance format is based on NICE style.
123	SH	Royal College of Paediatrics and Child Health	3	4.1.1	Should include carers and parents as a group targeted in the scope.	Thank you for your comment. 'Carers' have been included in review questions where appropriate.
124	SH	Royal College of Paediatrics and Child Health	4	4.3	We feel that there is a lot of duplication here with items appearing under more than one heading and items that are headings also appearing as items under that or other headings. This requires some editing and re-ordering; however, it appears to cover the key/important areas of practice.	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
125	SH	Royal College of Paediatrics and Child Health	5	4.3 and 4.4	Also some inconsistency in the terms used, e.g. some paragraphs use adverse events and others use adverse effects.	Thank you for your comment. An adverse event is different to an adverse effect in the context that these words are used.
126	SH	Royal College of	6	4.3.1a	**Evidence-informed decision making:**	Thank you for your comment. The key

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		Paediatrics and Child Health			Satisfaction with information received is relatively meaningless - need to focus not on an easily reduced and reported satisfaction and more on a measure of adequacy and accessibility.	issues section of the scope has been amended to reflect your comment.
127	SH	Royal College of Paediatrics and Child Health	7	4.3.1c	**Evidence-informed decision making:** Such as when prescribed a new medicine or other key circumstances change – supply, capacity, geography, dependence/independence. Needs spelling out who is sharing the decision and in reality this is rarely a reality, More important is an understanding of appropriate administration options and their implications in daily life. Pharmacist is likely to be the better source of this information.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
128	SH	Royal College of Paediatrics and Child Health	8	4.3.1	**Intra- and inter- professional collaboration:** Ensure there is no a main focus on the secondary setting when the majority of opportunities probably present in primary care and with community pharmacists.	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
129	SH	Royal College of Paediatrics and Child Health	9	4.3.1	**Reducing medicines-related patient safety incidents:** Community based pharmacists are conspicuously absent from this yet hold the greatest monitoring opportunity. Any case for networking pharmacies and providing optimisation oversight?	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
130	SH	Royal College of Paediatrics and Child Health	10	4.3.2	We are concern that medicines adherence is not being included as it is covered by a previous NICE document CG76; however, this document excludes children and young people so that leaves a gap in relation to adherence for children and adolescents which should be considered.	Thank you for your comment. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). NICE have separate processes for reviewing existing NICE guidance. The main outcomes section includes 'patient-related outcomes' which will

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						include medicines adherence as an outcome, where appropriate cross-reference will be made.
131	SH	Royal College of Paediatrics and Child Health	11	4.4	**Outcomes:** Satisfaction with decision making – what does this mean to patients? Satisfaction with the decision? With the offer of participating in that decision?	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
132	SH	Gloucestershire Hospitals NHS Foundation Trust	1	General	Comments are …. Link to reference sites is a good idea, however sites can change so the full reference to published articles should be used	Thank you for your comment. The final scope will be reviewed by NICE publishing team prior to publication.
133	SH	Gloucestershire Hospitals NHS Foundation Trust	2	General	Comments are …. Use of compliance aids at the insistence of care agencies for the commercial benefit of the agency and not the patient needs to be addressed, and eliminated. Such compliance aids I am told are requested to - Minimise involvement of care agency staff in patient care - To reduce training requirements of agency staff, so maximising profits - To minimise insurance premiums for such companies, again to maximise profits In some areas like Solihull (west midlands) prompts are provided and a Blue Book is initialled to confirm that the medication has been seem to be take. Replying on the compliance aid itself without actually seeing the patient take the medication, does not support medicine concordance. Contracts with care agencies are not sufficiently robust to describe either way that such practice is acceptable or not. It is recommended that guidance is issued to contractors of services that contracts stipulate	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.

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					that the: - Use of compliance aids should adhere to Disability Discrimination Act - Carers should view the taking of medication and	
134	SH	Boots	1	General	**Pharmacists and medicines optimisation**: Pharmacists are the experts on medicines. They have comprehensive training on all aspects of medicines, covering all stages from development, manufacturing, supply and use by patients. Pharmacists are at the heart of developing the newly emerging area of medicines optimisation. We strongly believe that the proposed NICE guidance should be explicit on the need to involve pharmacists in all sectors (hospital, primary care and community) in the development and implementation of medicines optimisation processes, at national, local and individual patient levels. Our definition of medicines optimisation (See Comment 2, below) recognises that this has to be a process "with pharmacy at its heart" making changes for the benefit of individual patients.	Thank you for your comment.
135	SH	Boots	2	3a	**Definition of medicines optimisation**: The definition of medicines optimisation should be more positive and action focused. It should start more along the lines that "*Medicines optimisation is the result of actions taken by patients and their healthcare professionals and carers to obtain the best outcomes…"* This makes it clear that medicines optimisation is about individuals' actions and actions taken for individuals, rather than system wide changes (as in medicines management). Medicines	Thank you for your comment. The definition of medicines optimisation has been amended.

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					optimisation involves and requires good prescribing but goes beyond this (See Comment 3, below). The current definition (Para 3a) does not seem to apply to anyone and is unlikely to be helpful in practice (ie, to those working in patient-facing care). The definition should place greater emphasis on ■ Actions taken by individuals working directly with patients ■ Taking actions that make situations easier or better for patients (in regard of medicines) ■ Keeping situations under review and involving patients and/or carers in decisions ■ Collaborations between healthcare professionals and sharing relevant information about changes ■ Actions not systems ■ That medicines optimisation has to be an issue with pharmacy at its heart working in the interests of patients	
136	SH	Boots	3	General	**Breadth and depth of medicines optimisation**: Medicines optimisation will involve or require high quality prescribing, but that is not enough in itself. For example, the prescription may be clinically correct and in compliance with all relevant NICE, NHS or professional guidance, but if the patient is physically unable or is unwilling to take the medicine as prescribed then the medicine taking cannot be described as optimal. Alternatively, if a patient is not being prescribed something that might be beneficial,	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.

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					then there is sub-optimal prescribing. Other issues, beyond prescribing, can affect medicines taking, including the use of other prescription and non-prescription medicines, patients' physical or mental conditions, care issues, eyesight, etc. Pharmacists are experts in all aspects of medicines development, procurement, supply and support and should be at the heart of the medicines optimisation process.	
137	SH	Boots	4	General	We strongly believe that it is not possible to separate medicines optimisation and medicines adherence. The ultimate goal of medicines optimisation is to ensure better adherence to medicines with the aim of getting the best outcomes for patients. Medicines optimisation without medicines adherence is pointless.	Thank you for your comment. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). NICE have separate processes for reviewing existing NICE guidance. The main outcomes section includes 'patient-related outcomes' which will include medicines adherence as an outcome, where appropriate cross-reference will be made.
138	SH	Boots	5	General	**Groups to be covered**: The guidance should make specific mention of those who supply medicines (ie, pharmacies) and those who give advice about medicines taking (pharmacists working in community, primary care and secondary care settings). See Comment 6, below.	Thank you for your comment. The population section of the scope has been amended.
139	SH	Boots	6	4.1.1 b	**Groups covered**: This should be expanded to specifically cover "All practitioners who supply medicines to patients" and "All practitioners who give advice on medicines and their use to patients and health care professionals"	Thank you for your comment. The population section of the scope has been amended.

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					We would consider the term "administer" to refer only to the physical activity of giving medicines to individuals at a specific time of day, rather than those who supply whole courses of medicines to be taken by patients (or administered by other carers or professionals), ie, pharmacists working in community or hospital settings.	
140	SH	Boots	7	4.3.2	**Areas that will not be covered**: As discussed under Comment 4 above, we believe that it is perverse to artificially consider medicines optimisation and medicines adherence as separate topics. In our view, the entire aim of medicines optimisation is to maximise medicines adherence with the aim of getting optimal outcomes. The two are inseparable, in our opinion.	Thank you for your comment. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). NICE have separate processes for reviewing existing NICE guidance.
141	SH	Boots	8	4.5	**Review questions**: Questions e) and f) concentrate only on "safe and effective prescribing". As described in Comment 3 above, effective prescribing is only a part of the wider goal of medicines optimisation. Good prescribing without medicines adherence is pointless activity.	Thank you for your comment. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). The main outcomes section includes 'patient-related outcomes' which will include medicines adherence as an outcome, where appropriate cross-reference will be made.
142	SH	Boots	9	4.5	Given that "medicines optimisation" is relatively new terminology, and that there is still considerable discussion within the pharmacy profession as to its full meaning, we question what value will be achieved from a systematic literature search using only this term. The review will need to take account of literature using related terminology, including "medicines	Thank you for your comment. The NICE methodology for short clinical guidelines will be followed.

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					adherence", "concordance", "compliance" and "pharmaceutical care" among others.	
143	SH	Boots	10	General	We believe that the guidance should also examine where interventions to increase medicines optimisation can be undertaken (ie, GP surgeries, pharmacies, hospitals, clinics, domiciliary outreach) and who should be involved (prescribers, pharmacists, patients, carers).	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
144	SH	Boots	11	General	The guidance should be explicit that medicines optimisation has to happen at a patient level to be effective. It is not a "systems approach".	Thank you for your comment. The definition of medicines optimisation has been amended to reflect your comment.
145	SH	Royal Pharmaceutical Society	1	3a	**Definition of medicines optimisation**: The definition of medicines optimisation should be more positive and action and patient focused. It should start more along the lines that "*Medicines optimisation is the result of actions taken by patients and their healthcare professionals and carers to obtain the best outcomes…"* This makes it clear that medicines optimisation is about individuals' actions and actions taken for individuals, rather than system wide changes (as in medicines management). The current definition (Para 3a) does not seem to apply to anyone and is unlikely to be helpful in practice (i.e., to those working in patient-facing care). The definition should place greater emphasis on ■ Actions taken by individuals working directly with patients ■ Taking actions that make situations easier or better for patients (in regard of medicines)	Thank you for your comment. The definition of medicines optimisation has been amended. The development of the guidance will follow NICE short clinical guideline methodology.

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					■ Keeping situations under review and involving patients and/or carers in decisions ■ Collaborations between healthcare professionals and sharing relevant information about changes ■ Actions not systems ■ That medicines optimisation has to be an issue with pharmacy at its heart	
146	SH	Royal Pharmaceutical Society	2	General	**Breadth and depth of medicines optimisation**: Medicines optimisation will involve or require high quality prescribing, but that is not enough in itself. For example, the prescription may be clinically correct and in compliance with all relevant NICE, NHS or professional guidance, but if the patient is physically unable or is unwilling to take the medicine as prescribed then the medicine taking cannot be described as optimal. Other issues, beyond prescribing, can affect medicines taking, including the use of other prescription and non-prescription medicines, patients' physical or mental conditions, patients' beliefs, experiences, attitude and cultural influences, care issues, eyesight, etc. Pharmacists are experts in all aspects of medicines development, procurement, supply and support and should be at the heart of the medicines optimisation process. Medicines optimisation is also about minimising harm and risks from medicines. The risks of medicines can change with age so medicines optimisation has to be an ongoing process to ensure patient safety. More thorough and regular medication	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.

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					reviews (undertaken by pharmacists) could have a positive impact on minimising risk and improving patient safety, particularly for those patients who are vulnerable.	
147	SH	Royal Pharmaceutical Society	3	General	**Groups to be covered**: The guidance should make specific mention of those who supply medicines (predominately pharmacies) and those who give advice about medicines taking (e.g. pharmacists working in community, primary care and secondary care settings)	Thank you for your comment. The population section of the scope has been amended.
148	SH	Royal Pharmaceutical Society	4	4.1.1 a	**Groups covered:** Patients who reside in Care Homes or other institutions such as patients with learning needs should be a particular additional group that is covered by this guidance.	Thank you for your comment. NICE are developing good practice guidance for managing medicine in care homes.
149	SH	Royal Pharmaceutical Society	5	4.1.1 b	**Groups covered**: This should be expanded to specifically cover "All practitioners who supply or administer medicines to patients" and "All practitioners who give advice on medicines and their use to patients and health care professionals" We would consider the term "administer" to refer only to the physical activity of giving medicines to individuals at a specific time of day, rather than those who supply whole courses of medicines to be taken by patients (or administered by other carers or professionals)	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
150	SH	Royal Pharmaceutical Society	6	4.3.1	**Areas that will be covered: Transferring medicines information across care settings (g) and Reducing preventable medicines-related admissions and re-admissions (h).** Referring to *practitioners with a medicines optimisation remit* contradicts the importance of multidisciplinary team working and the role all	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.

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					health care professionals play in medicines optimisation in all healthcare settings. We believe that pharmacists have the skills and knowledge to lead and play a pivotal role in the delivery of medicines optimisation but other healthcare professionals also need to be involved. Referring specifically to practice-based pharmacists and medicines management discharge technicians may limit the perceived applicability of this short Clinical Guideline as medicines optimisation should not be perceived solely for these categories.	
151	SH	Royal Pharmaceutical Society	7	4.3.2	**Areas that will not be covered**: We strongly believe that it is not possible to separate medicines optimisation and medicines adherence. The ultimate goal of medicines optimisation is to ensure better adherence to medicines with the aim of getting the best outcomes for patients from their medicines. Medicines optimisation without medicines adherence is pointless. We believe that it is perverse to artificially consider medicines optimisation and medicines adherence as separate topics. In our view, the entire aim of medicines optimisation is to maximise medicines adherence with the aim of getting optimal outcomes. The two are inseparable, in our opinion as even if you prescribe the right medicines for the right patient at the right time, if the patient is not supported to take that medicine through a shared decision making process then they are unlikely to achieve the best outcomes possible. Medicines adherence, therefore, Medicines Optimisation, could also result in patients choosing not to take a particular	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.

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					medicine as part of an informed, shared decision making process. Although the NICE adherence guidance will be signposted as an additional resource, it will be one among many and we believe that medicines adherence needs to be integral to the MO guidance. There should be references made, and support of, evidence based interventions on medicines adherence.	
152	SH	Royal Pharmaceutical Society	8	4.5	**Review questions**: Questions e) and f) concentrate only on "safe and effective prescribing". As described in Comment 2 above, effective prescribing is only a part of the wider goal of medicines optimisation. Good prescribing without medicines adherence will not achieve the best outcomes for patients.	
153	SH	Royal Pharmaceutical Society	9	4.5	Given that "medicines optimisation" is a relatively new piece of terminology, and that there is still considerable discussion within the NHS as to its full meaning, we question what value will be achieved from a systematic literature search using only this term. The review will need to take account of literature using related terminology, including "medicines adherence", "concordance", "compliance", "pharmaceutical care" among others.	Thank you for your comment. The systematic literature search will not use on the term 'medicines optimisation'. The development of the guidance will follow NICE short clinical guideline methodology.
154	SH	Royal Pharmaceutical Society	10	General	We believe that the guidance should also examine where interventions to increase medicines optimisation can be undertaken (e.g. GP surgeries, pharmacies, hospitals, clinics, outreach) and who should be involved (e.g. prescribers, pharmacists, patients, carers).	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
155	SH	Royal Pharmaceutical Society	11	General	The guidance should be explicit that medicines optimisation has to happen at a patient level to be effective. It is not a "systems approach". Although having the right environment in which	Thank you for your comment. The definition of medicines optimisation has been amended to reflect your comment.

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					to deliver medicines optimisation will require the right systems, such as contractual arrangements etc, to be in place.	
156	SH	Royal Pharmaceutical Society	12	General	Prescription charges have been shown to be a barrier to effective medicines-taking behaviour with a survey of nearly 4,000 people with long-term conditions in England (*Paying the Price*, March 2013, www.prescriptionchargescoalition/paying_the_price.pdf) showing that one third of those with long-term conditions who are paying for each prescription item had not collected medication due to the cost. Three quarters of this group reported that their health got worse as a result, with 10% reporting that they were hospitalised as a direct consequence. Survey respondents also reported cutting pills in half, missing doses or substituting cheaper over-the-counter alternatives to eke medicine out for longer because of the cost. This also needs to be taken into account when optimising medicines for individual patients.	Thank you for your comment. Unfortunately NICE is unable to amend legislation relating to prescription charges.
157	SH	European Medicines Group		**GENERAL**	The use of medicines touches almost every aspect of the healthcare system and the clinical teams who aim to deliver improved patient outcomes and maximise the use of available resources. We therefore welcome the breadth of the areas covered by the draft scope. However, we are concerned that, as currently expressed, the achievement of improved patient outcomes through the use of medicines has received disproportionately little emphasis in comparison with reducing waste and the risks of using medicines. Whilst we fully endorse	Thank you for your comment. The scope has been amended following your comment. The definition of medicines optimisation has been amended to reflect your comment. Thank you for your comment. Access to medicines is considered in the NICE good practice guidance on developing and updating local formularies. This will not be

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					minimising the risk of harm and expenditure on medicines that are not used, we believe that the guideline should put greater emphasis on encouraging use of medicines that optimises health outcomes and considers their value in delivering those outcomes along the length of the patient pathway. This would be supported by more emphasis on *understanding and improving the patient experience*. In this regard, we would recommend throughout the scope that any reference to 'available resources' be couched in terms of 'maximising the use of available resources'. The achievement of medicines optimisation as a strategy which puts patients at the centre of healthcare and focuses on health outcomes and patient experience, as opposed to a focus on systems to contain use of and spend on medicines, will require considerable cultural change across the NHS. Our interpretation of the scope is that the guideline will be directed primarily at pharmacists; however, we would contend that medicines optimisation applies to all health professionals, including doctors and nurses who have specific professional guidance on prescribing and managing medicines, and commissioners. We believe that this collective responsibility for medicines optimisation should be recognised in the guideline. Related to this, we are disappointed that there is no reference to local formulary development and local medicines decision-making, and how	considered as part of this guideline. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject).

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					medicines optimisation should be considered in this context. We believe this is a missed opportunity as medicines optimisation is central to improving the quality of local medicines decision-making and instilling the right mind-set and behaviours. Whilst we recognise separate guidelines on *Developing Local Formularies* do exist, this is so fundamentally linked to medicines optimisation we believe it must be included within the scope. Similarly, there are existing guidelines on *Medicines Adherence* but we believe specifically excluding it from the scope and guideline may limit the guideline unnecessarily since medicines adherence and patient involvement in decision making is so inextricably linked to achieving optimal use of medicines.	
158	SH	European Medicines Group	1	3.a	We welcome the attempt to define medicines optimisation, which is no mean challenge. However, we believe the definition misses the opportunity to emphasise improved patient experience as part of 'best possible outcomes' from use of medicines. In order to reflect one key aim of medicines optimisation, to ensure best use of available resources, we believe that the final sentence should be phrased 'in order to maximise available resources' in place of 'within available resources'. We also believe that the definition needs to explicitly state that the 'available resources' reflects total pathway costs not just the cost of a medicine in order to ensure	**Thank you for your comment. The definition of medicines optimisation has been amended to reflect your comment.** Reference to resources has been removed.

