National Institute for Health and Clinical Excellence

Developing and updating local formularies: Good practice guidance consultation 10 September – 8 October 2012

Good practice guidance consultation comments table

Ref No	Type	Stakeholder	Order No	Section No	Page No	Comments Please insert each new comment in a new row	Project team and GDG response Please respond to each comment
1	STH	MSD	1	General		MSD welcomes this draft guidance as a useful policy development to improve consistency in patient access to medicines across the NHS, building on the commitments most recently made in the report 'Innovation, Health and Wealth' This guidance provides a helpful reminder of the existing expectations for local formularies, especially around the statutory requirement that medicines positively appraised by NICE should be made available 90 days post-recommendation. It is very helpful to have these re-stated and clearly set out. This is especially important in a time of organisational change for local NHS; we would be interested to hear plans for how these principles will be disseminated throughout the NHS. We support that the guidance maintains the principle of local decision-making for	Thank you for your comment. No response required. Thank you for your comment. NICE Communications team and the Department of Health will work to ensure this guidance is disseminated throughout the NHS.

						formularies. The principle of deciding on the use of medicines is rightly a decision to be made at a local level reflecting local priorities. Too often we see unacceptable variations in practice and health outcomes through inappropriate decision-making processes around formularies, including for those medicines with a positive NICE appraisal. We also feel that the guidance could be further strengthened by focussing more on the access issues associated with medicines which do not undergo a NICE Technology Appraisal. This represents the majority of medicines used in the NHS and should be central to this guidance if it is to be effective at reducing variation.	Thank you for your comment. No response required. Thank you for your comment. The guidance covers the process and outlines explicit criteria for identifying, prioritising and selecting medicines for consideration, including medicines not subject to a NICE technology appraisal. See recommendation 2.5.4.
2	STH	MSD	2	1.2	4	The definition includes disinvestment. The guidance should make it clear that disinvestment decisions need to be handled appropriately to ensure that resources can be freed up where possible, but balancing that against the need to ensure appropriate access to medicines for patients.	Thank you for your comment. The GDG concluded that in circumstances where a medicine is not recommended in a NICE technology appraisal, discussions and actions on withdrawing and decommissioning a medicine should be considered in line with NICE recommendations. See recommendation 2.5.3.
3	STH	MSD	3	4.1.2	11	The guidance states "*there is a need to secure engagement and buy-in with all relevant clinicians"* on line 3 of this section. MSD feels that this wording should be more specific and include specialist clinicians within a Trust, as in some past instances these stakeholders have missed the opportunity to input into local guidance. We suggest the line could read as follows:" all relevant clinicians including local specialist clinicians from hospital trusts".	Thank you for your comment. This is covered within clinical groups and networks in recommendations 2.4.1, 2.13.1 and 2.16.2.

4	STH	MSD	4	4.8.2	15	The draft guidance states that: “Medicines with a positive NICE technology appraisal should be included in the local formulary automatically.” MSD suggests the addition of: “including details of NICE’s recommendation on the position of the medicine in the patients’ treatment pathway” at the end of this first sentence.	Thank you for your comment. The relevant recommendation has now been reworded. See recommendation 2.6.1.
5	STH	MSD	5	4.8.4	15	The draft guidance states that: “Where a NICE technology appraisal does not recommend a medicine, discussion and action should focus on decommissioning and withdrawing the use of the medicine as appropriate within local care pathway(s).” MSD suggests that instead it builds on the general approach in NICE TAs and states: ““Where a NICE technology appraisal does not recommend a medicine, discussion and action should allow the option for continued treatment for patients on the medicine until they and their clinicians consider it appropriate to stop”. For example: TA143 for ankylosing spondylitis does not recommend infliximab as a treatment option, but states “Patients currently receiving infliximab for the treatment of ankylosing spondylitis should have the option to continue therapy until they and their clinicians consider it appropriate to stop”.	Thank you for your comment. Please see response to comment 2.
6	STH	MSD	6	4.8.6	16	The guidance states that "updating or removal of healthcare treatments from the formulary is clear, robust and transparent". We suggest adding " All stakeholders including manufacturers of existing or new products should be informed of any update or removal from formulary"	Thank you for your comment. Manufacturers are included as stakeholders within recommendation 2.4.1. Section 4.14 on communication and dissemination emphasises the importance of communication with stakeholders and dissemination of formulary information. There is now a

							recommendation for local formulary decision-making groups to publish all relevant local formulary information online, in a clear, simple and transparent way, so that patients, the public and stakeholders can easily understand it. This includes formulary policies, minutes of meetings, decision outcomes and associated decision outputs (see 2.14.1).
7	STH	MSD	7	4.9.2	17	The guidance states that: 'where an NICE technology appraisal states 'option for treatment' the medicines should be adopted onto the local formulary and decision-making groups should assess its place in the local pathway". Where NICE comments on the position of a medicine in the treatment pathway, we would suggest that local formularies should be consistent with this.	Thank you for your comment. The NICE definition of the term 'option for treatment' has now been incorporated into the good practice guidance. See recommendation 2.6.2.
8	STH	MSD	8	4.10.1	17	MSD would suggest that the last bullet point "stakeholder views" be amended to read "the views of relevant stakeholders as set out in section 4.7.1".	Thank you for your comment. Wording was considered by the NICE editorial team.
9	STH	MSD	9	4.11.1	18	To add clarity to this point MSD suggests including NICE clinical guidelines as an example of nationally available evidence summaries. i.e. "*Local formulary groups should use nationally available evidence summaries (e.g. NICE clinical guidelines), ensuring…".*	Thank you for your comment. The GDG agreed that NICE clinical guidelines were an important source of high quality evidence for local decision-making. The recommendation has now been reworded. See recommendation 2.8.2.
10	STH	MSD	10	4.17	20	Whilst MSD endorses this point we feel that there should also be process for patients to feedback as this would be consistent with the innovation score card and the principles set out	Thank you for your comment. The recommendations have now been reworded. See recommendations 2.14.1 and 2.14.3

						in Innovation Health and Wealth.	
11	STH	MSD	11	4.18	21	MSD would suggest that this point needs expanding to include a process to escalate appeals above the local level and further clarity on how this would fit with the principles set out in Innovation Health & Wealth.	Thank you for your comment. Recommendations in section 4.15 outline the importance of establishing a formal appeals process for local formulary decisions. The GDG concluded that the guidance should outline the principles for reconsiderations and appeals, but the details should necessarily be for local consideration and determination.
12	STH	MSD	12	4.19.2	22	We would suggest that this point could be further strengthened by setting or suggesting a subsequent review date to signpost when guidance will be updated. Furthermore, a statement which caters for review of new medicines launched after the formulary has been issued should be included. We suggest the following wording could be included "formularies will need to be reviewed more regularly if a new medicines is available ".	Thank you for your comment. The GDG agreed that a review date is important, but concluded that the frequency of review should be considered and determined by local formulary decision-making groups. The proactive approach to the identification and consideration of newly marketed medicines (see recommendations 2.5.1, 2.5.4 and 2.16.1) should ensure that the current recommendations within a formulary are reviewed, rather than the new medicine alone.
13	STH	MSD	13	4.20	23	MSD feel it would be helpful if the flowchart acknowledged local decision making pathway such as IFR and CDF. MSD would suggest that the box indicating that a technology has not been subject to a NICE TA which currently states “No” be re-worded. We believe this gives a negative perception of these	Thank you for your comments. The flowchart is intended to summarise the local formulary process clearly and concisely, and does not consider the entirety of local arrangements. Some of these may vary in different localities. The flowchart has now been amended to reflect this comment.

						technologies and therefore suggest an alternative wording which could be: “Not subject to NICE TA”. It would be useful if the flowchart contained expected timelines for adopting positive recommendations on formulary and topic prioritisation.	The expected timeline for adopting a positive NICE technology appraisal is clear and unambiguous throughout the good practice guidance. Inclusion within the flowchart would add complexity when the aim of the flowchart is a concise summary.
14	STH	NHS Plymouth	1	general		Very little reference (apart for one comment about risk assessing in 4.1.1) to the safety and governance role of the DTC (or other relevant committees) especially when introducing a new treatments. We normally evaluate all injections according to the NPSA assessment and all unlicensed medicines are assessed for risk level. More recently we have specifically asked for assurances about NICE approved medicines (e.g. eye tests with fingolimod), and non NICE medicines (e.g. IV zoledronic acid and accidental co administration of oral bisphosphonates). My own view is that there should be a little more emphasis on the safe introduction of medicines in the final report.	Thank you for your comment. The GDG agreed that patient safety is an important consideration. This is referred to on a number of occasions in the guidance (see 4.7, 4.9, 4.15 and 4.16) with a specific recommendation to incorporate drug safety updates routinely (see recommendation 2.9.1).
15	STH	NHS Plymouth	2	4.19	22	4.19 page 22 mentions reviewing the formulary but makes no reference to removing any medicines, the document needs to broach and put equal emphasis on the ability to remove medicines which may no longer be the drug of choice. The guidance needs to help produce a streamlined, clinical and cost efficient formulary, not just an ever expanding formulary.	Thank you for your comment. The recommendation has been reworded to reflect this comment. See recommendation 2.16.1.

16	STH	NHS Plymouth	3	general		There is little help / guidance on affordability of some drugs in these times of financial hardship.	Thank you for your comment. Outside of the recommendation following a NICE technology appraisal, local decision-making groups should determine whether or not to include medicines within their formularies. Such considerations should be wider than simple affordability. See recommendations 2.5.4 and 2.7.1.
17	STH	NHS Plymouth	4	1.1	4	Expand on what statutory requirements re Local Decision Making and NICE	Thank you for your comment. The GDG agreed that the amount of context was appropriate for this guidance.
18	STH	NHS Plymouth	5	1.3	4	Providing clarity and expectations regarding individual clinicians responsibility within the care pathway.	Thank you for your comment. There are a number of recommendations regarding the responsibilities of individual clinicians. See recommendations 2.5.5, 2.5.7, 2.15.2 and 2.15.3
19	STH	NHS Plymouth	6	1.3	4	Add in 'Improving safety'. Link to Innovation Health & Wealth, support safe and clinically appropriate practice.	Thank you for your comment. The relevant text has been reworded. The points are not in order of importance.
20	STH	NHS Plymouth	7	1.3	5	Last point – patient factors, don't put this last put this first.	Thank you for your comment. Please see response to comment 19.
21	STH	NHS Plymouth	8	1.5	6	Include Local Decision Making and NHS Constitution	Thank you for your comment. Local decision-making and the NHS Constitution is already covered in this section.
22	STH	NHS Plymouth	9	4.1	10	Embedded in Care Pathway Redesign	Thank you for your comment. Pathways and their importance are reflected in sections 1.4, 4.1, 4.2, 4.6 and 4.13.
23	STH	NHS Plymouth	10	4.1.1	11	Needs to be explicit regarding place of CD cohort policies, cohorts should be included in formularies	Thank you for your comment. Unfortunately, the point of this comment is not clear.

24	STH	NHS Plymouth	11	4.1.1	11	Implementation	Thank you for your comment. Implementation is out of scope. Parallel work streams overseen by the Department of Health have been established to provide support to the NHS to implement this good practice guidance.
25	STH	NHS Plymouth	12	4.1.1	11	Negative TAGs included in the formulary	Thank you for your comment. In situations where a NICE technology appraisal does not recommend a medicine, see recommendation 2.5.3.
26	STH	NHS Plymouth	13	4.2	11	Joint Formularies should encompass the whole Care Pathway and not organisational boundaries.	Thank you for your comment. The GDG agreed that a formulary operating solely within one organisation is not likely to cover the whole care pathway. This is reflected in the guidance (see section 4.2). However, the scope of the local formulary should be agreed locally through consultation with all locally defined stakeholders (see recommendation 2.2.1).
27	STH	NHS Plymouth	14	4.2	11	Some Joint Formularies only include those drugs used both in primary and secondary care and have a separate formulary for those drugs used only in the hospital. Not necessarily appropriate given the drive to move care into community settings i.e. organisational boundaries may blur further as time moves on.	Thank you for your comment. See response to comment 26.
28	STH	NHS Plymouth	15	4.2.3	12	Extra recommendation, include all drugs across whole care pathway and not focussed on organisations.	Thank you for your comment. See response to comment 26.
29	STH	NHS Plymouth	16	4.5.2	13	Would be helpful to include more information regarding this re economies of scale vs. organisational ‘buy in’ and ownership.	Thank you for your comment. See response to comment 26 and section 4.2.
30	STH	NHS Plymouth	17	4.7	14	Extra bullet points: via care pathway redesign	Thank you for your comment. The list is

						and links with Map of Medicine	not intended to be exhaustive, and highlights a small number of the many examples that could be provided.
31	STH	NHS Plymouth	18	4.8.4	15	Standing item too as need to address variation as per Innovation Health & Wealth	Thank you for your comment. See recommendation 2.5.1.
32	STH	NHS Plymouth	19	4.8.6	16	Needs to be transparent if that is the case with appropriate declarations of interest	Thank you for your comment. See recommendations 2.5.5 and 2.5.7.
33	STH	NHS Plymouth	20	4.9.1	17	Add bit about appropriate governance being in place for safe effective delivery	Thank you for your comment. See recommendation 2.6.1.
34	STH	NHS Plymouth	21	4.11.1	18	Would be helpful to have a steer re. nationally available	Thank you for your comment. An appendix has been added to include examples of national and regional sources of evidence summaries and medicines information relevant to local formularies.
35	STH	Royal College of Physicians	1	General	General	The RCP is grateful for the opportunity to respond to the draft guidance consultation. We would like to make the following comments. We believe that the BNF is an excellent source of reference for prescribers but that it cannot act as a local formulary. At the heart of the consultation is the conflict between the perfectly legitimate aims of the DH which wants all NICE approved drugs to be commissioned and the authors of local formularies who wish to control/ rationalise the supply of drugs. Our experts believe that these aims can be reconciled if it is appreciated that there can be a difference between a list of drugs which PCTs/CCGs will pay for and of those recommended locally. We believe it eminently sensible that in an attempt to reduce errors, to optimise cost-effectiveness and to keep within the practicalities of pharmacy space that there be a limit to the number of	Thank you for your comment. Many of the points raised support the rationale for this good practice guidance and the purpose of local formularies as described in section 1.3. Directions issued by the Secretary of State for Health make it a statutory obligation for commissioners to make funding available within 3 months for medicines that have been recommended by a NICE technology appraisal, unless they are directed otherwise by the Secretary of State for Health. See section 4.6 and recommendations 2.6.1 and 2.6.2.