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					economic considerations are taken into account fully.	
159	SH	European Medicines Group	2	3	This section should also emphasise the current rates of medicines non-adherence and the need for medicines optimisation to focus on patient participation and empowerment.	Thank you for your comment. The need for the guideline section has been amended to reflect your comment.
160	SH	European Medicines Group	4	4.1.1 b	We believe the guideline should apply to all health practitioners involved in the patient journey and should also be broadened to include those who prescribe, dispense and monitor the use of medicines not just those who 'administer' medicines. As stated in 'GENERAL' above, our interpretation of the scope is that the guideline will be directed primarily at pharmacists; however, we would contend that medicines optimisation applies to commissioners and all health professionals who have a role in delivering medicines to patients, many of whom have specific professional guidance relating to prescribing and managing medicines, and that this collective responsibility for medicines optimisation should be recognised in the guideline.	Thank you for your comment. The population section of the scope has been amended to reflect your comment. The need for the guideline section has been amended to reflect your comment.
161	SH	European Medicines Group	5	4.2 a	We believe the settings should be broadened to include tertiary care.	Thank you for your comment. The settings section of the scope has been amended to reflect your comment.
162	SH	European Medicines Group	6	4.3.1 Patient and Carer Engagement	This section would benefit from more explicit reference to empowering patients to take ownership of their own treatment. In the final guideline, inclusion of some live examples to	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.

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					enhance understanding would be valuable. We would like to suggest that the scope includes the use of technology as a means of supporting patients, information provision and decision making. We appreciate that the scale and potential future development of technology may also merit consideration as a stand-alone topic in the future.	
163	SH	European Medicines Group	7	4.3.1 Evidence-informed Decision Making	We believe this section would benefit from reference to local formularies and local medicines decision-making, specifically recognising that medicines optimisation must be embedded within these processes if attitudinal, behavioural and cultural changes (from medicines management to medicines optimisation) are to be made. This section should make reference to the rights of patients to have access to NICE approved medicines and information about all available treatment options in order to facilitate informed decision- making.	Thank you for your comment. The key issues section of the scope has been amended. Access to medicines is considered in the NICE good practice guidance on developing and updating local formularies. This will not be considered as part of this guideline.
164	SH	European Medicines Group	8	4.3.1 Intra- and inter-professional collaboration	We welcome the acknowledgement that a multi-disciplinary team- working approach will be required in order to achieve the ambitions and potential of medicines optimisation. We are concerned that if the requirement of a multi-disciplinary approach is not emphasised throughout the scope (and the guideline), the responsibility and focus for delivering medicines optimisation will rest predominantly with	Thank you for your comment. The need for the guideline section has been amended to reflect your comment.

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					pharmacists and may lead to a lack of focus on the totality of the patient experience and care pathway. We recommend greater emphasis be given to the need for collective responsibility for medicines optimisation whereby commissioners and health professionals work together to improve patient outcomes and experience and value from NHS investment in medicines.	
165	SH	European Medicines Group	9	4.3.1 Transferring medicines information across settings	Under point g) we believe the practitioners with a medicines optimisation remit are much broader than pharmacists and pharmacy based services. This should be reflected in the guideline in order to ensure a genuine multi-disciplinary team approach is achieved which is focused on the whole patient experience and care pathway.	Thank you for your comment. The need for the guideline section has been amended to reflect your comment.
166	SH	European Medicines Group	10	4.3.2	As stated above, we believe that the areas medicines adherence and access to medicines, despite having existing and comprehensive guidelines, are so pivotal to the success of medicines optimisation that they should not be specifically excluded from this scope and guideline.	Thank you for your comment. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). The main outcomes section includes 'patient-related outcomes' which will include medicines adherence as an outcome, where appropriate cross-reference will be made.
167	SH	European Medicines Group	11	4.4	We would suggest that improved health be included as a key outcome as well as mortality and morbidity.	Thank you for your comment. The outcome 'health and social care quality of life' would capture this.
168	SH	Society and College of Radiographers	General		Supply, administration and prescribing of medicines are three different mechanisms and we feel this needs to be reflected in the language used.	Thank you for your comment. The population section of the scope has been amended to reflect your comment.

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					For example, "4.1.1 b) All practitioners who administer medicines" Would this just be administration, excluding supply and/or prescribing?	
169	SH	Asthma UK	1	3 a) and b)	The guideline must clarify the difference between medicines optimisation, a concept which focuses on achieving the best outcomes for the patient and involves effective patient engagement, and the process of medicines management. The scope should also clarify whether the guideline is intended to cover medicines management – it is described as a separate entity but also as an enabler of medicines optimisation. It is unclear whether, as an enabler, it is in or out of scope.	Thank you for your comment. The need for the guideline section has been amended to reflect your comment.
170	SH	Asthma UK	2	4.1.1 Groups that will be covered a)	As the guideline will cover children and adolescents it will also need to consider parents and carers as, particularly with younger children, they will be a vital part of the engagement process that results in decision-making about medicines and in reporting outcomes.	Thank you for your comment. The 'key issues' and 'review questions' sections of the guidance have been amended to reflect your comment.
171	SH	Asthma UK	3	4.2 Setting	The range of healthcare professionals covered by the guidance should be comprehensive, covering all those likely to be involved in medicines optimisation – so social care practitioners and healthcare assistants as well as GPs, clinicians and pharmacists. It would be useful to set this out in the scope.	Thank you for your comment. The settings section of the scope has been amended to reflect your comment.
172	SH	Asthma UK	4	4.3.1 Intra- and inter-professional collaboration f)	There are many different types of clinical network, and NICE should ensure that consideration here is not restricted to, for	Thank you for your comment.

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					example, the Strategic Clinical Networks designated by NHS England, as only four conditions/patientsgroups are covered by these.	
173	SH	Asthma UK	5	4.3.1 Reducing medicines-related patient safety incidents e)	The types of medicine review covered by the scope should go beyond pharmacist review and consider, for example, the annual structured reviews that GPs should provide (and are incentivised to do so by QOF) for people with asthma. It is recommended that such reviews include consideration of asthma control and the potential for "stepping down" people's medication where appropriate.	Thank you for your comment. The guideline will not cover specific clinical conditions.
174	SH	Asthma UK	6	4.3.1 Reducing medicines-related patient safety incidents	The importance of a regular clinical audit process should be included here.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
175	SH	British Association of Dermatologists	1	General	We agree with the definition of '*medicines optimisation*'.	Thank you for your comment.
176	SH	British Association of Dermatologists	2	General	We agree with the priorities of the guidelines, which will focus on patient safety, improving patient information with regard to their medicines and creating systems to avoid prescribing and dispensing errors.	Thank you for your comment.
177	SH	British Association of Dermatologists	3	General	We would like the role of pharmacogenetics in improving safety and outcome to be considered.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
178	SH	British Association of Dermatologists	4	General	We recommend that the value of improving efficacy and compliance, particularly with topical and inhaled products, by nurse-directed education of patients should be addressed.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.

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179	SH	British Association of Dermatologists	5	General	We recommend that the scope should explicitly address different modes of treatment including topical, inhaled, orals and injectables.	Thank you for your comment. The guideline will not cover specific clinical conditions.
180	SH	British Association of Dermatologists	6	4.1.1	We strongly recommend the scope should include both inpatients and outpatients, as well as day cases – currently it mentions medicines on discharge of patients, which implies the inclusion of only inpatients.	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
181	SH	British Association of Dermatologists	7	4.1.1	We recommend the scope should also include pregnant and breastfeeding female patients.	Thank you for your comment. The population section of the scope has been amended.
182	SH	British Association of Dermatologists	8	4.1.1	We recommend that neonates and infants should be given particular consideration.	Thank you for your comment. The population section of the scope has been amended.
183	SH	British Association of Dermatologists	9	4.1.1	We recommend that people with long-term conditions (not just multiple) should also be mentioned.	Thank you for your comment. The population section of the scope has been amended.
184	SH	British Association of Dermatologists	10	4.3.1	We agree with the inclusion of '*interventions to reduce inappropriate variations in prescribing, such as variation in the uptake of NICE-approved medicines and in the implementation of NICE guidance*' in the scope. The prescribing of e.g. biological therapies is patchy and inconsistent with NICE guidance in all areas of the UK, and this needs to be addressed.	Thank you for your comment. Access to medicines is considered in the NICE good practice guidance on developing and updating local formularies. This will not be considered as part of this guideline.
185	SH	British Association of Dermatologists	11	4.3.1	We agree with the inclusion of '*interventions to reduce medicines-related patient safety incidents, including prescribing errors, dispensing errors, administration errors and monitoring errors*' in the scope. Although specific named medicines are out-of-scope, we strongly feel that isotretinoin and the ineffectiveness of the associated Pregnancy Prevention Plan should be explicitly highlighted.	Thank you for your comment. The guideline will not cover specific clinical conditions.
186	SH	British	12	4.3.1	Increasing safety of prescribing medications	Thank you for your comment. The

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		Association of Dermatologists			should specifically address drug interactions.	detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
187	SH	British Association of Dermatologists	13	General	NHS organisations responsible for prescribing policies and formularies should ensure that when generic substitutions are made, there are adequate safeguards to ensure that patients with allergy to components of a product other than the principal ingredient are not accidentally treated with a substance to which they are allergic, and that such policies guidelines and formularies include explicit provision to ensure that there are safe arrangements for patients with relevant allergies to continue to receive appropriate products if generic substitutions are to be recommended by a Healthcare Organisation or Practitioner.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
188	SH	Pfizer	1	General	Pfizer support the Department of Health's position on Medicines Optimisation and very much want to see it developed and implemented to the highest possible standard. We believe there needs to be a cultural shift in the NHS away from medicines management, processes and systems to a strong focus on the patient experience and defined patient outcomes. There needs to be a clear direction on how to improve patient outcomes and how to realise the full value of medicines taken by patients. Developing a series of reviews and publications, including this clinical guideline and the Royal Pharmaceutical Society (RPS) Medicines Optimisation Good Practice Guide, are extremely positive steps. The real challenge will be in translating these guides into practical	Thank you for your comment.

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					and meaningful changes to the way patients are managed and medicines are used. It requires practitioners and commissioners to take practical steps to translate the directives within this and other recommendations into making a real difference with patients. Aligned to this we need to give patients a greater say in how their care is delivered. From the introduction of the Health and Social Care Bill to its completion as an act, we gained the phrase 'no decision about me without me.' This is ingrained in the NHS Constitution that patients should be able to have a say in what is the right treatment for them. Pfizer believes informed choice is an important component of Medicines Optimisation and we would like this to be reflected in the scope. Therefore giving patients and clinicians the option of what is right for them not organisations on their behalf. Whilst there are a number of studies that may be used to inform Medicines Optimisation practice, such as EQUIP [1] and CHUMS [2], we believe that the number of randomised controlled trials are limited when compared to other areas of care. In the absence of sufficient gold standard quantitative data, Pfizer believe that NICE should accept other more qualitative data, real world data and best practice to inform this guideline. The recently published Berwick Report [3] highlights the need for education of the workforce and cultural change for ensuring	

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					patient safety. Pfizer would recommend that NICE aligns with the spirit of this report and includes within the guideline similar messages - ones of culture and behaviour change and the need for the workforce (those involved with medicines) irrespective of their setting to understand the concepts of ensuring safe and effective use of medicines. Pfizer supports the need for the guideline to focus on patient safety as a priority over cost containment • EQUIP study: Dornan T, Ashcroft D, Heathfield , Lewis P, Miles J, Taylor D, Tully M, Waas V. An in depth investigation into causes of prescribing errors by foundation trainees in relation to their medical education. EQIP Study. 2009 A report to the General Medical Council 2009. • CHUMS study: Carpenter J, Dean-Franklin B, Dickinson R, Garfield S, Jesson B, Lim R, Raynor DK, Savage I, Standage C, Wadsworth P, Woloshynowych M, Zermansky AG. Care homes use of medicines study (CHUMS). Report to the Patient safety {Portfolio, department of Health). 2009. • Medicines Optimisation: Helping patients to make the most of medicines Good practice guidance for healthcare professionals in England. May 2013 Berwick Report 2013	
189	SH	Pfizer	2	Page 1	We believe that the opening two statements can	Thank you for your comment. The

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				3 a) & b)	be combined to be more succinct. The wider value of medicines also needs to be reflected here such that the final paragraph reads: Medicines optimisation ensures people obtain the best possible outcomes from their medicines while minimising the risk of harm within available budget. The broader value of medicines, to include outcomes, adverse events avoided, community nursing and the patient experience, needs to be considered within the context of available resource Medicines management is an important enabler of medicines optimisation and is a term that has been used historically in the NHS for managing people's medicines.	definition of medicines optimisation has been amended.
190	SH	Pfizer	3	Page 1 3 b)	The scope states that "medicines optimisation focuses on outcomes for patients obtained from their medicines." Medicines Optimisation is broader than this and described as such in the RPS document. We would like to see this reflected in this paragraph such that this sentence reads "medicines optimisation focuses on outcomes for patients obtained from their medicines, the patient experience and a fundamental change in the way practitioners, carers and patients work with and use medicines ."	Thank you for your comment. The definition of medicines optimisation has been amended.
191	SH	Pfizer	4	Page 2&3 3h), 3i) & 3j)	The focus of this clinical guideline should always be on the patient. This is in terms of their safety, outcomes achieved and their experience; 3h) directly references the Francis report. We believe in line with this focus, these three points (3h, 3i & 3j) need to be raised earlier in the list	Thank you for your comment. The need for the guideline section has been amended to reflect your comment.

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					under 'need for this guideline.' Whilst we appreciate the list does not represent a decrease in priority, it might be that some attach significance to the order the points appear in. We are concerned that the first two points listed after the 'definition (3a and 3b),' are related to cost in terms of money spent and money wasted, and that this sends the wrong message that this is more about cutting cost; medicines optimisation should fundamentally be about quality and outcomes first and foremost. Getting all the other elements right should naturally lead to reducing waste and cost savings. We believe the order should be – (combination of a&b) followed by g, h, I, j, c, d, e, f, j, k, l, m	
192	SH	Pfizer	5	Page 4 4.1.1 b)	The scope states that groups covered by the guideline will include 'All practitioners who administer medicines.' Using the term administer might be confusing so should be changed to *prescribe, dispense, supply or administer.* This would then embrace drugs supplied against patient group directions, which in most instances are supplied to a patient (by a pharmacist or others) but not administered at the time of supply. We also believe this extends to some non practitioners and should therefore be amended to more clearly describe all people who are involved right across the patient journey. This will typically include healthcare professionals, but also should be taken to include carers, patient support groups and even administrative staff as appropriate.	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
193	SH	Pfizer	6	Page 4	**Groups that will be covered**	Thank you for your comment. The

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				4.1.1 a)	Pfizer believe this should change so that it states **all** people taking a medicine. By creating a list of groups covered by the guidance there is a risks of groups being excluded by virtue of not being included. Need to ensure equality of access for all people taking or using medicines irrespective of the setting in which they live or stay. In line with comments at the NICE scoping meeting we believe that the last bullet of the original list should remain which states – "**people who are not receiving medicines when they should or could benefit from medicines**. This will ensure that the guideline included patients who fit within the category of 'unmet need' because of either sub-therapeutic treatment/inappropriate treatment or not receiving treatment for variety of reasons	population section of the scope has been amended to reflect your comment.
194	SH	Pfizer	7	Page 4 4.2 a)	Under Settings, the guide states 'All publicly-funded health and social care provided in primary care, secondary care….' For completion we believe this should also include tertiary care.	Thank you for your comment. The settings section of the scope has been amended to reflect your comment.
195	SH	Pfizer	8	Page 5 4.3.1	It is critical that the right medicine is made available to the right patient at the right time and to that end the practitioner and patient must have access to all NICE approved medicines. As stated in the report, Innovation Health & Wealth - Accelerating Adoption and Diffusion in the NHS, there should be no local barriers to	Thank you for your comment. Access to medicines is considered in the NICE good practice guidance on developing and updating local formularies. This will not be considered as part of this guideline.

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					accessing technologies recommended in NICE appraisals, beyond a clinical decision relating to an individual patient The scope states that access to medicines will not be covered in this guide (page 9, 4.3.2), however active and robust application of NICE guidance is fundamental to this guideline. We believe it needs to be reflected in this clinical guideline and its scope, and in its recommendations for systems, processes and behaviours to facilitate this. There are other sentinel markers of optimal medicine use we would like to see reflected in this guideline, which are: a. Medicines should have an evidence base and be supplied for the licensed indication and reflect best practice. b. NICE guidance should be followed c. Patients should be given an informed choice to what is right for them d. Formulation must be suitable for patient needs to aid compliance e. Expectations of medicine outcomes communicated to ensure the patient understands what can reasonably be expected of a medicine. f. Recognition that certain medicines need to be prescribed by brand e.g. Certain antiepileptic and other medicines with identified bioequivalence issues including those which are available in dosage forms which impact bioequivalence such as modified release formulations Innovation Health and Wealth: Accelerating	

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					Adoption and Diffusion in the NHS – Gateway reference 16978 December 2011:	
196	SH	Pfizer	9	Page 5 4.3.1	This section focuses on the key element of Medicines Optimisation, the consideration of what is appropriate for the patient as identified through an informed discussion with their practitioner. We believe this section should therefore be strengthened to reflect patient empowerment and their input in improving their care. It needs to reflect patient choice and the importance of the patient's view in their management. Pfizer believes that evidence informed decision making must not be restricted to NICE appraised medicines (guidance, guidelines, evidence summaries) but should also cover all licensed medicines.	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
197	SH	Pfizer	10	Page 5 4.3.1 e)	Medicines optimisation focuses on "personalised and individualised care." Pfizer believe the guide must acknowledge that tensions may arise between NHS drivers of prescribing, such as QOF or CCGOIS that are at odds with what the patient wants and should receive. There needs to be allowance for clinical discretion to avoid bias towards incentives that may not be in the patients' best interest. An example of this is the overuse in aspirin in AF that is rewarded in QoF, but would be questioned by clinical experts.	Thank you for your comment. The key issues section of the scope has been amended.
198	SH	Pfizer	11	Page 6 4.3.1	Under the heading *Transferring medicines information across care settings*, the scope talks about communication at critical points in the care pathway. Communication is very important, but we believe organisations and individuals need to consider integration of all functions	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.

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					related to medicines optimisation across different settings and as such this needs to be included here.	
199	SH	Pfizer	12	Page 6 4.3.1	Under the heading *Transferring medicines information across care settings*, the scope talks about *specific responsibilities* and refers to *practice-based pharmacists and medicines management discharge technicians.* Naming these roles specifically, might be perceived as implying Medicines Optimisation differentially relates to these traditional medicines related roles, whereas it is much broader with equal implication to all prescribers including doctors and nurses. We would like to see these roles reflected here to support this becoming routine practice.	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
200	SH	Pfizer	13	Page 9 4.3.2	We recognise that the guideline will not cover all areas, notably where these have been addressed in previous guidance such as adherence. We do however feel there are important areas which should be included in the scope that have been omitted. These are: • 4.3.2 b) Certain antiepileptic and other medicines with identified bioequivalence issues including those which are available in dosage forms which impact bioequivalence such as modified release formulations • 4.3.2 Counterfeit Medicines: The entry of counterfeit medicines into the supply chain represents a real threat to patient safety, both in terms of the dangers of untested and potentially dangerous	Thank you for your comment. The key issues section of the scope has been amended. Key issues within the scope have been prioritised. These suggestions are not felt to be a priority in comparison with those key issues selected.