						drugs used in a local area - be that a hospital Trust or the local GP community. Doctors can only be expected to know the complexities of one or at most two drugs from a class and locally these should be the same drugs to avoid confusion. Thus it might be reasonable for a PCT/CCG to say that they will pay for any of the drugs from a given class but for the formulary to recommend one as first line and another as second. Any doctor wishing to deviate from this recommendation should be expected to justify why they are choosing a drug other than the first line pair. It should be noted that due to differences in local contracts and health priorities the drugs selected for first line use may differ from area to area.	
						Our experts consider it extremely important that the DH and NICE urgently consider some of the problems with NICE advice and not expect it in its present form to eradicate post code prescribing. We believe this work is necessary and preferable to an approach enforcing inclusion of all NICE drugs in local formularies.	Please refer to the response above.
						As an example, if we look at advice on statins for the primary prevention of CVD the guidance was to use a statin but to choose the cheapest. This was to avoid being caught out by changes in price when generic alternatives became available. However, local contracts might mean that in one area simvastatin is the drug advised first choice and in another area it is pravastatin. Thus the drugs in a local formulary might reasonably be different although all patients	Please refer to the response above.

						would have access to a statin. More importantly, NICE has approved a number of anti TNFs for use in rheumatoid arthritis and other inflammatory disorders each generally considered in a separate STA. Interpreting the present advice rigidly would suggest that all have to be on any local formulary. This of course would not be feasible and highlights one of the difficulties with STAs. A more subtle problem is illustrated by the recent FAD for denosumab where its use is approved for prostate and other solid tumours other than breast cancer to prevent bone metastases where a bisphosphonate would otherwise be used. Of course this means in areas where local guidelines suggest a bisphosphonate for these conditions denosumab would be commissioned but in areas where the local guidance and commissioning does not approve bisphosphonates in these conditions denosumab would not be used.	
36	STH	NHS Nottinghamshire County	1	General		It would be helpful to include examples of good practice throughout the document including documentation which could be adapted for local use.	Thank you for your comment. This is out of scope. See response to comment 24.
37	STH	NHS Nottinghamshire County	2	1.3	4	We would suggest that the word rapid is removed from the fourth point of potential benefits as we aren't aware that rapid access improves quality.	Thank you for your comment. This point has been reworded.
38	STH	NHS Nottinghamshire County	3	3.1	8	It is disappointing that the scope does not include processes relating to implementation of the formulary as this can be challenging.	Thank you for your comment. This is out of scope. See response to comment 24.
39	STH	NHS	4	4.7.1	14	We agree that strategies should include	Thank you for your comment. The

		Nottinghamshire County				engagement with the first 3 points in the list, however we don't think that engaging with manufacturers should come under this as we would consider this to be optional. The reason for this is that there is significant resource implications in terms of time to meet with manufacturers to gather information which is often already in the public domain.	GDG agreed that local strategies should include engagement with relevant manufacturers, but this should be proportionate to the type of decision being made and the medicine being considered. See recommendations 2.4.1 and 2.4.2.
40	STH	NHS Nottinghamshire County	5	4.8.2	15	This statement is qualified in section 4.9.2 but it would be useful to have this qualifier in the same section of the document for clarity.	Thank you for your comment. The recommendations are now consistently worded. See recommendations 2.6.1 and 2.6.2.
41	STH	NHS Nottinghamshire County	6	4.8.8	16	It would be useful to add details of consultation/consensus across the whole healthcare community to which the formulary applies to this list of information to be included in applications	Thank you for your comment. Local formulary decision-making groups should make appropriate arrangements, depending on the scope and geographical coverage of the formulary. See recommendations 2.2.1, 2.2.2 and 2.5.7.
42	STH	NHS Nottinghamshire County	7	4.8.8	16	It would be useful to have some guidance on best practice if a conflict of interest from a clinician making a submission is identified.	Thank you for your comment. The GDG agreed that this should be for local determination.
43	STH	Cambridge University Hospitals NHS FT	1	General		Overall this is a welcome document that will help overcome some of the barriers that have developed across health care settings in recent years. It offers opportunities that we have not considered locally and supports areas of good practice already in place. It provides clarity on a number of areas that cause delays in implementation currently.	Thank you for your comment. No further response required.
44	STH	Cambridge University Hospitals NHS FT	2	4.1.2.	11	Engagement with both primary and secondary care clinicians is welcomed. To include specialist nurses (and perhaps midwives) as well by name.	Thank you for your comment. Please see response to comment 3.
45	STH	Cambridge	3	4.4.1	13	To include clinicians from both primary and	Thank you for your comment. The

		University Hospitals NHS FT				secondary care as key stakeholders, especially as clinicians (GPs) will be playing a larger role in managing finances of their local health economy,	GDG agreed that membership of local formulary decision-making groups should include a locally-defined mix of members from partner organisations and key stakeholders.
46	STH	Cambridge University Hospitals NHS FT	4	4.8.8	16	A review of existing treatments in the pathway and removal of any obsolete medicines	Thank you for your comment. The recommendation has now been reworded to reflect this comment. See recommendation 2.5.7.
47	STH	Cambridge University Hospitals NHS FT	5	4.8.8	16	Agreement to review use and outcomes, both expected and unexpected, of an agreed new inclusion within a specified period	Thank you for your comment. Please see response to comment 41.
48	STH	Cambridge University Hospitals NHS FT	6	4.9.2	17	This comment is particularly welcomed to clarify. Adopting as per NICE leaves currently room for interpretation especially in term of where it would fit within a local treatment pathway.	Thank you for your comment. Please see response to comment 7.
49	STH	Cambridge University Hospitals NHS FT	7	4.10.1	17	Include to state if another medicine is to be removed from the formulary	Thank you for your comment. The guidance has now been reworded to reflect this comment. See recommendation 2.5.7.
50	STH	Cambridge University Hospitals NHS FT	8	4.11.1	18	Need to state sources of evidence used in the appraisal for the medicine	Thank you for your comment. Please see response to comment 34.
51	STH	Cambridge University Hospitals NHS FT	9	4.12.1	18/19	This is welcomed	Thank you for your comment. No response required.
52	STH	Cambridge University Hospitals NHS FT	10	4.13.3	19	This should be included in the Terms of Reference of the Formulary Committee	Thank you for your comment. The method by which final decisions are made is included within the terms of reference for the local formulary decision-making group. See recommendation 2.3.1

53	STH	Cambridge University Hospitals NHS FT	11	4.20	23	Is there an appeal mechanism in place to allow local formulary groups to appeal against a published TAG? For example: locally agreed not to adopt dronedarone based on risks exposed post publication of NICE. Do NICE itself review puclications following emergence of new evidence (as for dronedarone as above?)	Thank you for your comment. There is an appeals process for NICE technology appraisals.
54	STH	Greater Manchester Medicines Management Group	1	general	4	The definition of a local formulary makes sense in the context of it not being a national formulary however most will be produced by a group of commissioning, or providing organisations who have their individual management structures. The term “local” then becomes confusing when applied to local arrangements for implementation, performance management, governance arrangements, lines of accountability and reporting arrangements (4.3.2), local care pathways (4.8.4). Would ‘health economy’ be a more appropriate term? The clear definition of ‘formulary’ is a fundamental point in the understanding and implementation of the guidance. The guidance needs to clarify (or acknowledge) further that a formulary may be interpreted differently depending on the *‘local healthcare system, service or organisation’* that it is being applied to. In a hospital a formulary will be the entire list of what is stocked and can be prescribed by that organisation, therefore if products are not listed, they will not be available to prescribers. In a wider Health economy formulary, this is not enforceable, and may not be desirable. The ability to reduce variation for the majority of	Thank you for your comment. The GDG agreed that ‘health economy’ would be a more appropriate term and the guidance has been reworded to reflect this comment. Thank you for your comment. The GDG agreed that the definition of a local formulary is sufficiently broad to allow for local interpretation.

						prescribing is essential, but if this is to apply to 100% of prescribing, the product will add no further value over the BNF. A rational, clinically agreed approach to reducing inappropriate prescribing is just as important as ensuring that NICE and other nationally approved treatments are fairly available to all eligible patients. A formulary should be able to address both ends of this spectrum, in support of all principles of QIPP.	
55	STH	Greater Manchester Medicines Management Group	2	1.3	4	Formularies increase quality of prescribing, patient safety and facilitate innovation. Through evidence-based evaluation of the clinical data and supporting the implementation of cost-effective drug choices a formulary will increase local familiarisation with a core set of drugs which improves safety, reduces unnecessary or inappropriate variation in care and facilitates continuity of care.	Thank you for your comment. Please see response to comment 19.
56	STH	Greater Manchester Medicines Management Group	3	4.1.1	11	It may not be feasible for existing medicines related decision making groups in the local area and healthcare economies to be fully mapped and understood and kept up to date given the range of providers a particular CCG will contract from	Thank you for your comment. While the GDG acknowledge that this may be potentially complex, it would still constitute good practice.
57	STH	Greater Manchester Medicines Management Group	4	4.2	11	Formulary scope. It needs to be acknowledged within this guidance that the boundaries of health organisations that develop and adopt a formulary may need to accommodate a range of clinical care pathways. Providers of secondary and tertiary care may have disparate views on therapies / pathways.	Thank you for your comment. The guidance has been reworded. See section 4.2.
58	STH	Greater Manchester	5	4.2.3	12	There needs to be a published timeline for products being added and removed from the	Thank you for your comment. The GDG considered the important

		Medicines Management Group				formulary. Perhaps a “minded to remove” or “minded to include” period as well as an immediate removal process for drugs deemed to be unsafe / discontinued, based on defined criteria.	principle of regular review. See recommendation 2.16.1. The finer details of the process are for local determination, as they may be moderated by individual circumstances.
59	STH	Greater Manchester Medicines Management Group	6	4.5	13	Resourcing – It is important to stress the need to resource background activities for a formulary e.g. producing, promoting and maintaining the formulary. In particular resources for communication of formulary decisions, changes and electronic update of local formularies need to be considered.	Thank you for your comment. See recommendations 2.3.5 and 2.3.6.
60	STH	Greater Manchester Medicines Management Group	7	4.8.4	15	Often NICE HTAs that “do not recommend” a drug do not recommend that treatment should be withdrawn from existing patients. Is it the role of the formulary group to undertake this activity?	Thank you for your comment. Please see response to comment 2.
61	STH	Greater Manchester Medicines Management Group	8	4.9.1	17	Non-inclusion of a drug in a formulary does not necessarily equate to a NICE HTA approved drug not being available. NICE HTA may recommend a drug for a niche group of patients. These may not be covered by a formulary designed to cover 80% of all new patients.	Thank you for your comment. Recommendations 2.6.1 and 2.6.2 consider this point.
62	STH	Greater Manchester Medicines Management Group	9	4.9.2		Where a NICE TA states that a medicine is an option for treatment it may not be a first or second choice option so would not currently be included in the GM Formulary according to set criteria.	Thank you for your comment. See response to comment 7.
63	STH	NHS Hertfordshire and the clinical commissioning groups covering	1	1	4,5,6	The broad background and context in which this document has been produced is clear and in line with process followed locally.	Thank you for your comment. No response required.

		Hertfordshire population.					
64	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	2	3	8,9	The methodology used appears sound, bearing in mind the paucity of published evidence. It would be helpful to know, in an Appendix, the level of published information that was found. We would recommend that as a research issue, the guideline encourages that good practice, in line with recommendations, is published.	Thank you for your comment. The literature search is included in an appendix.
65	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	3	4.1,4.1.1	10-11	We agree with the recommendations. These are in line with the process followed by Hertfordshire in arriving at the current structure for decision-making across the Hertfordshire health economy area. As part of this process, mapping of current decision-making groups and clinical networks was undertaken. The county-wide committee is led by commissioners with membership from all provider stakeholders. The structure outlines the function of local provider committees and clinical networks and their relationship to the health economy-wide process. Implementation of NICE TAs is discussed with specialists and ratified through the health-economy wide group.	Thank you for your comment. No response required.
66	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	4	4.2.1	12	Agree. Suggest that you add to this section that local stakeholders need to be proactive in identifying the areas of interest for consideration via the formulary process. Otherwise, local decision-making groups will be spending time on areas of no interest to their stakeholders.	Thank you for your comment. Please see response to comment 24.
67	STH	NHS Hertfordshire	5	4.2.2	12	Agree. In Hertfordshire, we ensure duplication is avoided by scoping out what has been	Thank you for your comment. No response required.

		and the clinical commissioning groups covering Hertfordshire population.				produced by NICE, SMC, All Wales Group, London New Drugs Group, UKMI and by surrounding healthcare organisations. The NHS has always worked in this way and this is worth noting in the principles.	
68	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	6	4.2.3	12	We agree. We suggest that consideration is given to ensuring size of such groups versus obtaining engagement with front-line clinicians as stakeholders. Our experience shows that this is really important and varies from treatment to treatment.	Thank you for your comment. See response to comment 26.
69	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	7	4.3.1-4.3.3	12	Agree. Suggest that Terms of Reference outlines the full process for decision-making, including appeals process.	Thank you for your comment. The GDG agreed that the local formulary appeals process should be considered separately from the terms of reference of the group. See recommendation 2.15.4.
70	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	8	4.4.1	13	We agree with the recommendation in relation to membership of local decision making groups. Commissioners have to consider the needs of the patients and the impact on the rest of the population. Therefore, it would be helpful to get clearer direction in relation to “patient” involvement. If the patient with interest in treatment is included, how will a commissioner obtain the views of the rest of the population to ensure equity? We suggest that this section outlines how various stakeholders can be consulted without being members of a group.	Thank you for your comment. The GDG agreed that the recommendations should outline the principles for membership of the local formulary decision-making group, but the details of the process are necessarily for local consideration and determination.
71	STH	NHS	9	4.5.2	13	We agree about collaboration to ensure	Thank you for your comment. The

		Hertfordshire and the clinical commissioning groups covering Hertfordshire population.				consistency and sharing of workload and resources. As outlined in 4.2.2 above, the collaborative drug review activities are not duplicated. However, there is a need locally to translate these in formats easily understood by various stakeholders. We suggest that this section also highlights the need of size to reflect how stakeholder engagement is maintained.	recommendation has now been reworded to reflect this comment. See recommendation 2.3.6, and also 2.14.1. Thank you for your comment. Please see response to comment 26.
72	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	10	4.6.1-4.6.2	14	We agree with these recommendations.	Thank you for your comment. No response required.
73	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	11	4.7	14	We agree with the statement that engagement can be costly and time-consuming and therefore this needs to be balanced with timeliness of decision-making. Our experience suggests that it is vital to get this balance right to ensure that stakeholder engagement in process is retained. Resources needed to undertake timely engagement are significant and we suggest that this section makes a reference to this.	Thank you for your comment. This section has been reworded following further discussion by the GDG. See recommendations 2.4.1 and 2.4.2.
74	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	12	4.8.1	15	We agree with this statement. As outlined in 4.2.2 above, we believe that every effort should be made to reduce duplication of effort. The horizon scanning, undertaken by UKMI, is extremely valuable and used by all NHS organisations for local planning.	Thank you for your comment. No response required.
75	STH	NHS	13	4.8.2 –	15	We agree. However, we would like the principle	Thank you for your comment. This