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					substances being ingested, but also treatments being ineffective and the ramifications of this. In addition, the research and huge investment made by the pharmaceutical industry in discovering and bringing innovative medicines to patients is undermined. It is vital to ensure medicines have come from a robust source and that patients and NHS can be confident in what it is getting. We note the MHRA's position on the EU Falsified Medicines Directive and we would urge that this guidance takes a more robust position. In particular we believe that the only way to really be confident in the legitimate supply chain is if **all** prescription medicines are in scope and **all** are checked out of the proposed verification system at the point of dispensing. This should become a routine part of a pharmacist's role in Medicines Optimisation • 4.3.2 Behaviors and cultural change: For many years the focus has been on medicines management rather than Medicines Optimisation. Changing the way healthcare practitioners work with medicines requires not just a new way of thinking about the problems they face, but a real change in behaviors, culture and possibly incentives. This will ensure Medicines Optimisation becomes routine and sustained practice. There needs to be re-framed thinking	

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					such that all staff associated with the patient journey understand and appreciate the importance of Medicines Optimisation so that it becomes part of everyday practice. The mindset has to be that outcomes and safety need to take precedent above reducing waste and saving money.	
201	SH	Pfizer	14	Page 9 4.3.2 (a)	**Areas that will not be covered** We recognise that adherence has been covered previously in CG76. Whilst we understand it not being within the scope of this short clinical guideline, we do feel there needs to clear acknowledgement of CG76 and a link to it in the final version of this medicines optimisation guideline. This is extremely important, firstly given that adherence is such a fundamental part of medicines optimisation and secondly, this guideline will inform the development of the Quality Standard.	Thank you for your comment. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). The main outcomes section includes 'patient-related outcomes' which will include medicines adherence as an outcome, where appropriate cross-reference will be made.
202	SH	Pfizer	15	Page 9 4.4	We broadly support the outcomes listed in this section of the scope, however believe that they need some refinement. a) Mortality and morbidity – It is difficult to assign cause and effect for outcomes such as mortality, especially with a topic such as this so we believe it should change to Improved patient clinical outcomes. b) Hospitalisation and health-care utilisation – We believe this should be changed to Reduced hospitalisation and length of stay due to medication errors or adverse events which is aligned to Domain 5 of the NHS Outcomes	Thank you for your comment. The main outcomes section of the scope has been amended to reflect your comment.

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					Framework. c) Planned and unplanned contact – medicines optimisation should result in the patient condition resolving or improving sooner so we believe this should change to Reduction in repeat consultations. d) Medication-related problems, including prescribing errors, monitoring errors and adverse effects – We believe this should be simplified to Reduced adverse events which is aligned to Domain 5 of the NHS Outcomes Framework. e) Patient-reported outcomes e.g. reduced uncertainty, satisfaction with decision-making – Given the focus on the patient experience, we believe this should change to Improved Patient Experience which is aligned to Domain 4 of the NHS OF f) Other non-patient related outcomes such as, NICE compliance / uptake of NICE-approved medicines and reduction in waste medicines – We believe this should be made more specific so to change to Reduction of wastage of medicines and Improved implementation of NICE guidance	
203	SH	Roche Products	1	3 (a)	The definition should be explicit that medicines optimisation applies equally: (i) in all healthcare settings, the patient's home and workplace; and (ii) irrespective of whether a patient is self-administering a medicine or whether the	Thank you for your comment. The definition of medicines optimisation has been amended.

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					medicine is administered to them – by whatever route – by a carer or healthcare professional.	
204	SH	Roche Products	2	3 (c) – 3 (m)	NICE guidance on medicines optimisation is needed in both secondary and primary care. However, this is not adequately reflected in section 3 and could be misinterpreted as the focus of medicines optimisation being in the community. In 2010/11 the NHS medicines bill was £12.9 billion. Of this 68% was spent in primary care and 32% in secondary care (NHS North of England, June 2012 [available at: link]). Between 2005 and 2010, 75% of medication incidents reported to the National Reporting and Learning System in England in Wales were from acute general hospitals (Cousins D, Gerrett D, Warner B. Reporting and Learning System in England and Wales over six years (2005 – 2010) Br J Clin Pharmacol. 2012 DOi:10.1111/j.1365-2125.2011.04166) Recent data published by the NRLS [available at: link] shows that in the 6 month period October 2012 – March 2013 between 9.9% and 10.8% of all incidents reported by acute trusts were medication incidents.	Thank you for your comment. The need for the guideline section has been amended.
205	SH	Roche Products	3	4.1.1 (a)	Roche believes the guideline development group should also make particular consideration of people with mental health problems. Two reports from the National Mental Health Development Unit have highlighted the importance of appropriately managing medicines in acute mental health wards (Getting the Medicines Right link) and crisis resolution and home treatment teams (Getting the Medicines Right 2 link). These reports acknowledge that	Thank you for your comment. The population section of the scope has been amended. Guidance development will follow NICE's equality policy.

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					better management of medicines will: culminate in a number of beneficial outcomes including reduced admissions to acute services; provide an effective clinical approach to the use of treatments that have a good evidence base; tackle interventions around concordance; improve medicine safety; and reduce waste.	
206	SH	Roche Products	4	4.1.1 (b)	Given the broad scope proposed for the short Clinical Guideline and the importance of integrating medicines into care pathways the stated groups covered should include all practitioners who prescribe, dispense or administer medicines to patients and those involved in educating and coaching patients and carers concerning their medicines.	Thank you for your comment. The population section of the scope has been amended.
207	SH	Roche Products	5	4.3.1	Roche agree that all the proposed areas to be covered are appropriate **Patient and carer engagement in shared decision making** (c, e) The differences between patient-centred, individualised and personalised care need to be clarified in the scope. **Evidence-informed decision making** (a) Patients and carers should have access to appropriate information on all medicines which may be suitable for them – in the context of their care pathway – to facilitate informed choice. **Intra- and inter-professional collaboration** Roche feels it is particularly important that the role of all professions is considered to ensure an appropriate focus on patient choice, consent and patient outcome. The Royal Pharmaceutical Society has taken a lead in providing a framework for medicines optimisation and NICE guidance will play a central role in ensuring	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.

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					multidisciplinary application. **Transferring medicines information across care settings** (g) Referring to *practitioners with a medicines optimisation remit* contradicts the importance of multidisciplinary team working and the role all health care professionals play in medicines optimisation in all healthcare settings. Referring specifically to practice-based pharmacists and medicines management discharge technicians may limit the perceived applicability of the short Clinical Guideline. **Reducing medicines-related patient safety incidents** With European pharmacovigilance legislation requiring medication incidents to be reported as adverse events (link) Roche welcomes the focus on this area of practice. We assume that legacy projects of the *National Patient Safety Agency* such as the risk assessment of high-risk injectable medicines will be considered by the Guideline Development Group. Reporting systems and learning from medicines-related incidents reported by patients and their carers should be addressed.	
208	SH	Roche Products	6	4.3.2 (h)	With regards to access to medicines, the NHS Constitution states: "*You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.*" Although NHS England has an Interim Commissioning Policy in place for Individual Funding Requests	Thank you for your comment. Access to medicines is considered in the NICE good practice guidance on developing and updating local formularies. This will not be considered as part of this guideline.

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					(NHSCB/CP/03; link) Roche believes unacceptable variation exists amongst other commissioners. The reason for exclusion of this topic by NICE is given as "*Crosses remit of other national organisations such as the MHRA. Outside control of audience for this guidance.*" Healthcare professionals make local decisions regarding individual patient care when medicines are not included in local formularies and Roche believes the Guideline Development Group should consider the topic unless another NHS body is developing appropriate guidance.	
209	SH	Lundbeck UK	1	General	Lundbeck Ltd welcome the decision to provide further clarity regarding medicines optimisation through development of this guideline which will help ensure NHS patients get the best possible outcomes from their medicines. This will also help support the change in culture and direction required from purely medicines management to the broader medicines optimisation focused on improving outcomes.	Thank you for your comment.
210	SH	Lundbeck UK	2	3a	The definition of medicines optimisation (second paragraph) outlining what it required would benefit from including improved patient experience as part of the outcomes to be delivered. In order to reflect one key aim of medicines optimisation i.e. to ensure best use of available resources, we believe that the final sentence should be phrased 'in order to maximise available resources' instead of 'within available resources'.	Thank you for your comment. The definition of medicines optimisation has been amended to reflect your comment.
211	SH	Lundbeck UK	3	4.1.1a.	We welcome the inclusion of the groups set out	Thank you for your comment. The

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					in the scope for the guideline, in particular people using multiple medicines and people with multiple long-term conditions. We believe the guideline should also include a particular focus on people with mental illness. Medicines optimisation is extremely important for this group of patients for the reasons set out below and this is not a specific clinical condition. A recent report from the King's Fund and the Centre for Mental Health highlighted that more than four million people in England with a long-term physical health condition also have mental health problems[ix]. In addition, the report found that between 12 and 18% of all money spent by the NHS on long-term physical health conditions is linked to poor mental health[x]. People with serious mental illness are twice as likely to die from heart disease as the general population, and three times more likely to die from cancer than other cancer patients[xi]. People with schizophrenia, for example, have an increased risk of premature death from coronary heart disease[xii], and prevalence of type 2 diabetes is two to three times higher for people with schizophrenia than for the general population[xiii].	population section of the scope has been amended.
212	SH	Lundbeck UK	4	4.1.1b	As it currently stands, the guideline appears to be directed only at those administering medicines e.g. pharmacists; however there are many commissioners and health professionals who have a role in the delivery of medicines to patients, many of whom have specific professional guidance relating to prescribing and	Thank you for your comment. The population section of the scope has been amended to reflect your comment.

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					managing medicines. Therefore we believe this part of the guideline should be broadened to include all those who prescribe, dispense and monitor the use of medicines during the patient journey not just those who 'administer' medicines.	
213	SH	Lundbeck UK	5	4.3.1 Evidence informed decision making	This section should include decisions regarding 'choice of medicines' i.e. medicines should have an evidence base, be supplied for the licensed indication where possible and reflect best practice. NICE guidance should be followed (where available) and the formulation must be suitable for the patient (patient choice) to help them realise the full benefits of their medicines.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
214	SH	Lundbeck UK	6	4.3.1g Transferring medicines information across settings	We believe the practitioners with a medicines optimisation remit are much broader than pharmacists and pharmacy based services. This should be reflected in the guideline in order to ensure a genuine multi-disciplinary team approach is achieved which is focused on the whole patient experience and care pathway. We suggest changing this aspect to read 'all healthcare professionals involved with medicines'.	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
215	SH	Lundbeck UK	7	4.3.1 Areas that will be covered	We believe that reviewing and monitoring patient outcomes through medication reviews, medicines use reviews (MURs) and drug monitoring should not be limited to the section of the guideline that relates to reducing medicines-related patient safety incidents. This issue should also be addressed in the earlier section on patient and carer involvement in shared decision making, as it is relevant to improving patient outcomes and patient satisfaction with treatment more broadly.	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.

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216	SH	Lundbeck UK	8	4.3.2a	We understand the reasoning behind excluding adherence from the scope due to the existence of a separate guideline CG76, however adherence is intrinsically embedded within Medicines Optimisation as it is impacted by the degree to which there is an understanding of the patient circumstances to ensure in return that the right formulation, dose, medicine &/or class of medicine is chosen. This is key to ensuring the best outcome from the medicines and thus we believe adherence should formally flagged as an important component of medicines optimisation and clear statements made within this guideline to highlight the importance of implementing CG76 as part of any medicines optimisation programme.	Thank you for your comment. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). The main outcomes section includes 'patient-related outcomes' which will include medicines adherence as an outcome, where appropriate cross-reference will be made.
217	SH	Lundbeck UK	9	4.3.2j	There will be a need for some education and re-training around the principles of medicines optimisation. Sustainable change in behaviour requires a fundamental change in culture. To change the mind-set to one where focus on outcomes and safety takes precedence above just reducing waste and saving money requires re-framed thinking and a culture that allows this to happen e.g. economic considerations being based on the impact of the medicine on total pathway costs and not just medicines acquisition costs.	Thank you for your comment.
218	SH	Lundbeck UK	10	4.5	An additional question to consider for inclusion: For all patients using medicines what is the most effective system and process for ensuring outcomes from medicines use are routinely captured?	Thank you for your comment. The development of the guidance will follow NICE short clinical guideline methodology. Due to the time available to develop the guideline,

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						prioritisation of the review questions has been required. Therefore unfortunately you additional review questions cannot be considered.
219	SH	Otsuka Pharmaceuticals UK Ltd	1	4.1.1 – The groups that will be covered	We welcome the inclusion of the groups set out in the scope for the guideline, in particular, people using multiple medicines and people with multiple long-term conditions. We believe the guideline should also include a particular focus on people with mental illness. Medicines optimisation is extremely important for this group of patients for the reasons set out below. A recent report from The King's Fund and the Centre for Mental Health highlighted that more than four million people in England with a long-term physical health condition also have mental health problems[xiv]. In addition, the report found that between 12% and 18% of all money spent by the NHS on long-term physical health conditions is linked to poor mental health[xv]. People with serious mental illness are twice as likely to die from heart disease as the general population, and people with schizophrenia are three times more likely to die from cancer than other cancer patients in the general population[xvi]. As an example, people with schizophrenia, for example, have an increased risk of premature death from coronary heart disease[xvii], and prevalence of type 2 diabetes is two to three times higher for people with schizophrenia than for the general population[xviii].	Thank you for your comment. The population section of the scope has been amended.
220	SH	Otsuka		4.3.1 – Areas that	We support the scope's focus on patient and	Thank you for your comment. Specific

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		Pharmaceuticals UK Ltd	2	will be covered	carer involvement in shared decision making and the effect of evidence-informed decision making processes. We would welcome a particular focus on shared decision making for people with serious mental illness. **We note that the scope of this consultation excludes specific clinical conditions but, given our expertise in this area, we cite schizophrenia as an example within serious mental illnesses to illustrate the points made.** The National Schizophrenia Audit has reported that many people with schizophrenia feel they are not provided with information about their medication in an adequately understandable form[xix]. Only 62% reported that the information was in a form they could properly understand. Further, people reported not always feeling sufficiently involved in the final decision about which medication they should take. While clinical staff reported that they thought they had involved people with schizophrenia in the choice of medication in 62% of cases, only 41% of people with schizophrenia felt their views were taken into account[xx]. The guideline should also address the provision of timely information on treatment and care options. It is important that involvement in decision making is not limited to times of crisis or relapse, when a person's ability to make an informed decision may be impaired. When patients with schizophrenia make a joint	conditions are areas that will not be included in the guideline.

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					decision with their clinician, both are more likely to adhere to their treatment plan[xxi]. In addition, the more stable people are, the more they are able to exercise choice in their treatment pathway before their condition worsens. In schizophrenia treatment, the high confidence of clinicians in perceiving that they know the attitudes of their patients often means that they do not properly understand what motivates patients' choices[xxii]. It is therefore important to explore how health professionals can work towards objectives that are defined by the patient and not by the clinician, in order to help them to achieve their personal goals.	
221	SH	Otsuka Pharmaceuticals UK Ltd	3	4.3.1 – Areas that will be covered	We believe that reviewing and monitoring patient outcomes through medication reviews, medicines use reviews (MURs) and drug monitoring should not be limited to the section of the guideline that relates to reducing medicines-related patient safety incidents. This issue should also be addressed in the earlier section on patient and carer involvement in shared decision making, as it is relevant to improving patient outcomes and patient satisfaction with treatment more broadly. The Department of Health convened a roundtable event in January 2011 to identify practical steps that might be taken to help reduce waste, optimise medicine taking and improve health outcomes[xxiii]. One of the key messages from the roundtable event was that there is much scope to improve MURs for mental health conditions. The group was in	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.

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					agreement that MURs are an important development in helping patients to understand their medicines and relay concerns and in picking up those patients who are most at risk of making less effective use of their medicines[xxiv].	
222	SH	Otsuka Pharmaceuticals UK Ltd	4	4.3.1 – Areas that will be covered	It is unclear from the scope whether the section on reducing preventable medicines-related hospital admissions would include admissions which are related to non-concordance with treatment plans. As explained further in the section below, there is an important relationship between medicines optimisation and medicines concordance, which should be acknowledged in the scope. A key part of preventing admissions and readmissions to hospital for people with schizophrenia is in doing everything possible to prevent relapse. Non-adherence to medication is the most common cause of relapse for people with schizophrenia[xxv].	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
223	SH	Otsuka Pharmaceuticals UK Ltd	5	4.3.2 – Areas that will not be covered	Although we understand the reasoning behind excluding medicines adherence from the scope, due to the existence of a separate guideline on this topic, there is inevitably some crossover between the two guidelines. This should be acknowledged in the scope and addressed in the guideline itself. There is a strong relationship between medicines optimisation and medicines concordance and this should therefore be referred to in the section of the guideline on patient and carer involvement in decision making. This is particularly relevant for people	Thank you for your comment. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). The main outcomes section includes 'patient-related outcomes' which will include medicines adherence as an outcome, where appropriate cross-reference will be made. Specific conditions are areas that will not be included in the guideline.

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					with serious mental illness. The reasons for non-concordance with medicines for people with serious mental illness are complex. Non-concordance with medicines results in patients failing to access the best treatment, resulting in poor outcomes and reduced quality of life. There is evidence to suggest that people with conditions that are viewed as stigmatising (including schizophrenia, depression, HIV and epilepsy) can be reluctant to take medicine for fear of disclosing their illness and marking themselves out as different[xxvi]. The 2009 Department of Health-commissioned report, *Evaluation of the Scale, Causes and Costs of Waste Medicines,* found that of all categories of drugs, those for the central nervous system accounted for the largest proportion of those drugs that are dispensed but unused by patients, representing over a quarter of the overall costs of drugs wasted in this manner[xxvii]. Over three quarters (77%) of patients with schizophrenia who are prescribed medication deviate from their treatment recommendations[xxviii]. A recent study found that 29% of patients are intentionally non-adherent to their treatment regimen and 71% are unintentionally non-adherent[xxix]. Poor adherence to treatment for people with schizophrenia is a major risk factor of relapse which results in increased mortality. Non-adherence to medication results in an increased	

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					relapse risk of up to five times that of adherent patients[xxx].	
224	SH	Association of the British Pharmaceutical Industry	1	General	The Association of the British Pharmaceutical Industry (ABPI) supports the Department of Health and NHS England positions on Medicines Optimisation and is keen to see these implemented consistently to the highest possible standard. We believe there needs to be a cultural shift by all healthcare professionals and strategic leads in the NHS to embrace not only the process focus of medicines management but also a greater focus on patient experience and patient outcomes. The development of this short NICE clinical guideline is welcomed and has the potential to contribute to the achievement of these aims. ABPI believes there is a need for clear direction from NICE to support the NHS in adopting Medicines Optimisation principles and actions in order to improve patient outcomes and help realise the full value of medicines. This short guideline together with the Royal Pharmaceutical Society (RPS) Medicines Optimisation Principles and appropriate implementation tools are essential for this to happen. The real challenge will be in translating these into practical and meaningful changes to the way patients are managed, decisions are made and medicines are used. The challenge requires practitioners and commissioners to take practical steps to adopt different behaviours to translate the recommendations which will be made into tangible which actions which make a	Thank you for your comment. The development of the guidance will follow NICE short clinical guideline methodology.

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					real difference to patients. ABPI would support the preparation of a needs assessment for implementation tools to run in parallel with the development of the guideline. ABPI would support the timely development of appropriate NICE implementation tools for stakeholders to use to embed medicines optimisation into routine practice. This would help provide consistency of messages to all healthcare practitioners as well as help the NHS implement the recommendations to be made in the guideline. For this particular guideline, the GDG will need to adopt a specific process for determining the level of acceptable evidence to inform the recommendations. This is likely to be different from other disease –based short clinical guidelines. ABPI believes that alongside robust published evidence from UK and international sources, there will be a need to call for evidence through oral testimony, case studies and patient stories. NICE have already adopted this approach in the development of two previous good practice guidelines with this form of evidence being rigorously assessed by the guidance development groups and NICE project teams. ABPI would anticipate the same level of rigour can be applied to the evidence base from these various sources for this guideline.	