		Hertfordshire and the clinical commissioning groups covering Hertfordshire population.		4.8.4		to clarify that such inclusion should be in line with criteria outlined in the technology appraisal. At the front-line, our experience has shown most providers do not read the NICE TA fully. See example of local practice at the end of these comments.	section has been reworded following further discussion by the GDG. See section 4.5.
76	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	14	4.8.5	15-16	We agree with the criteria and suggest that affordability and /or areas of disinvestment are included in this section. We believe that transparency should include the difficult choices commissioners have to make and the need for stakeholder engagement in making these difficult choices.	Thank you for your comment. Please see response to comment 16 and recommendations 2.2.2, 2.3.2, 2.4.1, 2.4.2, 2.7.1, 2.14.1 and 2.16.2.
77	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	15	4.8.6-4.8.8	16	We agree but again reiterate the need to include affordability and prioritisation of treatments and services.	Thank you for your comment. Please see response to comment 16.
78	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	16	4.9.1-4.9.2	17	We agree. Commissioners would find it very helpful, if NICE, as part of its appraisal consultation process, took account of the available resources to commissioners.	Thank you for your comment. This is outside the scope of this good practice guidance.
79	STH	NHS Hertfordshire and the clinical commissioning	17	4.10.1	17	We agree with the recommendation of the multi-criteria tool. Hertfordshire uses an Ethical Framework which includes the criteria suggested in this recommendation. We would	Thank you for your comment. The GDG concluded these would be included within 'local health priorities' assessments within a multi-criteria

		groups covering Hertfordshire population.				suggest that the needs of the population and needs of the community are also considered and this section outlines the principle of priority setting based on such criteria.	decision tool. See recommendation 2.7.1.
80	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	18	4.11.1-4.11.2	18	We agree with these recommendations.	Thank you for your comment. No response required.
81	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	19	4.12.1	18-18	We agree that close working with finance and commissioners is required to ensure that the whole health system costs are considered along-side new technologies. This is what we aim to do in Hertfordshire. We would suggest that the principle here also includes consideration of safety because long-term safety with medicines is only apparent over time. If clinical pathways are changed as part of innovation, patient care may suffer if such innovations are withdrawn.	Thank you for your comment. Please see response to comment 14.
82	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	20	4.13.1-4.13.3	19	We agree with all these recommendations.	Thank you for your comment. No response required.
83	STH	NHS Hertfordshire and the clinical commissioning	21	4.14.1	19-20	We agree with this recommendation	Thank you for your comment. No response required.

		groups covering Hertfordshire population.					
84	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	22	4.15.1	20	We agree with this recommendation.	Thank you for your comment. No response required.
85	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	23	4.16.1	20	We agree with this recommendation	Thank you for your comment. No response required.
86	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	24	4.17.1-4.17.13	21	We agree with this recommendation. In section 4.17.2, you state “communication uses clear language and in an appropriate format”. Can it be clarified whether this “clear language” is meant for professionals” OR do you mean members of the public.	Thank you for your comment. The section has been reworded. Please see recommendation 2.14.1.
87	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire	25	4.18.1-4.18.2	21-22	We agree with 4.18.1 and this is line with our process. With respect to 4.18.2, the implications on NHS resources must be considered. Setting up independent panels is difficult and costly. Independent panels can only review process followed, not outputs.	Thank you for your comment. These recommendations have been reworded following further discussion by the GDG. Please see recommendations 2.15.1 – 2.15.6.

		population.					
88	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	26	4.19	22	We agree with the recommendations. The resource implications must be outlined in this section. As the type and variety of evidence is vast, we would find it extremely helpful if this section also makes recommendations regarding the responsibility of interested clinicians to apply to decision-making groups when new evidence is published. Local Decision making can only be efficient if clinicians collaborate and contribute to the workplan of such groups.	Thank you for your comment. No response required.
89	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	27	General		It would be helpful to clarify who these principles apply to. We would suggest that the document clarifies that such principles apply to all bodies making decisions e.g. National Commission Board policy making as well as any private organisations involved in NHS services and clinical commissioning groups.	Thank you for your comment. The purpose and scope of the guidance is stated in section 1.
90	STH	NHS Hertfordshire and the clinical commissioning groups covering Hertfordshire population.	28	General		We agree that local formularies should include treatments approved by NICE technology appraisals. Our process for implementing NICE Technology appraisal **is outlined below**. We seek clarification on NICE's responsiveness to updating their technology appraisals and ensuring that these are reviewed in a timely manner or when factors, that influence the recommendations, change. The dilemma faced by commissioners is that NICE TAs approval process is reactive to submission from PHARMA companies and DH prioritisation. Therefore, TAs are not always reviewed in a timely fashion. This creates	Thank you for your comment. The NICE review process for technology appraisals is outside the scope of this good practice guidance.

						tension between clinicians and commissioners, especially when the latter consider a TA is no longer applicable. An example of this is NICE TA 162, Erlotinib for Lung Cancer (non-small cell) where NICE States: "1.1 Erlotinib is recommended, within its licensed indication, as an alternative to docetaxel as a second-line treatment option for patients with non-small-cell lung cancer (NSCLC) only **on the basis that it is provided by the manufacturer at an overall treatment cost (including administration, adverse events and monitoring costs) equal to that of docetaxel".** Docetaxel is now off-patent and the whole pathway is considerably cheaper than using Erlotinib.	
91	STH	Coastal West Sussex Clinical Commissioning Group	1	4.1.2	11	This section refers to both organisations and individual professional groups involved. At times this happens in the same sentence. The two concepts could be separated and be explicitly defined. There should be separate lists of possible clinicians and organisations.	Thank you for your comment. The GDG concluded that it was not appropriate to have definitive lists of possible clinicians and organisations. These will be for local determination.
92	STH	Coastal West Sussex Clinical Commissioning Group	2	4.8.3	15	The MHRA DSU may be beyond the scope of a formulary. Often this relates to an individual patient/prescriber decision and may not be appropriate in a wider formulary context surrounding medicines choice. It may form part of the decision making process but not necessarily be incorporated as a separate entity.	Thank you for your comment. The GDG concluded that this is an important consideration for local formulary decision-making groups.
93	STH	Coastal West Sussex Clinical Commissioning Group	3	4.8.2	15	There should be a mechanism in place for review of NICE TAG or CG formulary inclusion where there is a significant change in the evidence base or safety concern. Recent examples of this include dronedarone and Omacor.	Thank you for your comment. The recommendation has been reworded following further discussion by the GDG. See recommendation 2.16.1.

94	STH	Coastal West Sussex Clinical Commissioning Group	4	4.8.6	16	'Applications should be submitted by a clinician, although manufacturers may support evidence gathering'. On the whole this should be an independent NHS led process – thus this should only occur where the pharmaceutical industry can add value and not occur due to lack of resource/support internally within the organisation.	Thank you for your comment. The GDG concluded that the recommendations within this section reflect good practice. Recommendation 2.5.5 states that the reactive applications should be submitted by a clinician.
95	STH	Coastal West Sussex Clinical Commissioning Group	5	4.9.2	17	'Where a NICE technology appraisal states 'option for treatment' the medicine should be adopted onto the local formulary and decision-making groups should assess its place in the local pathway'. Would placing a drug 2nd line in a pathway not constitute a barrier to Innovation, Health and Wealth requirements?	Thank you for your comment. The NICE definition of the term 'option for treatment' is incorporated into the good practice guidance. See section 4.6 and recommendation 2.6.2.
96	STH	Coastal West Sussex Clinical Commissioning Group	6	4.10.1	17	Affordability should be included as a distinct criteria	Thank you for your comment. Please see response to comment 16.
97	STH	Coastal West Sussex Clinical Commissioning Group	7	General	General	Clear guidance should be given as to whether formularies should be mandatory or advisory in terms of commissioning medicines.	Thank you for your comment. Please see section 4.6 and recommendations 2.6.1 and 2.6.2.
98	STH	UK Medicines Information	1	1		We agree with the broad background section as presented and the interpretation of the context in which this document has been produced.	Thank you for your comment. No response required.
99	STH	UK Medicines Information	2	3		We are reasonably happy with the methodology used to develop this document. It is perhaps not surprising that there is a limited published evidence base in this area as it is not an area in which publication would often be pursued. The gap analysis approach, call for submissions from	Thank you for your comment. No response required.