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					ABPI would suggest that NICE consider calling for case studies published by the pharmaceutical industry and other stakeholders as well as NHS practitioners. A number of robust case studies are available from ABPI as well as directly from individual companies. One such case study focussing on Chronic Obstructive Pulmonary Disease (COPD) provided to NHS England (NHSE) as an example of successful Medicines Optimisation and successful collaboration with industry was well received by NHSE and can be shared on request from ABPI.	
225	SH	Association of the British Pharmaceutical Industry	2	Page 1 3 a) & b)	We believe that the opening two statements can be combined to be more succinct. This statement should also reflect the wider value of medicines , therefore the final paragraph for this section could read: Medicines optimisation ensures people obtain the best possible outcomes from their medicines while minimising the risk of harm within available budget. The broader value of medicines should include outcomes, adverse events avoided, community nursing and the patient experience, needs to be considered within the context of available resource Medicines management has been an important forerunner for medicines optimisation and is a term that has been used historically in the NHS for managing people's medicines.	Thank you for your comment. The key issues section of the scope has been amended.
226	SH	Association of the British Pharmaceutical Industry	3	Page 2 3(c)	The recently published study from Office for Health Economics (OHE) **Projecting expenditure on medicines in the NHS** indicates that total current UK spend on medicines accounts for less than 10% of total NHS expenditure for the UK. "The study	Thank you for your comment.

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					debunks the myth that medicines costs in the UK are high and rising. From the data, we can see how the growth in spending on branded medicines is projected to be just 1.3% annually up to 2015, compared to total growth of NHS expenditure on medicines of 2.5% a year between 2011 and 2015"(OHE 2013).	
227	SH	Association of the British Pharmaceutical Industry	4	Page 2&3 3h), 3i) & 3j)	The focus of this short guideline should include the patient, in terms of their safety, outcomes achieved and their experience; 3h) directly references the Francis report. Therefore ABPI believe that, in line with this focus, these three points (3h, 3i & 3j) should be raised earlier in the list under 'need for this guideline.' We are concerned that the first two points listed after the 'definition (definition points 3a and 3b),' are related to cost in terms of money spent and money wasted, and that this sends the wrong message that Medicines Optimisation is focused on cost containment or savings. Therefore ABPI believe the order should be – (definition a&b) followed by g, h, I, j, c, d, e, f, j, k, l, m	Thank you for your comment. The need for the guideline section of the scope has been amended. The definition of medicines optimisation has been amended to reflect your comment. Reference to resources has been removed
228	SH	Association of the British Pharmaceutical Industry	5	Page 2 g)	The NHS Constitution referenced here outlines the right of patients to "*be involved in discussions & their decisions about their health & Care*." ABPI believes it is essential that the two medicines related sentences of the Constitution are also added as these form the basis for the principles of shared decision making, patient	Thank you for your comment. The purpose of the need for the guideline section is to provide an overview not to go into the detail as suggested in your comment.

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					empowerment and evidence based choice of medicines. "*You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you*" "*You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you*"	
229	SH	Association of the British Pharmaceutical Industry	6	Page 2 (h)	ABPI supports the absolute need for the guideline to focus on patient safety as a priority over cost containment The recently publish Berwick Report highlights the need for education of the workforce and cultural change for ensuring patient safety. ABPI would recommend that the GDG considers alignment with the spirit of this report in developing the guideline. - Messages such as culture and behaviour change and the need for the workforce (those involved with medicines) irrespective of their setting to understand the concepts of ensuring safe and effective use of medicines.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
230	SH	Association of the British Pharmaceutical Industry	7	Page 4 4.1.1 a)	**Groups that will be covered** This should change so that it states **all** people taking a medicine and is therefore wholly inclusive Need to ensure equality of access for all people taking or using all licenced medicines for all indications irrespective of the setting in which they live or stay.	Thank you for your comment. The population section of the scope has been amended to reflect your comment.

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					However, ABPI believes that the last bullet of the original list is important which states – "**people who are not receiving medicines when they should or could benefit from medicines**. This will ensure that the guideline can include patients who fit within the category of 'unmet need' because of either sub-therapeutic treatment/inappropriate treatment or not receiving treatment for a variety of reasons	
231	SH	Association of the British Pharmaceutical Industry	8	Page 4 4.1.1 b)	'All practitioners who administer medicines' is incomplete. ABPI believes this statement should be changed to read …administer, supply or prescribe	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
232	SH	Association of the British Pharmaceutical Industry	9	Page 4 4.2 a)	This should be simplified to say 'all health and social care settings including prisons '	Thank you for your comment. The settings section of the scope has been amended.
233	SH	Association of the British Pharmaceutical Industry	10	**Page 5** 4.3.1	**Patient and carer engagement in shared decision making** ABPI believes the title and content of this section needs to be strengthened to reflect patient empowerment and patient responsibility for their health care and use of the medicines. This position of patient empowerment should be mirrored by carer empowerment to support the patient if needed. The patient and healthcare professional need to be able to have an informed discussion about the patient's care.	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
234	SH	Association of the British	11	4.3.1 a)	Currently states "Evidence-informed decision making, including patient engagement."	Thank you for your comment. The key issues section of the scope has been

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		Pharmaceutical Industry			ABPI believe there is a need to include 'clinical judgment' within the decision-making process so that it reads "Evidence-informed decision making, including patient engagement and clinical judgment."	amended.
235	SH	Association of the British Pharmaceutical Industry	12	4.3.1	We would like to see the addition of "**in the absence of robust clinical trial data** to inform decision making, there needs to be acknowledgement from NICE as already stated that other levels of evidence will be required to support the development of the guideline e.g. clinical opinion, case studies, patient reports .	Thank you for your comment. The development of the guidance will follow NICE short clinical guideline methodology.
236	SH	Association of the British Pharmaceutical Industry	13	4.3.1 e)	ABPI considers that although there is a focus on "personalised and individualised care," the guide must acknowledge that tensions may arise between NHS drivers of prescribing, such as QOF or CCGOIS that are at odds with what the patient wants and should receive. There needs to be allowance for clinical discretion to avoid bias towards incentives that may not always be in the patients' best interest.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
237	SH	Association of the British Pharmaceutical Industry	14	4.3.1 e)	**Evidence-informed decision making** ABPI considers that this section needs to include patients rights (NHS Constitution) to innovative medicines (NICE technology appraisals) AND medicines not (or not yet) appraised by NICE ABPI believes that evidence informed decision making must not be restricted to NICE appraised medicines but should also cover all licenced medicines.	Thank you for your comment. The key issues section of the scope has been amended.

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					"*Ability of patients to raise and discuss medicines issues, such as side effects*." ABPI would like to see added "and which medicine will give the patient the best chance of the desired outcome." This section focuses on the key element of Medicines Optimisation, which is what is appropriate for the patient as identified through an informed discussion with their practitioner. ABPI believes this section should therefore be strengthened to reflect patient empowerment and their input in improving their care. It needs to reflect patient choice and the importance of the patient's view in their management.	
238	SH	Association of the British Pharmaceutical Industry	15	Page 6 4.3.1.(b) 4.3.1 (g)	**Intra and Inter professional collaboration** The word 'communication' can be considered a one way process. ABPI believes this section needs to reflect a culture change that moves towards 2-way dialogue with patents/carers 'working with the pharmaceutical industry' – ABPI welcomes reference to working with the industry however this should be clarified in the guideline so that collaboration is accepted as a genuine benefit to patient care and improving outcomes.	Thank you for your comment. The key issues section of the scope has been amended.
239	SH	Association of the British Pharmaceutical Industry	16	Page 6 4.3.1	**Transferring medicines information across care settings** Medicines optimisation needs to be integrated at all points in the patient pathway. The scope currently refers to '*practitioners with a medicines optimisation remit such as practice-*	Thank you for your comment. The key issues section of the scope has been amended.

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					based pharmacists/technicians' ABPI would wish to stress the need for the guideline to be applicable for all healthcare professionals involved with medicines, not just pharmacists. If the guideline is too pharmacist focused there is a risk that other professionals will deprioritise medicines optimisation and the philosophy will not become routine practice for all.	
240	SH	Association of the British Pharmaceutical Industry	17	Page 7 4.3.1	**Reducing medicine-related patient safety incidents** ABPI believes there is a need to ensure safe use of medicines features as a higher priority than cost efficiencies and prescribing targets within NHS mindsets. The adoption of the common patient record (Royal College of Physicians) would play a valuable role in standardising the data captured for analysis of patient safety incidents. This should also cover the requirements for brand named prescribing of all biological medicines which includes biosimilars.	Thank you for your comment. The key issues section of the scope has been amended.
241	SH	Association of the British Pharmaceutical Industry	18	Page 9 4.3.2 (b)	**Areas that will not be covered** Specific named medicines – in line with the ABPI position statement - we believe that the naming conventions for specific medicines to ensure patient safety and pharmacovigilence should be included within the guideline. This should include the requirements for brand named prescribing of all biological medicines which includes biosimilars.	Thank you for your comment. Specific named medicines will not be included in the guideline.
242	SH	Association of the British	19	Page 9 4.3.2 (a)	ABPI recognises that adherence has been covered previously in CG76. Whilst we	Thank you for your comment. Medicines adherence is not

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		Pharmaceutical Industry			understand it not being within the scope of this short clinical guideline, we do feel there needs to clear acknowledgement of CG76 and a link to it in the final version of this medicines optimisation guideline. This is extremely important, firstly given that adherence is such a fundamental part of medicines optimisation and secondly, because this guideline will inform the development of the Quality Standard.	specifically included in the scope (existing NICE guidance covers this subject). The main outcomes section includes 'patient-related outcomes' which will include medicines adherence as an outcome, where appropriate cross-reference will be made.
243	SH	Association of the British Pharmaceutical Industry	20	Page 9 4.3.2 (j)	Behaviours and cultural change- For many years the focus has been on medicines management rather than Medicines Optimisation. Changing the way healthcare practitioners work with medicines requires not just a new way of thinking about the problems they face, but a real change in behaviours and culture. This will ensure Medicines Optimisation becomes routine and sustained practice. There needs to be re-framed thinking such that all staff associated with the patient journey understand and appreciate the importance of Medicines Optimisation so that it becomes part of everyday practice. The mindset has to be that outcomes and safety need to take highest precedent above reducing waste and saving money.	Thank you for your comment.
244	SH	Association of the British Pharmaceutical Industry	21	Page 10 4.5	Review Question ABPI supports the review questions already included in this section. Given the importance of identifying measurable outcomes for medicines optimisation, we believe this section would be strengthened by the addition of a further question focused more specifically on measuring outcomes. For example: For all NHS and social care organisations are there any examples of local or	Thank you for your comment. The development of the guidance will follow NICE short clinical guideline methodology. Due to the time available to develop the guideline, prioritisation of the review questions has been required. Therefore unfortunately you additional review questions cannot be considered.

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					national Medicines Optimisation initiatives that demonstrate improved patient outcomes and more effective use of NHS resources.	
245	SH	Association of the British Pharmaceutical Industry	20	Page 9 4.4	**Main outcomes** ABPI believes that the outcomes listed in this section of the scope require some refinement and specificity to align to measurements that can demonstrate the benefits to patients from Medicines optimisation activities. The outcomes need to align to what can currently be captured within systems (e.g GP systems, Community Pharmacy services, Hospital admission data) but also pave the way for evolution of enhanced metrics that can be developed over 2-3 year period : For example • refined metrics for medicines reconciliation and post discharge medicines review, • all patients discharged with a medicines care plan that is integrated into community pharmacy as well as GP/community services, • enhanced patient experience survey and evaluation, • use of patient held technologies for assessing changes in clinical outcomes linked to effective medicines use e.g a) Mortality and morbidity – change to Improved patient clinical outcomes b) Hospitalisation and health-care utilisation – change to 'Reduced hospitalisation and length of	Thank you for your comment.

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					stay due to medication errors or adverse events (aligned to domain 5 of the NHS OF)' c) Planned and unplanned contact – change to 'Reduction in repeat consultations - patient condition resolves or improves sooner' d) Medication-related problems, including prescribing errors, monitoring errors and adverse effects – change to 'Reduced adverse events (aligned to domain 5 of the NHS OF)' e) Health-related quality of life – change to 'Improved health related quality of life – (aligned to Domain 2 of the NHS OF)' f) Patient-reported outcomes e.g. reduced uncertainty, satisfaction with decision-making – change to 'Improved understanding the Patient Experience (aligned to domain 4 of the NHS OF)' g) Other non-patient related outcomes such as, NICE compliance / uptake of NICE-approved medicines and reduction in waste medicines – change to 'Reduction of wastage of medicines and Improved implementation of NICE guidance' h)Decisions in accordance with the NHS Constitution	
246	SH	NHS Anglia Commissioning Support Unit	1	General	Will there be a definition of what constitutes a medicine for the purpose of the guidance? E.g. only drugs with UK license; excluding unlicensed supplements and herbal products – note place	Thank you for your comment. The term 'medicines' has been clarified.

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					of unlicensed specials.	
247	SH	NHS Anglia Commissioning Support Unit	2	General	Does medicines mean only prescribed or will it include over the counter medicines (P & GSL). This will be relevant to 4.1.1 (a) All people using medicines	Thank you for your comment. The term 'medicines' has been clarified. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
248	SH	NHS Anglia Commissioning Support Unit	3	General	Medicines are not just drugs – will it include ACBS sip feeds, gluten free foods, baby milks and other items prescribable on the NHS e.g. dressings and appliances? These are areas where there is much waste.	Thank you for your comment. The term 'medicines' has been clarified.
249	SH	NHS Anglia Commissioning Support Unit	4	4.1.1 (a)	Do we need to include hard to reach groups e.g. travellers?	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
250	SH	NHS Anglia Commissioning Support Unit	5	4.1.1 (b)	Should this not read "All practitioners who administer **and supply** medicines	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
251	SH	NHS Anglia Commissioning Support Unit	6	4.2 (a)	Scope states: All publicly-funded health and social care provided in primary care…….including prisons. I assume this will include services provided through community pharmacy – essential services Promoting self-care, advanced services NMS and MUR. Many people assume primary care to mean primary medical care.	Thank you for your comment. The settings section of the scope has been amended to reflect your comment.
252	SH	NHS Anglia Commissioning Support Unit	7	4.3.1 Patient and Carer engagement Evidence-informed decision making	Need to ensure pharmaceutical needs assessment takes place – this should include ordering prescriptions, delivery of medicines, homecare etc. – is this covered in 4.3.1 (c) Patient-centred care? Shared decision needs to cover decisions as to the level of pharmaceutical support an individual	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.

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					needs e.g. decision around use of medicine reminder charts, compliance aids, assisted administration etc.	
253	SH	NHS Anglia Commissioning Support Unit	8	4.3.1 Evidence-informed decision making (g)	Is the guidance going to include or exclude the effects of third party ordering of medicines for patients e.g. carer and 'automatic' ordering by pharmacists and dispensers.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
254	SH	NHS Anglia Commissioning Support Unit	9	4.3.1 Evidence-informed decision making (g)	Need to include self-care and also electronic prescription service (EPS)	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
255	SH	NHS Anglia Commissioning Support Unit	10	4.3.1 Inter- and Intra-professional collaboration (d)	Need to include emergency supplies through community pharmacy, and also supply and administration of medicines under PGD at say CASH clinics, MIUs etc. or specifically exclude.	Thank you for your comment. Supply of medicines via a patient group direction is considered in the NICE good practice guidance on patient group directions. This will not be covered as part of this guideline. The guideline will also not cover specific clinical conditions.
256	SH	NHS Anglia Commissioning Support Unit	11	4.3.1 Transferring medicines information across care settings (c)	Need to include emergency supplies through community pharmacy, and also supply and administration of medicines under PGD at say CASH clinics, MIUs etc. or specifically exclude. This is to ensure a complete picture of what patients are taking/accessing. We assume that Medicines Reconciliation will emphasise need for OTC and supplement history.	Thank you for your comment. Supply of medicines via a patient group direction is considered in the NICE good practice guidance on patient group directions. This will not be covered as part of this guideline. The guideline will also not cover specific clinical conditions.
257	SH	NHS Anglia Commissioning Support Unit	12	4.3.1 Inter- and Intra-professional collaboration	CG needs to address repeat dispensing/EPS communication between patient/dispenser/prescriber	Thank you for your comment. Repeat dispensing is an area that will not be covered in the guideline. This area of practice could warrant a guideline in itself and would be too large to include in this medicines optimisation

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						guideline.
258	SH	NHS Anglia Commissioning Support Unit	13	4.3.1 Transferring medicines information across care settings (g)	Needs to include role of community pharmacists (e.g. MUR/NMS) and GP dispensers (DRUMS)	Thank you for your comment. The key issues section of the scope has been amended.
259	SH	NHS Anglia Commissioning Support Unit	14	4.3.1 Transferring medicines information across care settings (h)	Should include EPS. Community pharmacist access to summary care record – patient safety also affected in relation to OTC and self-care.	Thank you for your comment. Electronic prescription service (EPS) is an area that will not be covered in the guideline. This area of practice could warrant a guideline in itself and would be too large to include in this medicines optimisation guideline.
260	SH	NHS Anglia Commissioning Support Unit	15	4.3.1 Reducing medicines-related patient safety incidents	Need to look at effect of third party ordering of medicines – system orders repeat medicine in advance of need however medicine may have been changed in hospital etc. – this is an issue with care homes. EPS may aggravate this risk. Also need to include	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
261	SH	NHS Anglia Commissioning Support Unit	16	4.3.1 Reducing medicines-related patient safety incidents	Need to address the issue (or exclude it) of "abuse" of systems e.g. patients accessing medicines from a range of prescribers e.g. MIU, walk in clinics, OOH, A&E – this could also feature in Transferring medicines information across care settings.	Thank you for your comment.
262	SH	NHS Anglia Commissioning Support Unit	17	4.3.1 Transferring medicines information across care settings Reducing medicines-related patient safety incidents	Trust discharge/outpatient prescriber- prescriber information – standard template? Need to include start/stop dates and follow GMC guidance on prescribing over shared care - We acknowledge exclusion as laid out in 4.3.2 (c) However need to include monitoring- lab tests – within these sections. E.g. cross ref to CG 169 Hospitals sometimes do tests but do not automatically share information with prescriber. Changes in smoking status – effect on patient and drug e.g. antihypertensives.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.