						the NHS, and subsequent review by the GDG seems a reasonable compromise, however. One thing which might be worth discussing is whether there is a critical organisational capacity for which the presence of a formulary is necessary. In the context of the current NHS reforms it is not clear, for example, where formulary responsibilities will sit; varying arrangements are emerging with pursuing some aggregated formulary functions seemingly a sensible solution in some geographies. It would be really useful to know, however, whether there is research describing ideal types.	Thank you for your comment. The GDG agreed that a formulary operating solely within one organisation is not likely to cover the whole care pathway. This is reflected in the guidance (see section 4.2). However, the scope of the local formulary should be agreed locally through consultation with all locally defined stakeholders (see recommendation 2.2.1).
100	STH	UK Medicines Information	3	4.1-4.1.1	11	We agree with the recommendations in relation to mapping and understanding the function of existing medicines related decision groups when designing and reviewing existing arrangements. You might also add that such a process should also be mindful of collaborative support arrangements that reduce duplication of effort, for example through local new medicines review groups, such as London New Drugs Group, as well as nationally through UKMi and medicines information services. Such support, although non-decision making, has the potential to significantly reduce duplication of effort across formulary processes.	Thank you for your comment. Please see response to comment 34.
101	STH	UK Medicines Information	4	4.2.1-4.2.3	12	We agree with the recommendations in relation to formulary scope. For point 4.2.2, you might also add that duplication of effort can be prevented through reference to support work carried across geographies by a variety of non-	Thank you for your comment. The recommendations have been reworded after further discussion by the GDG See recommendations 2.1.2, 2.2.1 and 2.2.2.

						decision making providers of such.	
102	STH	UK Medicines Information	5	4.3.1-4.3.3	12	We agree with the recommendations in relation to terms of reference. We wonder though whether mechanisms to handle appeals should also be included here? You mention appeals processes in some detail in section 4.18 so it would seem to make sense to tie these themes together.	Thank you for your comment. Please see response to comment 69.
103	STH	UK Medicines Information	6	4.4	13	With agree with the recommendations in relation to membership of local decision making groups. Given the broad nature of the groups being considered, providing specific detail on the exact nature of the professionals who sit on such is probably not appropriate. We wonder though, in line with the principle of "no decision about me, without me" whether clearer direction in relation to patient involvement should be given. We are not sure currently whether such involvement is a definite recommendation or not – this may need some clarification? It is undoubtedly the case that currently patient involvement in such processes is inconsistent but conversely it is important to avoid tokenism; some guiding principles as to what constitutes a reasonable level of patient involvement would be welcomed I think.	Thank you for your comment. The GDG concluded that it was appropriate to outline the principles for membership of the local formulary decision-making group, but the details should remain for local consideration and determination.
104	STH	UK Medicines Information	7	4.5.1-4.5.2	13	We agree with the recommendations. Again, however, we feel it would be worth highlighting the potential role of collaborative drug review activities, which whilst not necessarily decision making can provide technical, analytical, and	Thank you for your comment. Please see response to comment 34 and recommendation 2.8.2.

						financial expertise at scale thus ensuring efficient processes are in place. Such approaches will have a significant impact in reducing duplication of effort and helping tackle resource issues. In this section you may also wish to highlight that some technical and analytical expertise should be present or available which enables interrogation of health economic arguments. In sections 4.10.1 and 4.12 you mention a need to be able to assess cost-effectiveness, and it would seem that such should also be covered here as a potential consideration in relation to resource.	Thank you for your comment. The use of the local decision-making competency framework addresses this. See recommendation 2.3.3.
105	STH	UK Medicines Information	8	4.6.1-4.6.2	14	We agree with the recommendations.	Thank you for your comment. No response required.
106	STH	UK Medicines Information	9	4.7.1	14	We agree with the recommendations.	Thank you for your comment. No response required.
107	STH	UK Medicines Information	10	4.8.1-4.8.5	15	We agree with the recommendations. In particular we agree with recommendation 4.8.1 and would like to highlight the suite of horizon scanning and forward planning resources produced nationally by UKMi to reduce duplication of effort. It may perhaps help to include an appendix of the various resources available since those can significantly help formulary processes. You may wish to include mention of Prescribing Outlook publications and the New Drugs Online database. These products provide advanced notification both related to the impact of individual new	Thank you for your comment. No response required. Thank you for your comment. Please see response to comment 34.

						medicines, and in relation to the likely impact of new guidance on prescribing budgets. UKMi would be happy to provide further detail on these products as necessary.	
108	STH	UK Medicines Information	11	4.8.6-4.8.8	16	We agree with the recommendations.	Thank you for your comment. No response required.
109	STH	UK Medicines Information	12	4.9	16-17	We agree with the recommendations. In particular, the definition of "option for treatment" is reasonably consistent with our understanding of practice in this area. In determining how the phrase "option for treatment" is applied in practice, we note the current NICE definition which suggests that option refers to such at the point of care. However, perhaps it should be noted that inclusion as an option does not then necessarily affect update. Uptake will be affected by a range of factors including the extent to which disease prevalence in trials reflects the reality; clinician and patient preferences in the context of shared decision making; and whether clinicians feel it necessary to establish local pathways and guidelines reflective of the needs of their populations. We wonder whether perhaps some of these slightly more nuanced arguments in relation to adoption and uptake should be presented in the document? We also wonder in this section whether it might be possible to give some preliminary advice on what an organisation might need to think about in order to ensure compliance with NICE Quality Standards, particularly where those relate to the use of medicines.	Thank you for your comment. Please see response to comment 7 and recommendation 2.6.2. This guidance does not include processes relating to implementation and performance management of local formularies. This is out of scope. The recommendation has been reworded to specifically recommend the use of NICE clinical guidelines, and other sources of high quality information, where no NICE technology appraisal is available. See

							recommendation 2.8.2.
110	STH	UK Medicines Information	13	4.10.1	17	We agree with the recommendations. However, the elephant in the room perhaps for some formulary requests will be affordability and the commissioning view on such. It is probably not appropriate to make such arguments in this guideline though, given the generally implicit nature of priority setting in that regard.	Thank you for your comment. Please see response to comment 16.
111	STH	UK Medicines Information	14	4.11.1-4.11.3	18	We agree with the recommendations. For 4.11.1, you may also wish to highlight that in addition to nationally available reviews more regionally constituted groups also reduce duplication of effort by providing evidence summaries. For points 4.11.2 and 4.11.3, you may wish to highlight the role regional medicines information services can play in ensuring and supporting appropriate local evidence synthesis.	Thank you for your comment. The recommendations have been reworded to reflect this point explicitly. See recommendation 2.8.2.
112	STH	UK Medicines Information	15	4.12.1	18	We agree with this recommendation.	Thank you for your comment. No response required.
113	STH	UK Medicines Information	16	4.13.1-4.13.3	19	We agree with the recommendations.	Thank you for your comment. No response required.
114	STH	UK Medicines Information	17	4.14.1	19	We agree with this recommendation.	Thank you for your comment. No response required.
115	STH	UK Medicines Information	18	4.15.1	20	We agree with this recommendation.	Thank you for your comment. No response required.
116	STH	UK Medicines Information	19	4.16.1	20	We agree with this recommendation.	Thank you for your comment. No response required.
117	STH	UK Medicines Information	20	4.17.1-4.17.3	21	We agree with the recommendations.	Thank you for your comment. No response required.
118	STH	UK Medicines Information	21	4.18.1	21	We agree with the recommendations. We wonder, however, whether reference should be made to processes that should be followed where appeals remain unsuccessful. Perhaps it	Thank you for your comment. The GDG concluded that a formal appeals process should generally be reserved for circumstances where local

						is worth re-visiting some of the recommendations from Professor Mike Richards' 2008 report on improving access to medicines? At least some cross reference to that might be useful.	formulary processes may not have been followed. See section 4.15.
119	STH	UK Medicines Information	22	4.19	22	We agree with the recommendations.	Thank you for your comment. No response required.
120	STH	Royal Pharmaceutical Society	1	1	4,5,6	We agree with the broad background section as presented and the interpretation of the context in which this document has been produced.	Thank you for your comment. No response required.
121	STH	Royal Pharmaceutical Society	2	3	8,9	We are reasonably happy with the methodology used to develop this document. It is perhaps not surprising that there is a limited published evidence base in this area as it is not an area in which publication would often be pursued. However, the gap analysis approach, call for submissions from the NHS, and subsequent review by the GDG seems a reasonable compromise.	Thank you for your comment. No response required.
122	STH	Royal Pharmaceutical Society	3	4.1-4.1.1	11	We agree with the recommendations in relation to mapping and understanding the function of existing medicines related decision groups when designing and reviewing existing arrangements. This is an opportunity to streamline decision making but it does rather sound as though even more committees might be formed to consider formulary development rather than rationalising. You might also add that such a process should also be mindful of collaborative support arrangements that reduce duplication of effort, for example through local new medicines review	Thank you for your comment. This section has been reworded following further discussion by the GDG. Please see response to comment 34.

						groups, such as London New Drugs Group, as well as nationally through UKMi and medicines information services. Such support, although non-decision making, has the potential to significantly reduce duplication of effort across formulary processes.	
123	STH	Royal Pharmaceutical Society	4	4.2.1-4.2.3	12	We agree with the recommendations in relation to formulary scope. For point 4.2.2, you might also add that duplication of effort can be prevented through reference to support work carried across geographies by a variety of non-decision making providers of such (see our comments above).	Thank you for your comment. Please see response to comment 101.
124	STH	Royal Pharmaceutical Society	5	4.3.1-4.3.3	12	We agree with the recommendations in relation to terms of reference. We wonder though whether mechanisms to handle appeals should also be included here? You mention appeals processes in some detail in section 4.18 so it would seem to make sense to tie these themes together.	Thank you for your comment. Please see response to comment 102.
125	STH	Royal Pharmaceutical Society	6	4.4	13	With agree with the recommendations in relation to membership of local decision making groups. Given the broad nature of the groups being considered, providing specific detail on the exact nature of the professionals who sit on such is probably not appropriate. We wonder though, in line with the principle of "no decision about me, without me" whether clearer direction in relation to patient involvement should be given. We are not sure currently whether such involvement is a definite	Thank you for your comment. Please see response to comment 103.

						recommendation or not – this may need some clarification? It is undoubtedly the case that currently patient involvement in such processes is inconsistent but conversely it is important to avoid tokenism; some guiding principles as to what constitutes a reasonable level of patient involvement would be welcomed.	
126	STH	Royal Pharmaceutical Society	7	4.5.1-4.5.2	13	We agree with the recommendations. Again, however, we feel it would be worth highlighting the potential role of collaborative drug review activities, which whilst not necessarily decision making can provide technical, analytical, and financial expertise at scale thus ensuring efficient processes are in place. Such approaches will have a significant impact in reducing duplication of effort and helping tackle resource issues. In this section you may also wish to highlight that some technical and analytical expertise should be present or available which enables interrogation of health economic arguments. In sections 4.10.1 and 4.12 you mention a need to be able to assess cost-effectiveness, and it would seem that such should also be covered here as a potential consideration in relation to resource.	Thank you for your comment. Please see response to comment 104. Thank you for your comment. Please see response to comment 104.
127	STH	Royal Pharmaceutical Society	8	4.6.1-4.6.2	14	We agree with the recommendations.	Thank you for your comment. No response required.
128	STH	Royal Pharmaceutical Society	9	4.7.1	14	We agree with the recommendations.	Thank you for your comment. No response required.

129	STH	Royal Pharmaceutical Society	10	4.8.1-4.8.5	15	We agree with the recommendations. In particular we agree with recommendation 4.8.1 and would like to highlight the suite of horizon scanning and forward planning resources produced nationally by UKMi to reduce duplication of effort. It may perhaps help to include an appendix of the various resources available since those can significantly help formulary processes. You may wish to include mention of Prescribing Outlook publications and the New Drugs Online database. These products provide advanced notification both related to the impact of individual new medicines, and in relation to the likely impact of new guidance on prescribing budgets. UKMi would be happy to provide further detail on these products as necessary.	Thank you for your comment. Please see response to comment 107.
130	STH	Royal Pharmaceutical Society	11	4.8.6-4.8.8	16	We agree with the recommendations.	Thank you for your comment. No response required.
131	STH	Royal Pharmaceutical Society	12	4.9.1-4.9.2	17	We agree that NICE approved medicines should be included in local formularies. However, a number of medicines approved by NICE become extra therapy choices that are available to clinicians and local clinicians then rely on local guidelines in regards to their place in treatment respective to other therapies. Therefore, even medicines that are in local formularies perhaps do not get the uptake expected. Uptake is dependent on patient and clinician choice. NICE implementation is by shared decision making between the patient and the clinician so it is essential that shared decision aids form part of	Thank you for your comment. Please see response to comment 7 This guidance does not include processes relating to implementation and performance management of local formularies. This is out of scope.

						this process in order for informed decisions to be made at patient level i.e.in other words the 'Formulary Committee' needs to agree what drugs will be available for a patient cohort, but the process for individual decision making also needs to be clearly available. Predicting uptake of a medicine approved by NICE based on the prevalence or incidence of a disease or condition to be treated given the outcome of trials fails to take account of: • Existing treatment working to the satisfaction of the patient / clinician • Trials generally exclude patients with multiple pathology so the applicability to general population is not the same • Patient will make choices based on benefit vs risk and do not always choose what we, as clinicians, may think they will • Clinicians are generally conservative with new treatments that don't appear to add any 'significant' value above treatments already available	
132	STH	Royal Pharmaceutical Society	13	4.10.1	17	We agree with the recommendations. However, the elephant in the room perhaps for some formulary requests will be affordability and the commissioning view on such. It is probably not appropriate to make such arguments in this guideline though, given the generally implicit nature of priority setting in that regard.	Thank you for your comment. Please see response to comment 110.
133	STH	Royal Pharmaceutica	14	4.11.1-4.11.3	18	We agree with the recommendations. For 4.11.1, you may also wish to highlight that in	Thank you for your comment. Please see response to comment 111.