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263	SH	NHS Anglia Commissioning Support Unit	18	4.3.1 Reducing preventable medicines-related hospital admissions and re-admissions (h)	Community pharmacists have a remit in medicines optimisation both for regular repeat medication and OTC/Self-care.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
264	SH	NHS Anglia Commissioning Support Unit	19	4.5	Suggest add: For all patients using medicines what is the effect of third party ordering of medicines for patients? For all patients using medicines what is the effect of automatic sharing of monitoring information between trusts and primary medical care.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
265	SH	Amgen	1	4.3 (page 5)	We believe that to optimise medicines in the NHS the full value of a medicine to the NHS should be considered. For example, to make sure the best medicine is used in a particular situation then the following should be considered; patient outcomes, capacity release (including emergency admissions), administration requirements, adverse event profile, and patient experience. Currently many medicines are assessed purely on their acquisition cost through a procurement, non clinical, process. This over emphasis on drug price can result in medicines being selected which are not optimum to either the total local health economy, the prescribing physician, or to the patient. Currently the draft scope does not explicitly cover this issue; in the final version of the scope and the resultant guideline we recommend that this topic is included.	Thank you for your comment. Access to medicines is considered in the NICE good practice guidance on developing and updating local formularies. This will not be considered as part of this guideline.
266	SH	Amgen	2	Section 3k (page 3)	In section 3, the need for the guideline, the draft scope highlights that NICE recommendations	Thank you for your comment. Access to medicines is considered in the

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					are not uniformly implemented across the country; however on reading the issues to be covered in the guideline, section 4.3, this topic is not covered. We recommend that the variation in the implementation of NICE approved medicine is formally included as a topic that will be reviewed in the guideline in the final version of the scope.	NICE good practice guidance on developing and updating local formularies. This will not be considered as part of this guideline.
267	SH	Amgen	3	General	We welcome that the draft scope acknowledges that patients should be at the centre of decision making. In addition, we strongly believe that treating physicians should be empowered and have the authority to select the medicine which best suits an individual patient. Currently the draft scope does not recognise the importance of the treating physician's expert clinical opinion in the decision concerning medicine selection for patients. We would recommend that the issue be formally included in the final scope and the resultant guideline.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
268	SH	Amgen	4	Section 4.1 (page 4)	The draft scope states that the audience for this guideline covers "All practitioners who administer medicines". In reality, a majority of the decisions about which medicines are used in the NHS are determined by pharmacists and procurement professionals who are involved in commissioning. We feel the guideline would be strengthened if the final guideline scope included this group of professionals.	Thank you for your comment. The population section and the settings section of the scope have been amended to reflect your comment.
269	SH	Amgen	5	Section 3f (page 2)	The draft scope highlights that medicine optimisation is poor when patients are transferred from the hospital setting into primary care. We believe that some of the problem with this transfer is due to unintentional changes in medicine that is highlighted in the draft scope. In	Thank you for your comment. The need for the guideline section has been amended. Reference to resources has been removed.

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					addition, we also believe that there are changes to patients' medication as a result of the different sources of budget between primary and secondary care for drug acquisition cost and drug administration costs. In particular, some patients do not receive the optimal medicine for their condition because primary care providers will not cover the drug acquisition cost. Furthermore, some patients do not receive the optimal medicine in the community because the hospital trusts are generating income from administering less efficacious medicines via the IV route and they do not want to lose this revenue stream. We believe that for medicine use to be optimised the current silo budget approach between primary and secondary care for both drug acquisition costs and drug administration costs must be reviewed and optimised. We would welcome this issue being included in the final scope.	
270	SH	Amgen	6	Section 3a (page 1)	We welcome that the guideline is looking at evidence based decision making however we would like to highlight that following a NICE technology appraisal there should be no need for further regional appraisals of the evidence and further local decision making. This point has not been explicitly mentioned in the draft scope but we would urge the guideline development group to consider this point as is currently a source in regional variation in uptake of NICE technology appraisals.	Thank you for your comment. Access to medicines is considered in the NICE good practice guidance on developing and updating local formularies. This will not be considered as part of this guideline.
271	SH	Amgen	7	Section 4.3 'Intra and inter professional collaboration' section point g (page 6)	The guideline states that it wants to engage with the pharmaceutical industry. To achieve this we would recommend that the guideline development group proactively engage with the	Thank you for your comment. This has already been considered as part of the guideline development group recruitment.

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					ABPI and ideally have a member representing the pharmaceutical industry on the guideline development group.	
272	SH	Amgen	8	General	Currently a medicines optimisation CRG is being created by NHS England. We are unclear of the relationship between this guideline and the newly formed CRG. As such we recommend that the draft scope should include a brief description regarding the role of the medicines optimisation CRG.	Thank you for your comment. NICE use a standard template for the scope layout and therefore this information will not be included.
273	SH	Amgen	9	Section 4.3.2a (page 9)	It is surprising that medicine adherence is out of scope for the development this guideline, particularly as the guideline itself states in section 3d (page 2) that 'The cost of waste prescription medicines in primary and community care in England is estimated to be £300 million a year' and 'An estimated £90 million worth of unused prescription medicines are retained in people's home at any one time. We understand that NICE have already completed a guideline which covers adherence (CG76) however as this is still a significant cause of suboptimal medicine use then we feel it should be considered again as part of this new guideline. We would recommend that the issue of improving patient adherence with a view to improving medicine optimisation be included in the final scope for this guideline	Thank you for your comment. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). NICE have separate processes for reviewing existing NICE guidance. The main outcomes section includes 'patient-related outcomes' which will include medicines adherence as an outcome, where appropriate cross-reference will be made.
274	SH	Neonatal & Paediatric Pharmacists Group	1	general	NPPG welcomes the inclusion of children and adolescents in the population that will be covered in this guideline. Obtaining the best outcomes for medicines use is important for all ages of patients. It will be important therefore that the needs and views of parents and carers are captured in the development of this	Thank you for your comment.

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					guidance.	
275	SH	Neonatal & Paediatric Pharmacists Group	2	4.3.1 p 6	Medicines reconciliation – we are pleased to see that this will be covered in the paediatric population as this was not previously the case.	Thank you for your comment.
276	SH	Neonatal & Paediatric Pharmacists Group	3	4.3.1 p6	d) communication at critical points in the care pathway and a) transfer of care relating to the sharing of information about medicines when patient care moves from one setting to another. These issues are particularly important in children due to the number of medicines used which are not licensed and have to be purchased as specials. The communication of information relating to the manufacturer, concentration and dosing of such products is crucial to the continuity of care of children. We are pleased to see that this is to be covered in the guidance. We are also encouraged to see medicines reconciliation (MR) mentioned in a number of the work streams – this is an important aspect of management of medicines in children. National guidance from NICE in collaboration with National Patient Safety Agency (NPSA) previously excluded children from recommendations that MR is undertaken when children are admitted to hospital. We see this as another key priority for coverage in the new Medicines Optimisation guidance which will be developed.	Thank you for your comment.
277	SH	Neonatal & Paediatric Pharmacists Group	4	4.3.1 p7	a) interventions to reduce medicines-related patient safety incidents….. we are pleased to see the inclusion of this in the guidance. For a number of reasons infants and children are at increased risk of errors related to medicines at	Thank you for your comment.

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					all stages of the medicines use process.	
278	SH	Neonatal & Paediatric Pharmacists Group	5	4.3.2 a) p9	Medicines Adherence. We are disappointed to see that it is proposed that this will not be covered in the guideline. We realise that NICE CG 76 has already been published and provides guidance on this issue. However the NICE CG76 specifically excluded children in the population covered. This will therefore prove to be a significant gap in the proposed Medicines Optimisation Guideline since there will be no recommendation for Medicines Adherence in children. The equality and impact assessment of this needs to be considered. We would therefore urge that the decision to exclude Medicines Adherence from the scope is reconsidered in the case of children.	Thank you for your comment. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). The main outcomes section includes 'patient-related outcomes' which will include medicines adherence as an outcome, where appropriate cross-reference will be made.
279	SH	Ferring Pharmaceuticals	1	4.3.1.	Ferring would like to see this opportunity to fully engage the NHS in a partnership agenda with the pharmaceutical industry. The relationship between NHS and pharmaceutical industry has evolved over recent years, and continues to do so. This guideline represents a strong opportunity to direct clinicians and payers to proactively utilise the pharmaceutical industry fully in partnership in a transparent way to instigate programmes designed to drive optimal dosing, patient adherence, and patient outcomes which will drive cost saving efficiencies within the NHS.	Thank you for your comment.
280	SH	Ferring Pharmaceuticals	2	4.3.1 g) Patient and carer engagement in shared decision making	It is important to ensure that information on medicines, including access to appropriate information, is implemented widely to enable a shared decision making process, with the patient and carer, to ensure better compliance to long term therapies.	Thank you for your comment. Access to medicines is considered in the NICE good practice guidance on developing and updating local formularies. This will not be considered as part of this guideline.

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					The process by which the choice of drugs and devices is offered to patients and carers is unclear and not transparent. For example, for treatment with growth hormone, providers do not always have the full available range of drug and devices to offer to the patient and carer. The current situation across England is that many CCGs give direct instruction to their prescribers based on either: i. a list of preferred products permitted for prescribing ii. a list of those drugs not to be prescribed Providers should be bound to ensure that patients and carers are informed and offered a full range of products including all available administration routes, and services, including device training and support, so that product choice decisions are made after truly informed and shared decision making which includes assessment of all relevant parameters impacting on outcomes.	However, the detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
281	SH	Ferring Pharmaceuticals	3	4.3.1 g) Intra- and inter-professional collaboration	Ferring would like to suggest that NICE implement measured outcomes in order to evaluate the collaboration and working with the pharmaceutical industry.	Thank you for your comment. The development of the guidance will follow NICE short clinical guideline methodology.
282	SH	Ferring Pharmaceuticals	4	4.3.2 a)	Medicines adherence forms an integral part of medicines optimisation and therefore Ferring would like to request NICE to consider inclusion of medicines adherence within the medicines optimisation guideline.	Thank you for your comment. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). The main outcomes section includes 'patient-related outcomes' which will include medicines adherence as an outcome, where appropriate cross-reference will be made.

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283	SH	Ferring Pharmaceuticals	5	4.3.2 d)	It is not clear why shared care arrangements will be excluded from the scope of this guideline, when the following topics are included in the scope and are concerned with shared care practice: i. Section 4.3.1 Transferring medicines information across care settings ii. Section 4.4 g) Other non-patient related outcomes such as, NICE compliance / uptake of NICE-approved medicines iii. Section 4.5 a) For all patients using medicines what is the effect of patient and carer engagement in improving shared decision making between patients, carers and health practitioners compared to usual care? We agree that shared care arrangements are important, as stated under Section 3 f), and while these will be included under the NICE good practice guidelines, as stated in Section 4.3.2 d) of this scoping document, we suggest that shared care arrangements be also included in the scoping of the medicines optimisation guidelines.	Thank you for your comment. Shared care arrangements for medicines used across primary and secondary care has been already been identified for good practice guidance development.
284	SH	Ferring Pharmaceuticals	6	4.3.2 h)	We suggest that it is made clear that this exclusion criterion should not be applied to NICE-approved medicines.	Thank you for your comment. Access to medicines is considered in the NICE good practice guidance on developing and updating local formularies. This will not be considered as part of this guideline.
285	SH	Ferring Pharmaceuticals	7	4.5 c)	It will be helpful if under Section 4.5 c) it is clarified that intra- professional collaboration will include collaboration with the pharmaceutical industry and evaluating the value of joint working on improving patient outcomes.	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.

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286	SH	Ferring Pharmaceuticals	8	4.6.	Ferring would like to request NICE to consider including other parameters, in addition to QALY, to assess the cost effectiveness of medicines for single or short term use. QALYs apply to long term medical conditions and it will be useful to have other measures to assess cost-effectiveness where QALYs are not appropriate, such as in obstetrics, to assess uterotonics for prevention of uterine atony and prostaglandins for initiation of cervical ripening.	Thank you for your comment. The development of the guidance will follow NICE short clinical guideline methodology. Health economic aspects of the guideline will be advised as by health economists within NICE.
287	SH	Royal College of Physicians	1	General	The RCP is grateful for the opportunity to comment on the draft scope consultation. Our experts believe that the document needs to be greatly improved as it is unclear and repetitive in places. The RCP was represented at the recent scoping workshop and we note that the majority of attendees were pharmacists. Although pharmacists are clearly important to the topic we believe that it is critically important that the Guideline Development Group should include a clinical pharmacologist to provide a physicianly perspective with regard to good prescribing/rational therapeutics. We are therefore using our networks to promote this.	Thank you for your comment. The recruitment to the GDG has now closed. Only those individuals who have applied can be considered.
288	SH	Royal College of Physicians	2	3a)	Medicines optimisation requires definition and the wording here does not provide one. We would suggest that the definition is : *Medicines optimisation is the set of activities designed to prescribe or adjust medicines for an individual patient to ensure the best outcome.* Which are the parameters to optimise (what do	Thank you for your comment. The definition of medicines optimisation has been amended. The key issues section of the scope has been amended to reflect your comment.

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					we mean by 'best'? NICE has generally used cost/QALY [see 4.6 and 7: 'Medicines optimisation relates to the overarching principles of optimising the use of medicines to improve patient outcomes'] How does it differ from (rational) therapeutics?	
289	SH	Royal College of Physicians	3	4.1.1	People using medicines should also include the carers for younger children, older people, and those with disabilities - see 4.3.1 evidence based decision making (a) Should also include reference to people prescribed medicines but who do not take them	
290	SH	Royal College of Physicians	4	4.3.1	4.3.1 Our experts believe that the order of priorities should be reconsidered. **Evidence-informed decision making:** (e) There should be explicit recognition of the value of patient/care reporting, for example of adverse drug reactions via the Yellow cards scheme Inter-professional collaboration: (c) Consider the role of non-medical prescribers in skewing the balance between patient-centred and best(-value) care (g) We would suggest a change to 'Relations with the pharmaceutical industry'- optimising the use of medicines may run counter to the legitimate activities of the pharmaceutical industry, for example in promoting medicines and financing patient support groups. **Reducing medicines-related patient safety incidents** (h) A definition of 'waste medicine' is required (f) it should be noted that medicines are wasted	Thank you for your comment. The key issues section of the scope has been amended. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.

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					in different ways: unnecessary prescribing. poor adherence; excessive supply (j) role of NICE guidance and nuanced decisions **Reducing preventable medicines-related hospital admissions and re-admissions** (e) Intra- and inter- professional collaboration **Reducing medicines-related patient safety incidents** (b) Adverse events = bad things that happen while patient is taking medicine; should be described as 'harms from medicines.' NICE should probably confine this to considering adverse drug reactions (adverse drug effects, from the patient's perspective) and medication errors. **Preventable admissions** There is no robust definition of 'preventability' when assessing harms from medicines. (f) monitoring for harms from medicines is an almost evidence-free zone	
291	SH	Royal College of Physicians	5	4.4	How is it proposed to measure any of these outcomes? The introductory section suggests that the interventions should reduce money wasted on medicines and also reduce unwarranted variation in prescribing practice. These are not mentioned here. There is very little prospect of detecting the effect of a single guideline on overall NHS mortality and morbidity statistics. As stated	Thank you for your comment. The main outcomes section of the scope has been amended to reflect your comment.

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					above, there is no robust definition of 'preventability' when assessing harms from medicines.	
292	SH	Royal College of Physicians	6	4.5	(a) To assess improvement it must be stated exactly what is being optimised)? A definition of 'improving shared decision making' is required (b) This assumes that usual care is not informed by evidence. However, we are unsure that this assumption is itself informed by evidence. (d) 'medicines information' is ambiguous (e) Does this include computerized decision support (4.3.1 collaboration. Include as (g)?	Thank you for your comment. The review questions have been amended.
293	SH	Royal College of Physicians	7	7	Appendix See defining statement here...	Thank you for your comment.
294	SH	Royal College of Physicians	8	&	Our experts are interested that 'education of healthcare professionals' is deemed outside the scope. While not a major part of the story it certainly has a minor role. The justification given is that education is in HEEs remit but we believe that it is unlikely they will make any comment soon. We believe that a guideline that says nothing about this in relation to medicines (even if only to make negative comments) is neglecting a major area of NHS activity.	Thank you for your comment. Health Education England (HEE) was established as a special health authority in June 2012 and assumed full responsibilities from April 2013. HEE now hold responsibility for providing leadership, planning and development of the whole healthcare and public health workforce, in relation to education and training. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
295	SH	Primary & Community Care Pharmacy Network	1	4.1.1 a), bullet point 5	Patients may be admitted to and discharge from other bedded units than hospitals and prisons. In particular older people may be admitted to an intermediate care unit (e.g., council run care home with step-up or step-down beds and some medical input which may not be the patient's GP). The transfer of care from these types of	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.

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					units may also cause issues around medicines and should be included in the scope.	
296	SH	Primary & Community Care Pharmacy Network	2	4.1.1 a)	What is not stated is that children and young people with e.g. complex physical disabilities, including visual and hearing impairments, and associated learning difficulties may also transfer between different specialist centres and respite care and/or school with multiple medicines often useing 'off lable' and in liquid form or need to take 'a fraction' of a tablet. There are many issues regarding their medicines and this has not really been address fully in the scope.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
297	SH	Primary & Community Care Pharmacy Network	3	4.1.1 b)	It is unclear with what is meant by practitioners. Does this include healthcare assistants, care workers and carers?	Thank you for your comment. A glossary will define 'practitioners' in the final guideline.
298	SH	Primary & Community Care Pharmacy Network	4	4.2.a)	Suggest that this sentence is shortened to "All publicly-funded health and social care providers". Unhelpful to list the different sectors – this demarcation of sectors helps to set boundaries. Is this really relevant? If it is relevant then further information needs to be listed as currently this seems to refer to acute hospitals, GP, prisons and community pharmacy. Other sectors such as Community services (NHS organisations) are not listed nor is mental health nor hospices etc	Thank you for your comment. The settings section of the scope has been amended to reflect your comment.
299	SH	Primary & Community Care Pharmacy Network	5	4.3	There is no reference to consider the use to modern technology	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
300	SH	Primary & Community Care Pharmacy	6	4.3.1 "Evidence-informed decision making" g)	There is no reference to monitored dosages systems (Multiple Compartment Aids) which is often used inappropriately.	The detail of your comments may be considered in the review protocols to answer the finalised review questions

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		Network				when signed off by the GDG.
301	SH	Primary & Community Care Pharmacy Network	7	4.3.1 "Transferring medicines information across care settings" g)	Refers to specific roles for practitioners with a medicines optimisation remit and then use pharmacists and pharmacy technician as an example which is good. However, patients may be receiving care in bedded units (intermediate care) with no access to pharmacy staff or medical doctors or nurses. Care may be provided by care workers with limited professional input.	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
302	SH	Primary & Community Care Pharmacy Network	8	4.3.1 "Reducing medicines-related patient safety incidents" g)	Not all bedded units in the community have regular input by pharmacy staff to undertake medicines reconciliation.	Thank you for your comment.
303	SH	Primary & Community Care Pharmacy Network	9	General	Need to include adherence support options in the scope	Thank you for your comment. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). The main outcomes section includes 'patient-related outcomes' which will include medicines adherence as an outcome, where appropriate cross-reference will be made.
304	SH	Regional Drug and Therapeutics Centre	1	4.1.1 a	We would suggest adding mental health and/or people with learning disabilities to the list of groups where 'particular consideration' to medicines optimisation issues are covered.	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
305	SH	Regional Drug and Therapeutics Centre	2	4.1.1 b	We feel that Prescribers and Suppliers of medicines to patients play an equally if not greater role in medicines optimisation so should also be covered.	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
306	SH	Regional Drug and Therapeutics	3	4.3.1 patient and carer engagement	To include something here around managing patient expectations around what the drug is likely to achieve.	The detail of your comment may be considered in the review protocols to answer the finalised review questions

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		Centre				when signed off by the GDG.
307	SH	Regional Drug and Therapeutics Centre	4	4.3.1g patient and carer engagement	To include online sources of information and how patients know if it is good quality information. (and the dangers of forum based anecdotal evidence)	The detail of your comment may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
308	SH	Regional Drug and Therapeutics Centre	5	4.3.1 evidence informed decision making	Needs to address decision making from the perspective of co-morbidities and not just each treatment for each condition. Patient related health outcomes and risks of no treatment need to be included in the decision-making process.	Thank you for your comment.
309	SH	Regional Drug and Therapeutics Centre	6	4.3.1a evidence informed decision making	To consider including information on the condition as well as medicines.	Thank you for your comment.
310	SH	Regional Drug and Therapeutics Centre	7	4.3.1 c evidence informed decision making	Include personalised medicines information leaflets, passports and patient contracts that have been trialled in various regions.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
311	SH	Regional Drug and Therapeutics Centre	8	4.3.1 f evidence informed decision making	Where already available it would be useful to evaluate the usefulness of decision/support tools from the patient's perspective. What is the minimum amount of information they need to receive to help them make a decision?	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
312	SH	Regional Drug and Therapeutics Centre	9	4.3.1 d Intra- and inter-professional collaboration	The impact of electronic resources/activities, EPS and EPR and access to records by all professionals needs to be considered including pilots of patient-held records.	Thank you for your comment. Electronic prescription service (EPS) is an area that will not be covered in the guideline. This area of practice could warrant a guideline in itself and would be too large to include in this medicines optimisation guideline. Decision support has been included as a key issue.
313	SH	Regional Drug and	10	4.3.1 Intra- and inter-	Add working with volunteer organisations and patient representative organisations.	Thank you for your comment. The key issues section of the scope has been

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		Therapeutics Centre		professional collaboration		amended. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
314	SH	Regional Drug and Therapeutics Centre	11	4.3.1.g Transferring medicines information across care settings	Community pharmacy responsibilities should be included here, particularly those accredited to supply medicines to residential and nursing homes.	Thank you for your comment. The key issues section of the scope has been amended. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
315	SH	Regional Drug and Therapeutics Centre		4.3.1 f Reducing medicines-related patient incidents	As per 4.3.1 d intra and inter professional collaboration. Access to records in a timely manner and electronically across primary and secondary care.	Thank you for your comment. The key issues section of the scope has been amended. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
316	SH	Regional Drug and Therapeutics Centre	12	4.3.1 i Reducing medicines-related patient incidents	Explanation of how sub optimal medicines use would be identified? Is this part of the annual medication review – can specific questions that should be asked as a minimum be included?	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
317	SH	Regional Drug and Therapeutics Centre	13	4.3.1 f Reducing preventable Medicines-related hospital admissions/re-admissions	To include new medicines service provided by community pharmacy.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
318	SH	Regional Drug and Therapeutics Centre	14	General	We feel that there should be a separate section that deals with medicines optimisation at the point of supply to a patient e.g. new medicines support. Evaluation of inhaler technique etc.	Thank you for your comment. These suggestions are not felt to be as high a priority in comparison with those key issues selected.

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319	SH	GlaxoSmithKline	1	3 b	GSK appreciate the differentiation between medicines management and medicines optimisation. We do feel however, that it is not entirely clear as to whether medicines management is referenced as a pre-cursor to medicines optimisation or whether the two will operate concurrently. Clarity on this matter would be useful. In addition, we wish to draw attention to the potentially negative connotations associated with 'medicines management' in terms of cost containment and believe the distinction between this and the outcomes focus of medicines optimisation should be given absolute clarity. We would seek to emphasise the importance of the need for a real culture change to move to this new mindset.	Thank you for your comment. The need for the guideline section has been amended to reflect your comment. Reference to resources has been removed.
320	SH	GlaxoSmithKline	2	4.1.1 a	GSK supports the breadth of the groups listed. However, we are concerned that highlighting certain groups for particular consideration could lead to the list as being treated as exhaustive when this is not the intent. We recommend that the guidance should be clear that it is inclusive of all of those taking medicines as well as those "people who are not receiving medicines when they should or could benefit medicines".	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
321	SH	GlaxoSmithKline	3	4.1.1 b	We suggest that it would be helpful to give the category '*all practitioners who administer medicines*' further definition as its exact applicability is not clear. For example, is this	Thank you for your comment. The population section of the scope has been amended to reflect your comment.

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					definition intended to include those that prescribe medicines? GSK recommends that the definition should extend to all those healthcare professionals involved in the decision making and/or delivery of an individual's care.	
322	SH	GlaxoSmithKline	4	4.2 a	We suggest that the definition of 'setting' should be a broad one and should include all health and social care settings in order to ensure that consistency is achieved throughout the patient's journey.	Thank you for your comment. The settings section of the scope has been amended to reflect your comment.
323	SH	GlaxoSmithKline	5	4.3.1 Patient & Carer Engagement...(a)	GSK seeks clarity on the types of evidence and evidence sources that will be used for the purposes of the guidelines and seek for these to be referenced within the guidelines. We recommend that evidence types are not unduly restricted and that a wide spectrum of evidence is considered. We advocate the inclusion of patient reports and case studies.	Thank you for your comment. The development of the guidance will follow NICE short clinical guideline methodology.
324	SH	GlaxoSmithKline	6	4.3.1. Patient & Carer Engagement...(d)	We support the reference to patient engagement, but wish to emphasise the need for a genuine culture change to enable to this happen. To effectively facilitate 'shared decision making', there needs to be a meaningful dialogue, with both patients and carers, to ensure patient preferences are understood and that patients are informed and empowered to make such decisions.	Thank you for your comment.

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325	SH	GlaxoSmithKline	7	4.3.1 Evidence Informed Decision Making *General*	See comment 6.	Thank you for your comment.
326	SH	GlaxoSmithKline	8	4.3.1 Evidence Informed Decision Making (g)	While we do not disagree with paragraph (g), we would highlight that medicines management systems should not be considered in isolation, but should be viewed in conjunction with patient evidence.	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
327	SH	GlaxoSmithKline	9	4.3.1 Intra & Inter Professional Collaboration (d)	GSK endorses that which is stated in paragraph (d) and agree that concentration on communication at these interfaces could create significant benefits in medicines optimisation. We encourage consideration to be given to this matter and to how such opportunities for improvement can be optimised.	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
328	SH	GlaxoSmithKline	10	4.3.1 Transfer Medicines Information...(c)	We suggest that there is an appropriate role here for manufacturers to communicate to healthcare professionals.	Thank you for your comment.
329	SH	GlaxoSmithKline	11	4.3.1 Transfer Medicines Information *general*	In order to ensure a whole system, joined up approach, we suggest this section could make reference to the fact that all people involved in the delivery of patient care should play a role in the transfer of information.	Thank you for your comment. The key issues section of the scope has been amended.
330	SH	GlaxoSmithKline	12	4.3.2 a	GSK acknowledges the reasons for classifying medicine adherence as out of scope for these guidelines in that there are specific guidelines relating to adherence (CG76). That notwithstanding, we believe that medicine adherence forms a crucial part of medicines optimisation and must be considered as part of a fully integrated approach. To this end we would seek reassurance that: (1) The adherence guidelines are referenced in	Thank you for your comment. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). The main outcomes section includes 'patient-related outcomes' which will include medicines adherence as an outcome, where appropriate cross-reference will be made. NICE have separate processes for reviewing existing NICE guidance.

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					the medicines optimisation guidelines as part of the medicines optimisation approach; (2) The adherence guidelines are referenced in the medicines optimisation guidelines in such a way that they will form part of the Quality Standard; (3) The adherence guidelines are updated to reflect the medicines optimisation guidelines.	
331	SH	GlaxoSmithKline	13	4.3.2 f	We propose that recycling of waste materials is reconsidered as 'in scope' for the purpose of the guidelines. In our view, the process of recycling medicines presents the chance to assess that which is returned, i.e. unused medicines. This presents significant potential opportunity to understand if and why medicines are not being used as directed.	Thank you for your comment. Medicines waste is considered an outcome of failures in other aspects of the medicines optimisation system, therefore by addressing these problems the consequence of waste medicines is likely to reduce.
332	SH	GlaxoSmithKline	14	4.3.2 h	While GSK acknowledges that access to medicines has been listed as out of scope, we would like highlight the importance of appropriate choice in the decision making process. We believe there should be access at a local level to a range of medicines to enable clinicians and patients to make fully informed, evidence based decisions. We suggest that the guidelines should direct people to the relevant associated guidelines for developing and updating local formularies (GPGI).	Thank you for your comment. Access to medicines is considered in the NICE good practice guidance on developing and updating local formularies. This will not be considered as part of this guideline.
333	SH	GlaxoSmithKline	15	4.3.2.j	As stated above, there needs to be a significant culture shift towards a whole system approach in	Thank you for your comment. The implementation of NICE guidance will

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					order to ensure that medicines optimisation is adopted as part of routine practice. GSK would hope that there will be a strategy in place to guide the implementation of medicines optimisation and that its positioning and guidance is represented in healthcare and social care training.	be considered by the NICE implementation team working with the guideline development group (GDG).
334	SH	GlaxoSmithKline	15	4.4 f	We recommend that consideration is given to Patient Reported Experience Measures as well as Patient Reported Outcome Measures.	Thank you for your comment.
335	SH	GlaxoSmithKline	17	General	GSK suggests that the guidelines should include measurement of the impact of the medicines optimisation guidance on an ongoing basis. This should include measures which reflect achievement of medicines optimisation at both national and local levels. We would hope to see these measures as part of the future quality standard.	Thank you for your comment. NICE do not currently measure the impact of their clinical guidelines as part of their processes.
336	SH	GlaxoSmithKline	18	General	As discussed in specific points above, GSK wish to make an overarching recommendation that the guidelines should seek to give consideration to, and provide clarity on, the changes that are required in order to drive a holistic 'whole system' approach which incorporates medicines optimisation as an intrinsic part of day-to-day-practice.	Thank you for your comment. The implementation of NICE guidance will be considered by the NICE implementation team working with the guideline development group (GDG).
337	SH	GlaxoSmithKline	19	General	GSK would ask for consideration to be given to the ensuring the definition of medicines optimisation is reflected through CRGs.	Thank you for your comment. NICE does not have responsibility for the CRGs. This is the remit of NHS England.
338	SH	Merck Sharp & Dohme UK Ltd	1	3 a and 3 b	MSD agrees with the definition used in 3a for medicines optimisation. We also believe that it is useful for this guideline to provide definitions of	Thank you for your comment. The definition of medicines optimisation and the need for the guideline

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					medicines optimisation and medicines management. NICE should continue with this messaging as healthcare professionals can use the words interchangeably.	sections have been amended.
339	SH	Merck Sharp & Dohme UK Ltd	2	3 c	In section 3c of the draft scope the headline cost of medicine prescriptions in England in 2012 is highlighted. This total cost is misleading and needs to be considered with respect to how the cost has changed over time, as well as how the cost relates to the number of prescriptions. The £8.5 billion cost is related to an increased number of prescriptions in 2012 versus previous years, with the actual net cost of medicines decreasing[1]. Ref 1: http://www.hscic.gov.uk/article/3199/More-than-1-billion-prescription-items-dispensed-in-a-year---or-1900-a-minute	Thank you for your comment. This figure is taken from the 'Health and Social Care Information Centre website data.
340	SH	Merck Sharp & Dohme UK Ltd	3	3 l	Under point 3l a further justification on the need for this guideline is made with regard to the cost of prescribing medicines and the associated QIPP savings. MSD would again like to point out that all statements and arguments should be balanced. There are other considerations that would provide a fuller and more balanced picture when discussing QIPP savings, such as the corresponding rate of hospital admissions, or costs associated with patients receiving an inappropriate therapy that need to be taken into consideration.	Thank you for your comment. The need for the guideline section has been amended to reflect your comment.
341	SH	Merck Sharp & Dohme UK Ltd	4	4.1.1 a	For the groups that will be covered by the guideline: "people who are not receiving medicines when they should or could benefit from medicines". It is not clear how such	Thank you for your comment. The population section of the scope has been amended to reflect your comment.

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					assessment will be made. As part of development of the 2012 Experimental Statistics report, there were significant difficulties in the estimation of the scale of 'expected use' of some products (with this use being based on the size of the population eligible to receive a treatment in line with a NICE Technology Appraisal). This is evidenced by the number of products in Section 2 of the report (where estimates are more uncertain), and the number of products for which an estimate could not be generated. We believe that this is an important group to assess, and that every effort should be made to obtain an accurate figure, and would encourage NICE to collaborate with manufacturers and other stakeholders in the development of this.	
342	SH	Merck Sharp & Dohme UK Ltd	5	4.2 a	The pharmacy represents an important setting for the prescribing of medicines and interactions with the patient. An explicit reference to pharmacy should be made in this section.	Thank you for your comment. The settings section of the scope has been amended to reflect your comment.
343	SH	Merck Sharp & Dohme UK Ltd	6	4.3.1	Within the sub-section "Patient and carer engagement in shared decision making", it may be valuable to consider the process by which the 'self-efficacy' of patients is considered, i.e. the patients belief that they are adequately supported with appropriate therapy and/or interaction with healthcare professionals to ensure a successful treatment outcome.	Thank you for your comment. The key issues section of the scope has been amended.
344	SH	Merck Sharp & Dohme UK Ltd	7	4.3.1	Within the sub-section "Evidence-informed decision making", the choice of licensed medicines as well as NICE clinical guidelines, quality standards, and technology appraisals should be included. These pieces of NICE guidance and decisions form an important part of evidence-informed decision making about the	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.

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					prescribing of medicines and the content and quality of discussion between the patient and prescriber. We therefore feel that this should be discussed in this section.	
345	SH	Merck Sharp & Dohme UK Ltd	8	4.3.1	Within the sub-section "Evidence-informed decision making", point 'c' states "Patient and carer education relating to medicines, including targeted support for specific patients, such as when patients are prescribed a new medicine". It would be helpful if the draft scope included some examples of the type of support that may be deemed useful by NICE.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
346	SH	Merck Sharp & Dohme UK Ltd	9	4.3.1	Within the sub-section "Evidence-informed decision making", point 'c', patient literacy should be discussed in the guideline, in particular where language is a barrier due to English not being the first language.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
347	SH	Merck Sharp & Dohme UK Ltd	10	4.3.1	Within the sub-section "Evidence-informed decision making", point 'c', MSD believes that this should be changed to "patient and carer education relating to medicines *and their access*, including targeted…". For a more general discussion around access to medicines please see comment 16.	Thank you for your comment. Access to medicines is considered in the NICE good practice guidance on developing and updating local formularies. This will not be considered as part of this guideline.
348	SH	Merck Sharp & Dohme UK Ltd	11	4.3.1	Within the sub-section "Reducing medicines-related patient safety incidents" MSD would like to point out the importance of over-the-counter (OTC) medicines in relation to patient safety incidents. Clear communication between the prescriber, pharmacist and the patient could prevent safety incidents from potential drug-drug interactions of prescribed and OTC medicines. For this reason OTCs should be considered in this section.	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
349	SH	Merck Sharp &	12	4.3.1	Within the sub-section "Reducing medicines-	Thank you for your comment. The

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		Dohme UK Ltd			related patient safety incidents", one of the principles of the draft scope centres on patient involvement, communication, and collaboration. Patient and carer engagement should also be discussed in this section with regard to reducing patient safety incidents.	detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
350	SH	Merck Sharp & Dohme UK Ltd	13	4.3.1 j	Within the sub-section "Reducing medicines-related patient safety incidents", point 'j', interventions to reduce inappropriate variations in prescribing is in scope for the guideline. The definition of appropriate and inappropriate variations in prescribing needs to be clearly explained using a clinical evidence base and with an understanding as to how these definitions have been agreed. For individual medicines, NHS England have recently implemented a tool that uses a definition of inappropriate variation in prescribing as a prescribing rate that sits beyond two standard errors from the (national) mean prescribing rate. This definition appears to be arbitrary and not based on clinical evidence. An open and transparent discussion should be held before choosing what interventions should be used to reduce inappropriate variations in prescribing.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
351	SH	Merck Sharp & Dohme UK Ltd	14	4.3.2 a	"Medicines adherence" (point 'a') is listed as an area that will not be covered within the scope of the new guideline, due to the fact that this topic is covered by a separate clinical guideline (CG76).[2] Whilst MSD appreciates that NICE wish to avoid repetition when creating new clinical guidelines, we would like to stress our view that medicines adherence is absolutely fundamental to the subject of medicines optimisation. Ideally, medicines adherence	Thank you for your comment. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). NICE have separate processes for reviewing existing NICE guidance. The main outcomes section includes

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					should be one of the main measure/outcomes of medicines optimisation, as ineffective adherence could potentially be the precursor for several of the outcomes already proposed to be covered in the draft scope. MSD has noted that CG76 was last reviewed in 2011 (when it was decided that recommendations should remain unchanged as per the recommendations from 2009), and the next update is scheduled in 2015; consequently, there may be a period of time when best practice on medicines adherence is not adequately covered in NICE guidance (i.e. neither by the medicines optimisation guideline or CG76). Ref 2: NICE (2009) CG76: Medicines adherence: Involving patients in decisions about prescribed medicines and supporting adherence [Available at: http://publications.nice.org.uk/medicines-adherence-cg76]	'patient-related outcomes' which will include medicines adherence as an outcome, where appropriate cross-reference will be made.
352	SH	Merck Sharp & Dohme UK Ltd	15	4.3.2 b	Whilst MSD understands that specific named medicines are out of scope for this guideline, we feel that the scope should cover (in general terms) the importance of protecting the rights of patients to choose the medicines which are most appropriate for them, rather than having to accept an alternative, subject to appropriate NICE guidelines. One potential example of where this could be important is if patients are required to accept a biosimilar version of a biologic therapy or a lack of clarity around INN prescribing. Ensuring patient choice is protected	Thank you for your comment. The guideline will not cover specific clinical conditions.

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					leads to a greater chance of patient engagement, good levels of adherence, and a more efficient use of medicines.	
353	SH	Merck Sharp & Dohme UK Ltd	16	4.3.2 h	In section 4.3.2 'h', the draft scope states that access to medicines will not be covered in the clinical guideline. In the appendix NICE points to an overlap with the remit of the MHRA as a reason for not including this aspect. Regulatory authorities such as the MHRA and EMA are responsible for assessing the quality, safety, and efficacy of a medicinal product prior to the issuance of a marketing authorisation (product licence) and throughout the product lifecycle. Part of NICE's remit is to produce guidance that provide recommendations around the treatment and care of people with specific diseases and conditions. Technology Appraisals consider *licensed* medicines and are performed to ensure that all NHS patients have equitable access to the most clinically- and cost-effective treatments that are available. Access to medicines is a core part of NICE's role, and when considering licensed medicines, there is no overlap between the remits of NICE and MHRA. In addition to NICE preparing this clinical guideline on medicines optimisation, the Royal Pharmaceutical Society has also produced medicines optimisation good practice guidance for healthcare professionals in England[3] which is endorsed by NHS England. Evidence Based Choice of Medicines is identified as the second of their four principles of medicines optimisation,	Thank you for your comment. Access to medicines is considered in the NICE good practice guidance on developing and updating local formularies. This will not be considered as part of this guideline.

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					with access to medicines underpinning that principle. The key point of this principle is to "Ensure that the most appropriate choice of clinically and cost effective medicines (informed by the best available evidence base) are made that can best meet the needs of the patient." A key outcome for this principle is that "Decisions about access to medicines are transparent and in accordance with the NHS Constitution." In conclusion, MSD believes that it is essential for access to licensed medicines to be included in the scope of this clinical guideline to align with other published guidance and for the following reasons: enabling access to available medicines could have a significant bearing on the quality of consultations with a patient, the outcome of the consultation for the patient (i.e. whether the patient was given a choice of options), the validity of the consent process, and importantly the outcome of treatment in terms of efficacy and efficient use of medicine. Ref 3: http://www.in2health.org/wp-content/uploads/2013/08/2013-RPS-Medicines-Optimisation-Helping-patients-make-the-most-of-their-medicines.pdf	
354	SH	Merck Sharp & Dohme UK Ltd	17	4.3.2 j	Education and training of health and social care practitioners relating to medicines (point 'j') is listed as an area which will not be included within the scope of this guideline, due to the fact that it is a very broad area which crosses the remit of other national organisations, such as	Thank you for your comment. Health Education England (HEE) was established as a special health authority in June 2012 and assumed full responsibilities from April 2013. HEE now hold responsibility for

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					Health Education England. Whilst we appreciate that this is a broad area, it should be noted that in certain therapy areas the training of the health care professional (HCP) is critical to the appropriate fitting/administration of the therapy (an example being the long-acting reversible contraceptive implant 'Nexplanon'). The appropriate fitting/administration has a bearing on subsequent efficacy of the product, as well as patient satisfaction. Therefore, we kindly suggest that NICE considers including education and training of health and social care practitioners for products requiring specialist fitting/administration within the scope.	providing leadership, planning and development of the whole healthcare and public health workforce, in relation to education and training.
355	SH	Merck Sharp & Dohme UK Ltd	18	4.4	One of the main outcomes that has been listed within this section is "Patient-reported outcomes e.g. reduced uncertainty, satisfaction with decision making". MSD recognises that this outcome is aligned with one of the areas which will be covered by the scope ("Patient and carer engagement in shared decision making"). Nevertheless, it is suggested that it may be useful for the scope to make clear that "patient choice" should form part of the patient-reported outcome measure (PROM).	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
356	SH	Merck Sharp & Dohme UK Ltd	19	4.5	The review questions are very complicated and could result in little published evidence from the systematic review being identified. MSD feels that the questions will need to be amended in order to answer the review questions which underpin important aspects of this guideline.	Thank you for your comment. The development of the guidance will follow NICE short clinical guideline methodology. The review questions have been amended.
357	SH	Merck Sharp & Dohme UK Ltd	20	General	Could NICE please clarify the audience for this clinical guideline? Is it aimed at the GP, other healthcare professionals, commissioners,	Thank you for your comment. The settings section of the scope provides the audience for the guidance.

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					patients, carers or all of these stakeholders?	
358	SH	Royal College of Nursing	1	General	The Royal College of Nursing welcomes proposals to develop this guideline. It is timely.	Thank you for your comment.
359	SH	Royal College of Nursing	2	General	We agree with definition given, although it has to be recognised that not all patients/clients are in a position to engage fully with a decision making process.	Thank you for your comment.
360	SH	Royal College of Nursing	3	3 (f)	Not just discharge home, but transfer between specialities and or transition from child to adult services.	Thank you for your comment. The example provided is not meant to be an exhaustive list. The detail of your comment may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
361	SH	Royal College of Nursing	4	3 (i)	Much medicine information is written with the use of medical terminology and could be misinterpreted.	Thank you for your comment.
362	SH	Royal College of Nursing	5	4.3.2 (j)	From the healthcare assistant (HCA)'s perspective, we were looking for some sound advice on appropriate training and education of support staff – but then discovered that this is one of the "Areas that will not be covered" (4.3.2) j: Education and training of health and social care practitioners relating to medicines. The rationale that has been given is that this is a "Very broad area which crosses remit of other national organisations, such as Health Education England" In our view education and training is so essential to safe use of medicines and even one line stating that all staff expected to administer or support the administration of a medicine must be appropriately trained and supported, would be	Thank you for your comment. Health Education England (HEE) was established as a special health authority in June 2012 and assumed full responsibilities from April 2013. HEE now hold responsibility for providing leadership, planning and development of the whole healthcare and public health workforce, in relation to education and training. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.

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					most helpful. This is integral to the proposed work in the section on ***Reducing medicines-related patient safety incidents.***	
363	SH	Royal College of Nursing	6	General	The transition of adolescents from children to adult services is a logistical nightmare particularly relating to failure to follow up or loss to follow up patients at this stage in life. Medicine optimisation maybe very poor with QoL also poor. A medicine database for this age group to "flag up" if medicines had not been collected could improve long term outcomes.	Thank you for your comment.
364	SH	Royal College of Nursing	7	General	Medicine information in appropriate formats for the adolescent group – they would not read a leaflet or piece of paper. The use of Apps and text messaging would be more appropriate.	Thank you for your comment. Decision support has been included as a key issue.
365	SH	Royal College of Nursing	8	General	The RCN has a keen interest in the development of this guideline and will be attending the scoping workshop for this document on 30th September 2013.	Thank you for your comment.
366	SH	NHS Barking & Dagenham CCG	1	4.2.9	Our comment is - should this not read *All publicly-funded health and social care provid**ers**...*	Thank you for your comment. The settings section of the scope has been amended.
367	SH	Rotherham Doncaster and South Humber NHS Foundation Trust	1	3a.	There should be something in the definition about the treatment being successful in reaching agreed treatment goals.	Thank you for your comment. The definition of medicines optimisation has been amended.
368	SH	Rotherham Doncaster and South Humber NHS Foundation Trust	2	4.1.1a	Patients with limited capacity to make informed choices around compliance	Thank you for your comment. The population section of the scope has been amended to reflect your comment.

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369	SH	Rotherham Doncaster and South Humber NHS Foundation Trust	3	4.1.1b	To include practitioners who prescribe, supply or administer medicines	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
370						No comment recorded.
371	SH	Children's HIV Association	1	4.1.1 (a)	Children and Adults who are not native English Speakers will need to be considered	Thank you for your comment. The population section of the scope has been amended.
372	SH	Children's HIV Association	2	4.1.1 (a)	Children and Adults within the asylum system	Thank you for your comment. The population section of the scope has been amended.
373	SH	Children's HIV Association	3	4.1.1 (b)	Professionals who purchase, supply and dispense medication	Thank you for your comment. The population section of the scope has been amended.
374	SH	Children's HIV Association	4	4.3.1	Patient/Carer information	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
375	SH	Children's HIV Association	5	4.3.1(g)	And Home care delivery Systems	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
376	SH	Children's HIV Association	6	4.3.1	Communication relating to the patient e.g. Patient suitability of particular formulations. Formulary Challenges e.g. When Patients cannot take a Formulary Option – Alternatives should exist in the formulary recommendations.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
377	SH	NHS Cumbria Clinical Commissioning Group	1	3 a)	The definition as given broadly encompasses medicines optimisation as practised in primary care in Cumbria. There may be some debate about the precise wording but the definition should not be reduced to such an extent that it loses any of the elements in the current definition. In addition, our version of medicines	Thank you for your comment. The definition of medicines optimisation has been amended.

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					optimisation is performed in a holistic manner – looking at the patient and all their existing medication as a whole, so considering the use of OTC medicines by the patient, possible lifestyle changes, alterations to drug or dosage form and considering unmet need. Projects that only deal with one medication might contribute to medicines optimisation but would not be considered as medicines optimisation in its own right. Optimising medicines also involves considering the resources available and making cost effective choices so that all people in the local health economy can then benefit from evidence based medicine however the main focus of medicines optimisation is to work towards achieving patient orientated outcomes (i.e. that matter to the patient, not necessarily to the clinician).	
378	SH	NHS Cumbria Clinical Commissioning Group	2	4.1.1 b)	Suggest change to a broader group : All practitioners who prescribe, administer or manage medicines.	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
379	SH	NHS Cumbria Clinical Commissioning Group	3	4.3.1 Transferring medicines information g)	The role of practice based Medicines Managers could be considered here.	Thank you for your comment. The key issues section of the scope has been amended.
380	SH	NHS Cumbria Clinical Commissioning Group	4	4.3.1 Reducing preventable medicines-related hospital admissions h)	The role of practice based Medicines Managers could be considered here.	Thank you for your comment. The key issues section of the scope has been amended.

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381	SH	NHS Cumbria Clinical Commissioning Group	5	4.3.1 Reducing preventable medicines-related hospital admissions	Prescribing and non-medicinal treatments for **unmet need** could be considered here. e.g. for a patient at risk of falls - starting bone sparing medication.	Thank you for your comment. The key issues section of the scope has been amended to reflect your comment.
382	SH	NHS Cumbria Clinical Commissioning Group	6	4.3.2 a)	Whilst it is understood that medicines adherence does not need to be covered in this guideline as it is in CG76, exploring adherence is a key element of medicines optimisation so the final guideline should clearly emphasise this by reference to CG76.	Thank you for your comment. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). The main outcomes section includes 'patient-related outcomes' which will include medicines adherence as an outcome, where appropriate cross-reference will be made.
383	SH	NHS Cumbria Clinical Commissioning Group	7	GDG membership	The group should include a practice based primary care pharmacist (i.e. experienced in working in a GP practice in a medicines management, not a purely dispensing role) as medicines optimisation forms a significant part of their core role.	Thank you for your comment. This has already been considered as part of the guideline development group recruitment.
384	SH	King's College Hospital NHS Foundation Trust	1	General	We welcome guidance to improve patient outcomes from optimising the use of medicines	Thank you for your comment.
385	SH	King's College Hospital NHS Foundation Trust	2	4.3.1	More specifically we welcome inclusion of *Reducing medicines related patient safety incidents* from all aspects of the medicines process including prescribing, dispensing administration and monitoring	Thank you for your comment.
386	SH	King's College Hospital NHS Foundation Trust	3	4.4	We note however that while the main outcomes include medication related problems from prescribing errors, monitoring errors and adverse effects there is no mention of medication related problems associated with dispensing or administration errors.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.

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					Historically administration errors have been associated with secondary care but with the increasing trend toward homecare we feel it is essential to include optimisation of medicines administration in all settings within the scope of the document	
387	SH	King's College Hospital NHS Foundation Trust	4	4.5	We suggest inclusion of a review question addressing the safe and cost effective administration of medicines to reduce the risk of patient harm and optimise the outcome from medicines use in line with 4.5(e)	Thank you for your comment. Due to the time available to develop the guideline, prioritisation of the review questions has been required. Therefore unfortunately you additional review questions cannot be considered.
388	SH	Bayer plc	1	4.1.1	Groups that will be covered. **a)** We suggest that people with long-term conditions should be covered regardless of whether they have 'multiple conditions.' All people with long-term conditions have a requirement for on-going medicines optimisation commensurate with their evolving needs.	Thank you for your comment. The population section of the scope has been amended.
389	SH	Bayer plc	2	4.1.1	Groups that will be covered. **a)** We suggest that people in care homes are another important group who require particular consideration. We appreciate that there is a separate NICE good practice guideline in development covering the management of medicine in care homes, and suggest that as a minimum, a cross-reference is provided to this guideline so that this group are not omitted.	Thank you for your comment. The population section of the scope has been amended. NICE are developing good practice guidance for managing medicine in care homes where appropriate cross-reference will be made.
390	SH	Bayer plc	3	4.1.1	Groups that will be covered. **a)** We suggest that another group who should be given particular consideration are those taking	Thank you for your comment. The population section of the scope has been amended.

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					medicines that are commonly reported as causing problems - whether in terms of adherence, experience or safety. Whilst the scope mentions such classes of medicines in the context of reducing preventable medicines-related hospital admission, we feel some medicines may also have an effect on the quality of life of the patient. For example, it has been suggested that treatment with warfarin, with the need to "undergo frequent blood tests, limit activities and alcohol intake and avoid other drugs", may diminish quality of life.[1] 1. Robinson A, Thomson R, Parkin D, Sudlow M, Eccles M. How patients with atrial fibrillation value different health outcomes: a standard gamble study. J Health Serv Res Policy. 2001 Apr;6(2):92-8.	
391	SH	Bayer plc	4	4.1.1	Groups that will be covered. **b)** We suggest that "all practitioners who administer medicines" should be amended to reflect that all practitioners who are involved in prescribing, dispensing and reviewing medicines should be covered.	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
392	SH	Bayer plc	5	4.3.1	Areas that will be covered. **Patient and carer engagement in shared decision making** We welcome the inclusion of this area; it has been shown for example, that the provision of advance information regarding the potential effects of medication can increase user satisfaction "regardless of whether the symptom in question was actually experienced."[1] 1. Backman T, et al. Advance information improves user satisfaction with the	Thank you for your comment. The key issues section of the scope has been amended.

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					levonorgestrel intrauterine system. Obstet Gynecol. 2002 Apr;99(4):608-13.	
393	SH	Bayer plc	6	4.3.1	Areas that will be covered. **Evidence informed decision making** We agree that evidence informed decision making is a very important principle of medicines optimisation. As such, we suggest that the uptake of NICE approved medicines and the implementation of NICE guidance should be listed as an area that will be covered as part of this principle. It is acknowledged under the 'need for the guideline' that *"there is variation in the uptake of NICE approved medicines and the implementation of NICE guidance"*, and that *"NICE compliance/uptake of NICE-approved medicines"* is a main outcome of this guideline.	Thank you for your comment. Access to medicines is considered in the NICE good practice guidance on developing and updating local formularies. This will not be considered as part of this guideline.
394	SH	Bayer plc	7	4.3.1	Areas that will be covered. **Reducing medicines-related patient safety incidents** We also feel that medicines-related patient safety incidents can occur as a result of patients 'stockpiling' medicines previously prescribed. There may be risks in terms of stability, that the medication may not be taken for the intended purpose, or that a person other than the intended recipient may use the medication.	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
395	SH	Bayer plc	8	4.3.1	Areas that will be covered. **Reducing medicines-related patient safety incidents** a) Interventions to reduce medicines related patient safety incidents should include 'classes of medicines commonly associated with patient safety incidents.'	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
396	SH	Bayer plc	9	4.3.1	Areas that will be covered.	Thank you for your comment. The

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					Reducing medicines-related patient safety incidents We suggest adding to the list of topics to be considered 'appropriate systems to manage medication that is dispensed in multi-compartment compliance aids'. Some medications are not suitable for inclusion in multi-compartment compliance aids e.g. those with frequently changing doses or those whose stability could be affected.	detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
397	SH	Bayer plc	10	4.3.1	Areas that will be covered. We feel that the on-going management of medicines through medication reviews is also an important area to be covered. Whist the scope mentions such reviews in the context of reducing medicines-related patient safety incidents and in reducing preventable medicines-related hospital admissions, on-going medication reviews may also be important for enabling people with long-term conditions to feel supported to manage their condition over time and in the prevention of medicines wastage.	Thank you for your comment
398	SH	Bayer plc	11	4.3.1	Areas that will be covered. In addition to reducing medicines-related hospital admissions and re-admissions, we suggest that medicines optimisation also has the potential to reduce the burden on social care.	Thank you for your comment
399	SH	Prescription Charges Coalition		General	**The Prescription Charges Coalition** The Prescription Charges Coalition is an alliance of 29 organisations who share concerns about the impact of prescription charges on people with long-term conditions. A full, current membership is listed here, (www.prescriptionchargescoalition.org.uk/coalition-members.html) but includes organisations	Thank you for your comment.

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					such as Crohn's and Colitis UK, Asthma UK, the British Heart Foundation, National Rheumatoid Arthritis Society and the Royal Pharmaceutical Society. In March 2013, the Prescription Charges Coalition published a report *Paying the Price: Prescription Charges and People with Long-Term Conditions* (available at www.prescriptionchargescoalition.org.uk), based on a survey of more than 3,700 people with long-term conditions in England. The findings are relevant to this guideline on Medicines Optimisation. A high proportion of the respondents had multiple long-term conditions. Cost was found to be a significant barrier to effective medicines-taking behaviour with a reported impact in terms of health outcomes, unplanned contacts with the health service and hospitalisation. One third (36%) of those surveyed who were paying for each prescription item had not collected medication due to the cost. Three quarters of this group stated that their health got worse as a result, with 10% reporting that they were hospitalised as a direct consequence. Survey respondents also reported not taking their medicines as prescribed to delay having to pay for another prescription, for example, by cutting pills in half, missing doses or substituting cheaper over-the-counter alternatives. Three quarters of respondents were paying for their medicines. Schedules for repeat prescriptions were also a	

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					source of concern for over 36% of respondents, with cost and inconvenience the main reasons cited for this. Free text responses highlighted a move to more frequent prescribing for regular, long-term medication as a key driver for this dissatisfaction. There is considerable potential to address some of the issues above through this guideline if the relevant factors are included within the scope. We would raise two main areas that should be included within the scope of the guideline.	
400	SH	Prescription Charges Coalition	1	General	**Information about prescription charge exemptions, the Prescription Prepayment Certificate and NHS Low Income Scheme to be given routinely to people with long-term conditions at diagnosis, as part of care planning, where medicine is dispensed and in any relevant medicine reviews** In line with our research findings, and those outlined in other survey reports (e.g. Citizens Advice), there is a need for information about help with the cost of medicines to be communicated clearly and routinely to people with long-term conditions. Information leaflets should be prominently on display in all GP surgeries and pharmacies. Research shows that people with long-term conditions are often not aware of the Prescription Prepayment Certificate (PPC), which may represent a cost-saving for them, for some time after they have been diagnosed with their condition. Most often this is through the pharmacist (37%), while only 14% found out	Thank you for your comment. Unfortunately NICE is unable to amend legislation relating to prescription charges. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.

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					from their GP and 5% from their consultant. 23% had to rely on family and friends for this information. 76% of survey respondents had not heard of the NHS Low Income Scheme. There was also a lack of understanding about whether the PPC would be worthwhile, indicating the need for this to be part of discussions and inform decision-making about medicines. If people with long-term conditions are given information about the PPC, NHS Low Income Scheme and prescription charge exemptions, as part of wider information about medicines and treatments, this will aid informed decision-making and support self-management and patient-centred care. Our evidence suggests that reducing or removing the cost barrier for those for whom it has the biggest impact, through the more effective use of support mechanisms already in place, is also likely to positively affect health outcomes and unplanned contacts and hospitalisation. Practitioners with a medicines optimisation remit such as practice-based pharmacists could have a specific responsibility in relation to this. There is also an opportunity to use public information campaigns to raise general levels of awareness and improve access to the PPC, NHS Low Income Scheme and prescription charge exemptions.	
401	SH	Prescription Charges Coalition	2	General	**The frequency and duration of prescriptions for people on long-term maintenance medication for a stable, long-term condition should be based on individual needs and**	Thank you for your comment. Repeat dispensing and repeat prescribing systems are listed as areas that will not be covered in the guideline. This

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					circumstances and agreed between the prescriber and patient, not bound by rigid 28-day prescribing policies There is a wide variation in local prescribing policies, although many support a 28-day prescribing regime. However, for those with stable, long-term conditions, longer prescribing periods may be the optimal approach in terms of convenience and cost for the patient and cost to the NHS, for example, in terms of health professionals' time. The consequences of these policies could also increase unplanned contacts and hospitalisation as outlined in our first point. Respondents to the Prescription Charges Coalition survey reported concerns about having to take time off work in order to schedule additional appointments for ongoing maintenance medication, considerable anxiety about running out of medication and the difficulties of managing different prescribing durations for different medicines, with multiple visits to GPs and pharmacies and increased risk of running out of medication. Patient-centred care should address these aspects in order to ensure optimal use of medicines for those with long-term conditions and improve outcomes. Advice from the National Prescribing Centre published in *NHS Connect* in December 2008 was helpful in describing a framework for local prescribing policies in this regard. This could be usefully incorporated into this guideline to inform local policies and practices towards a more patient-centred approach, which would be likely	area of practice could warrant a guideline in itself and would be too large to include in this medicines optimisation guideline.

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					to have a positive impact on outcomes. www.npc.nhs.uk/resources/connect_issue_55.pdf	
402	SH	Prescription Charges Coalition			We hope these crucial points can be included within the scope of the medicines optimisation guideline and would be happy to provide any further information that may be helpful.	Thank you for your comment.
403	SH	Sanofi	1	General	Sanofi welcomes the opportunity to comment on this useful and important guideline draft scoping document, which looks very comprehensive.	Thank you for your comment.
404	SH	Sanofi	2	General	Discussion around medicines optimisation often includes the concept of medicines as an investment both to improve outcomes for patients and to reduce future healthcare resource utilisation. We would suggest that this broad definition be taken into consideration during the development of the guideline. We would also recommend that the outputs of this work are aligned with that of other respected bodies, such as the Royal Pharmaceutical Society, who recently published a report on Medicines optimisation.	Thank you for your comment. The need for the guideline section has been amended.
405	SH	Sanofi	3	3b	Medicines Management should be an enabler of medicines optimisation and it would be useful for this work to describe how medicines management activities can directly support a medicines optimisation objective.	Thank you for your comment.
406	SH	Sanofi	4	3h	Whilst education of staff on medicines is listed under 4.3.2 (areas that will not be covered) seems reasonable given the scope of this guideline – we would like to suggest that NICE should consider inclusion of the principle and spirit which is expressed in the overarching goal of the Berwick report and the first	Thank you for your comment. Health Education England (HEE) was established as a special health authority in June 2012 and assumed full responsibilities from April 2013. HEE now hold responsibility for providing leadership, planning and

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					recommendation: "The NHS should continually and forever reduce patient harm by embracing wholeheartedly an ethic of learning."	development of the whole healthcare and public health workforce, in relation to education and training. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG.
407	SH	Sanofi	5	4.1.1 (a)	Is it possible to further identify sub groups in the population where there is evidence (anecdotal or otherwise) of an increased risk of poor medicine usage? Potential populations may include: non-English speakers; those with alcohol dependence; those who use mental health services; those in nursing homes or are house bound. In order to make specific recommendations to support patients in these (or similar) categories.	Thank you for your comment. The population section of the scope has been amended.
408	SH	Sanofi	6	4.3.1 - Reducing medicines-related patient safety incidents	It will be important for the guideline, when considering medicines management systems, to reflect and align with advice from other bodies on the safe use of medicines, for example, considering the importance of brand/product-specific prescribing of biosimilar medicines.	Thank you for your comment. The guideline will not cover specific clinical conditions.
409	SH	North Bristol NHS Trust			My thoughts on the documentation; Medicines optimisation definition For the purpose of this guideline, we have outlined a definition of medicines optimisation (see section 3a). Do you agree with this definition? Yes 2. Breadth and depth of the guideline Medicines optimisation is a large and complex	Thank you for your comment. The detail of your comments may be considered in the review protocols to answer the finalised review questions when signed off by the GDG. The population section of the scope has been amended. The settings section of the scope outlines the intended audience for the guideline.

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					topic. There are many aspects of medicines that will affect patient outcomes. Accordingly, we are interested in knowing whether there are any specific areas throughout the patient journey that particularly need to improve in relation to medicines optimisation. What are the key priority areas for the guideline to focus on? □□□□□□□□Admission to hospital: patients present with adverse effects due to medications, medicines reconciliation □□□□□□□□Discharge: Communication of medications to patients on discharge, preventing waste of medications already at home, communication between care settings to prevent errors □□□□□□□□(During inpatient stay: ensuring medicines with most evidence is used, safe use of medicines) 3. Considering the group to be covered Are there any groups that should be covered within the guideline that have not been listed? (see section 4.1.1) □□□□□□□□Patient's on high risk medications e.g. anticoagulants)uld it also be possible to state who the guideline is aimed at? Is it everyone or certain practitioners i.e carers, nurses, doctors, pharmacists, social workers, physiotherapists etc.	
410	SH	Daiichi Sankyo	1	Consultation	The definition of 'medicines optimisation' should	Thank you for your comment.

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		UK		Question 1	reflect its strong association with 'medicines adherence'. It seems counter-intuitive to exclude 'medicines adherence' from the scope because it is "crosses" with NICE CG76. Can the Guidance and Quality Standard not incorporate the considerations of CG76? We believe that medicines optimisation – with the express aim of ensuring the best possible outcome for patients – is so closely related to (and largely dependent on) medicines adherence that they cannot be viewed in isolation.	Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). The main outcomes section includes 'patient-related outcomes' which will include medicines adherence as an outcome, where appropriate cross-reference will be made.
411	SH	Daiichi Sankyo UK	2	4.3.1: Evidence-informed decision making.	Please include reference to all interventions shown to increase patient adherence as an area that will be covered by the Scope. We agree that 'patients using multiple medicines' should be a group that is covered by the scope. In is well-understood that patients on multiple separate drugs often find it hard to adhere to therapy (1). It has been shown that improving patient adherence when taking medicines may have a greater impact on clinical outcomes than improving the treatments themselves (2), so it will be appropriate for this Scope to capture initiatives – such as the use of simplified dosing regimens – aimed at improving adherence for patients using multiple medicines. For example, across a number of disease areas, from hypertension to HIV to diabetes, the use of single tablet regimens in place of multiple separate medicines has been shown to improve patient adherence (3-9) and subsequently lead to fewer downstream admissions and resultantly	Thank you for your comment. The key issues section of the scope has been amended.

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					lower healthcare resource use (10-12) Although we appreciate that this guideline is not to be condition- or treatment specific, it will be very important for this guideline to broadly reflect those evidence-based initiatives shown to optimise the outcomes of medicines (via improved adherence). As the guidelines on medicines adherence recommend practical changes to the type of medicine or regimen as an intervention to increase adherence (13), it seems appropriate that the role of such guidelines and the interventions they recommend should be reflected in this Scope. *References:* 1. *Gerbino P and Shoheiber O. Am J Health Syst Pharm 2007;64(12):1279-1283.* 2. *Haynes RB, Ackloo E, Sahota N et al. Interventions for enhancing medication adherence. Cochrane Database Syst Rev 2008;(CD000011).* 3. *The use of single-pill combination treatments in patients with hypertension. Statement from the British Hypertension Society, Septembe2 2012. Available from http://www.bhsoc.org/files/5313/4910/8517/Single-Pill-Combination-therapy-in-hypertension-NP-15-Aug-2012.pdf. Accessed September 2013.* 4. *Mancia et al. Eur Heart J 2013; 34: 2159-2219.* 5. *Gupta AK et al. Hypertension 2010; 55:399-407.*	

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					6. *Yang W et al. Curr Med Res Opin 2010; 26:2065-2076.* 7. *Eron J, Yetzer E, Ruane P, Becker S, Sawyerr G, Fisher R, et al. Efficacy, safety, and adherence with a twice-daily combination lamivudine/zidovudine tablet formulation, plus a protease inhibitor, in HIV infection. AIDS 2000;14:671-81.* 8. *Simmons D, Upjohn M, Gamble G. Can medication packaging improve glycemic control and blood pressure in type 2 diabetes? Results from a randomized controlled trial. Diabetes Care 2000;23(2):153-6.* 9. *Thom S, et al. Effects of a fixed-dose combination strategy on adherence and risk factors in patients with or at high risk of CVD: the UMPIRE randomized clinical trial. JAMA. 2013 Sep 4;310(9):918-29* 10. *Trueman P et al. Evaluation of the Scale, Causes and Costs of Waste Medicines Report. 2010. York Health Economics Consortium and The School of Pharmacy, University of London.* 11. *Belsey JD. J Med Econ 2012; 15(5): 897-905.* 12. *Girvin B, McDermott BJ, Johnston GD. J Hypertens 1999; 17:1627-1631.* 13. *National Institute for Health and Care Excellence 2011. Hypertension: clinical management of primary hypertension in adults. CG127.*	
412	SH	Daiichi Sankyo UK	3	Consultation Question 3	Please can the group of patients who receive medication but whose disease is not adequately	Thank you for your comment. The population section of the scope has

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					controlled because of poorly-optimised medicine be added to the list of groups given particular consideration. This is a patient group with significant unmet need that may "fall through the cracks" of such an exercise as this if it is left as an un-named subset of people who are using medicines.	been amended to reflect your comment.
413	SH	Daiichi Sankyo UK	4	4.3.1	It will be important for generic substitution and the extent to which it impacts upon medicines optimisation to be explicitly considered. Using the treatment of hypertension as an example, evidence suggests that generic substitution can contribute to poor adherence to medicine. In one report, one third of patients indicated generic substitution made it more difficult for them to keep track of their medicines; twenty-nine percent said that starting to use a generically-substituted product made them feel anxious; and one in twenty used more than one equivalent generic product at the same time, resulting in double- or triple-dosing (1). As this example illustrates, the use of generic substitution as a medicines management tool needs to be an area of focus explicitly noted within the Scope, as it has the potential to impact patient outcomes. *Reference:* 1. *Håkonsen et al. CRMO 2009; 25:2525-21.*	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
414	SH	Daiichi Sankyo UK	5	4.4 - Outcomes	The scope currently includes 'NICE compliance' as an outcome. It is an issue across many	Thank you for your comment. Access to medicines is considered in the

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					disease areas that NICE-approved medicines may appear on formularies, but that regional or local guidelines/protocols for the same medicines restrict usage to such an extent that their use is effectively being blocked. Can the outcomes of this scope please be extended to include a more transparent account of genuine access? Formulary inclusion, while important, does not adequately capture true compliance in the spirit presumably intended by NICE.	NICE good practice guidance on developing and updating local formularies. This will not be considered as part of this guideline.
415	SH	Daiichi Sankyo UK	6	General	Please can the guideline provide guidance to address the potential conflicts of interest between service provision payments and medicines optimisation decisions which could potentially improve patient outcomes? As an example, in the case of anticoagulation, it is not uncommon for those involved in regional Area Prescribing Committee or local CCG/CCG cluster protocol/guideline decisions regarding novel oral anticoagulants to simultaneously be actively involved in the provision of warfarin anticoagulation clinic services (and hence with payments associated with these services). As the increased use of novel oral anticoagulants has the potential to reduce the need for warfarin monitoring clinics, there is a potential conflict between creating a formulary designed to optimise patient outcomes versus generating trust or practice income with warfarin monitoring. This is of course a disease-specific example, but it will be important for the guidance on medicines optimisation to address – at a non-disease-specific level – how to overcome such	Thank you for your comment. The population section of the scope has been amended to reflect your comment.

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					potential conflicts to the extent that they impact medicines optimisation.	
416	SH	NHS England	1	General	The brief need extending beyond prescribing to encompass prescribing, dispensing and administration.	Thank you for your comment. The population section of the scope has been amended to reflect your comment.
417	SH	NHS England	2	General	The brief needs to include Social Care as it relates to medicines use in NHS England.	Thank you for your comment. The settings section of the scope has been amended to reflect your comment.
418	SH	NHS England	3	General	Medicines Optimisation should subsume the systems approach of Medicines Management (see 2.4). The definition should be brief. It can be qualified, but must not be restrictive at the outset. One suggestion is Medicines optimisation ensures people obtain the best possible outcomes from their medicines while minimising the risk of harm and within the available resources. This may then be qualified to ensure 2.1 evidence-informed decision making about medicines, 2.2 effective patient engagement 2.3 professional collaboration to provide an individualised, person-centred approach to medicines use and 2.4 , optimise the systems of processes and behaviours determining how medicines are used by patients and the NHS.	Thank you for your comment. The definition of medicines optimisation has been amended to reflect your comment. Reference to resources has been removed
419	SH	NHS England	4	General	Medicines Optimisation is absolutely dependent on medication adherence. While cross referencing is identified, there needs to be demonstrable links between adherence and optimisation.	Thank you for your comment. Medicines adherence is not specifically included in the scope (existing NICE guidance covers this subject). The main outcomes section includes 'patient-related outcomes' which will

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						include medicines adherence as an outcome, where appropriate cross-reference will be made.

These organisations were approached but did not respond:

5 boroughs NHS Foundation Trust Partnership
Abbott Diabetes Care
Abbott Healthcare Products Ltd
Abbott Laboratories
ABPI Pharmaceutical Stroke Prevention of AF Initiative
Addenbrookes Hospital
Aintree University Hospital NHS Foundation Trust
Alder Hey Children's NHS Foundation Trust
Aneurin Bevan Health Board
Anglian Community Enterprise
Archimedes Pharma Ltd
Arden Commissioning Support
Association for Palliative Medicine of Great Britain
Association of Anaesthetists of Great Britain and Ireland
Astrazeneca UK Ltd
Barnsley Hospital NHS Foundation Trust
Barts Health NHS Trust
Berkshire Local Pharmaceutical Committees
Biogen Idec
Birmingham Children's Hospital NHS Foundation Trust
Boehringer Ingelheim
Bristol Myers Squibb Pharmaceuticals Ltd
British Association of Critical Care Nurses
British Dietetic Association
British Medical Association
British Medical Journal

British National Formulary
British Nuclear Cardiology Society
British Pain Society
British Pharmacological Society
British Psychological Society
British Red Cross
British Thoracic Society
British Transplantation Society
Bupa Care Services

Care Quality Commission (CQC)
Cegedimrx
Central & North West London NHS Foundation Trust
Central Eastern Commissioning Support Unit
Central London Community Health Care NHS Trust
Central Manchester University Hospitals NHS Foundation Trust
Chronic Myeloid Leukaemia Support Group
College of Mental Health Pharmacy
Company Chemists Association Ltd
Cornwall Partnership Trust
Crohn's and Colitis UK
Croydon Clinical Commissioning Group
Croydon University Hospital
Cumbria Partnership NHS Trust
Department of Health, Social Services and Public Safety Northern Ireland
Dermal Laboratories
Dudley and Walsall Mental Health Trust
East and North Hertfordshire NHS Trust
East Kent Hospitals University NHS Foundation Trust
East Lancashire Hospitals NHS Trust
Ethical Medicines Industry Group
Faculty of Pain Medicine of the Royal College of Anaesthetists
Faculty of Pharmaceutical Medicine
Gateshead Health NHS Foundation Trust
Gilead Sciences Ltd
Gloucestershire Care Services NHS Trust
Group B Strep Support

Guy's and St Thomas' NHS Foundation Trust
Hayward Medical Communications
Health and Social Care Board
Health Education Yorkshire and the Humber
Health Quality Improvement Partnership
Healthcare Improvement Scotland
Healthwatch East Sussex
Hertfordshire Partnership NHS Foundation Trust
Herts Valleys Clinical Commissioning Group
HIV Pharmacy Association
Hollister Ltd

Humber NHS Foundation Trust
Ipsen Ltd
Keele Centre for Medicines Optimisation
Kent and Medway Commissioning Support
Kent and Medway NHS and Social Care Partnership Trust
Lancashire Care NHS Foundation Trust
Lanes Health
Leeds Teaching Hospitals NHS Trust
Leo Pharma
Leonard Cheshire Disability
Lilly UK
Liverpool Community Health
Medicines and Healthcare products Regulatory Agency
Ministry of Defence
Napp Pharmaceuticals Ltd
National Association of Primary Care
National Clinical Guideline Centre
National Collaborating Centre for Cancer
National Collaborating Centre for Mental Health
National Collaborating Centre for Women's and Children's Health
National Deaf Children's Society
National Institute for Health Research Health Technology Assessment Programme
National Institute for Health Research Horizon Scanning Centre
National Patient Safety Agency
National Pharmacy Association

National Rheumatoid Arthritis Society
National Treatment Agency for Substance Misuse
NCRI Breast CSG Working Group on Symptom Management
NHS Alliance
NHS Barnsley Clinical Commissioning Group
NHS Bath and North East Somerset CCG
NHS Bedfordshire CCG
NHS Birmingham CrossCity CCG
NHS Birmingham South and Central CCG
NHS Bromley CCG
NHS Coastal West Sussex CCG
NHS Connecting for Health
NHS Coventry and Rugby CCG

NHS Direct
NHS Durham Dales,Easington and Sedgefield CCG
NHS Heywood, Middleton & Rochdale CCG
NHS Luton CCG
NHS Medway Clinical Commissioning Group
NHS Plus
NHS Portsmouth Clinical Commissioning Group
NHS Protect
NHS Sheffield CCG
NHS South Cheshire CCG
NHS South Worcestershire CCG
NHS Trust Development Authority
NHS Wakefield CCG
NHS Warwickshire North CCG
NHS West Kent
NHS West Lancashire CCG
NHS West Suffolk CCG
NHSBSA Prescription Services
Nordic Pharma
Norfolk Community Health and Care NHS Trust
Norfolk Medicines Support Service
Norgine Limited
North of England Commissioning Support
Northern, Eastern, Western Devon CCG

Northumbria Healthcare NHS Foundation Trust
Nottingham City Council
Nottinghamshire Healthcare NHS Trust
Novo Nordisk Ltd
Nutricia Clinical Care
Oxfordshire Clinical Commissioning Group
Pan London Acute Medicine Network
Patients & Relatives Committee of the Intensive Care Society
Pharmaceutical Advisers Group
Pharmaceutical Services Negotiating Committee
Physiotherapy Pain Association
Plymouth Hospitals NHS Trust
Primary Care Dermatology Society

Primary Care Partnerships
Primary Care Pharmacists Association
Public Health Wales NHS Trust
Public Health Wales NHS Trust
Queen Elizabeth Hospital King's Lynn NHS Trust
Queen's University Belfast
RDaSH NHS Foundation Trust
Rethink Mental Illness
Robert Jones & Agnes Hunt Orthopaedic & District Hospital NHS Trust
Roche Diagnostics
Royal College of General Practitioners
Royal College of General Practitioners in Wales
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists
Royal College of Ophthalmologists
Royal College of Pathologists Lay Advisory committee
Royal College of Psychiatrists
Royal College of Radiologists
Royal College of Surgeons of England
Rycroft Partnership LLP
Salisbury NHS Foundation Trust
Sanctuary Care
Sandoz Ltd
Scottish Intercollegiate Guidelines Network

Sense
Serious Hazards of Transfusion
Sheffield Health and Social Care NHS Foundation Trust
Sheffield Teaching Hospitals NHS Foundation Trust
Soar Beyond Ltd
Social Care Institute for Excellence
South Chadderton Health Centre
South East Staffordshire and Seisdon Pennisula CCG
South London & Maudsley NHS Trust
South Stadffordshire & shropshire Healthcare NHS Foundation Trust
South Tyneside NHS Foundation Trust

South West Essex Community Services
South West Yorkshire Partnership NHS Foundation Trust
Spirit Healthcare
Staffordshire and Stoke on Trent Partnership NHS Trust
Stockport Clinical Commissioning Group
Takeda UK Ltd
TB Action Group
Teva UK
The Association of the British Pharmaceutical Industry
The College & Fellowship of Podiatric Medicine
The Patients Association
The Practice Lincoln Green Medical Centre
The Rotherham NHS Foundation Trust
The University of Birmingham
UCB Pharma Ltd
University Hospital Birmingham NHS Foundation Trust
University of Nottingham
University of Southampton
Welsh Government
Western Sussex Hospitals NHS Trust
Wigan Borough Clinical Commissioning Group
Wirral GP Commissioning Consortium
York Hospitals NHS Foundation Trust

[i] Astellas Pharma Europe website, available at http://www.astellas.eu/therapy/urology/
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