		l Society				addition to nationally available reviews more regionally constituted groups also reduce duplication of effort by providing evidence summaries. For points 4.11.2 and 4.11.3, you may wish to highlight the role regional medicines information services can play in ensuring and supporting appropriate local evidence synthesis.	
134	STH	Royal Pharmaceutical Society	15	4.12.1	18	We agree with this recommendation.	Thank you for your comment. No response required.
135	STH	Royal Pharmaceutical Society	16	4.13.1-4.13.3	19	We agree with the recommendations.	Thank you for your comment. No response required.
136	STH	Royal Pharmaceutical Society	17	4.14.1	19	We agree with this recommendation.	Thank you for your comment. No response required.
137	STH	Royal Pharmaceutical Society	18	4.15.1	20	We agree with this recommendation.	Thank you for your comment. No response required.
138	STH	Royal Pharmaceutical Society	19	4.16.1	20	We agree with this recommendation.	Thank you for your comment. No response required.
139	STH	Royal Pharmaceutical Society	20	4.17.1-4.17.3	21	Section 4.17.3.states that 'Communications should include any associated policies. ...Communications should be electronic to support easy access, public availability and version control of documents.' Could NICE clarify what communications these are i.e. is this referring to the formulary itself and / or other information.	Thank you for your comment. The recommendations have been reworded. See recommendations 2.14.1 and 2.14.3.
140	STH	Royal Pharmaceutical Society	21	4.18.1	21	We agree with the recommendations. We wonder, however, whether reference should be made to processes that should be followed	Thank you for your comment. Please see response to comment 118.

						where appeals remain unsuccessful. Perhaps it is worth re-visiting some of the recommendations from Professor Mike Richards' 2008 report on improving access to medicines? At least some cross reference to that might be useful.	
141	STH	Royal Pharmaceutical Society	22	4.19	22	We agree with the recommendations.	Thank you for your comment. No response required.
142	STH	Royal Pharmaceutical Society	23	General		We have some concerns how local formularies will fit into the emerging NHS structures and exactly how local they will be. Within the new NHS structures the individual commissioning organisations are much smaller so guidance on working together and aggregated working on local formularies should be recommended.We believe that there should be some acknowledgement that there are tensions about the configuration of a 'Formulary Committee' and the area that it covers. Different models exist, none of which are perfect, particularly for providers who treat a population from a number of different commissioners. Traditionally much of this was provider led, but increasingly will form part of Commissioning Intentions	Thank you for your comment. This is reflected in recommendations 2.1.1, 2.2.1 and 2.3.6. The guidance does not define an optimum population size or number of provider organisations involved in developing and updating local formularies. The recommendations for practice allow organisations to balance the risks and benefits of different models locally.
143	STH	Royal Pharmaceutical Society	24	General		NICE are also currently producing a range of guidelines and standards, and although these are not binding in the same way as the implementation of the NICE Technology Appraisals, they will underpin the NHS Outcomes Framework. It would be useful to have clarity as to how all NICE publications fit into the new NHS systems.	Thank you for your comment. See response to comment 9.

144	STH	Royal Pharmaceutical Society	25	General		This draft good practice guidance does not make it clear as to what specifically is required to be published, the local formulary itself or the information that sets out which NICE Technology Appraisals should be included. This needs to be clarified.	Thank you for your comment. Please see section 4.14 and recommendations 2.14.1 and 2.14.2.
145	STH	Royal Pharmaceutical Society	26	General		It would be helpful if NICE could specify if there is a standard format the publication should be available in as well as the frequency of updates required.	Thank you for your comment. This is outside the scope of this guidance.
146	STH	Royal Pharmaceutical Society	27	General		In order for formularies to be effective for the patient they need to be common to all health care providers serving the same patient population. This minimises confusion and errors and eases transfer of care. We believe that this approach of joint partnership and patient focus needs to be strengthened in this guidance document.	Thank you for your comment. The GDG agree that a formulary operating solely within one organisation is not likely to cover the whole care pathway (see section 4.2). However, the scope of the local formulary should be agreed locally through consultation with all locally defined stakeholders (see recommendation 2.2.1). The guidance does not define an optimum population size or number of provider organisations involved in developing and updating local formularies. The recommendations for practice allow organisations to balance the risks and benefits of different models locally.
147	STH	Royal Cornwall Hospitals NHS Trust	1	1.3	4	It would be useful to have some description of the evidence base for why formularies are deemed to be a good idea.	The GDG reviewed the evidence and concluded that local formularies have a number of important benefits. See section 1.4.
148	STH	Royal Cornwall	2	4.5	13	Resourcing for how decisions are communicated, including to the public, and how	Thank you for your comment. Please see section 4.14 on communication.

		Hospitals NHS Trust				websites are updated is critical in this digital age. I'm not sure that this has previously been well factored in to how organisations work. In addition, although we believe we have very thorough, solid systems for considering formulary applications, 'formulary advice' also extends to the sorts of things that go into email communications to GPs eg use caps-not-tabs of drug X, use-the-branded-generic of drug Y. We may make these decisions in response to drug tariff changes but they are 'formulary' decisions of a sort, and if we have fast-moving, digital means of communicating the formulary then we need to have formal systems (and resources) for those decisions too.	
149	STH	Royal Cornwall Hospitals NHS Trust	3	4.6.2	14	Is there an example of good practice around accountability for local formulary decision making groups? That is, report to Commissioners and/or provider trust and/or other involved organisations eg mental health trust, community health services. Who should have ultimate responsibility for the group?	Thank you for your comment. See response to comment 24.
150	STH	Royal Cornwall Hospitals NHS Trust	4	4.7	14	Further advice on practical and pragmatic ways of gaining engagement from the public / patient groups would be helpful. This has always been a challenge especially for smaller healthcare communities. How deep and broad should this engagement be?	Thank you for your comment. See response to comment 24.
151	STH	Royal Cornwall Hospitals NHS Trust	5	4.8	15	In order to incorporate NICE TAGs into formularies in planned way, health communities need to be horizon scanning the NICE website and having discussions about pathway redesign, place in therapy of future NICE TAGs. This needs to be emphasised to avoid consideration	Thank you for your comment. See recommendations 2.5.1 and 2.5.2.

						of a NICE TAG only commencing on the day of final publication.	
152	STH	Royal Cornwall Hospitals NHS Trust	6	4.9	17	Uncertain of the benefit of including in a formulary a drug that has a NICE TAG status as 'an option' for treatment if no clinician wishes to use that option. The formulary entry would be redundant – why include it?	Thank you for your comment. Directions issued by the Secretary of State for Health make it a statutory obligation for commissioners to make funding available within 3 months for medicines that have been recommended by a NICE technology appraisal, unless they are directed otherwise by the Secretary of State for Health.
153	STH	Royal Cornwall Hospitals NHS Trust	7	4.9	17	Clarity over the status of drugs that are mentioned in Clinical Guidelines is required. With the link between CGs and NICE Quality Standards (and monitoring of such standards), is the expectation these drugs should be used in local health communities?	Thank you for your comment. Please see response to comment 9.
154	STH	Royal Cornwall Hospitals NHS Trust	8	4.9	17	What are the levers for getting GPs to recognise the NICE TAG imperative?	Thank you for your comment. See response to comment 24.
155	STH	Royal Cornwall Hospitals NHS Trust	9	4.12	18	When assessing financial and commissioning impact, should the process include attention given to programme budgeting information?	Thank you for your comment. This is outside the scope of this guidance.
156	STH	Royal Cornwall Hospitals NHS Trust	10	4.12	18	Decision making groups should also consider, when adding a new drug to the formulary, are there any opportunities to disinvest and if so how can this be undertaken safely and in a structured way?	Thank you for your comment. See recommendations 2.5.7 and 2.16.1.
157	STH	Royal Cornwall Hospitals NHS Trust	11	4.19	22	Yes having a review and updating process is important. Does NICE itself have such a process? Eg TAG on dronedarone and safety concerns that came to light after TAG	Thank you for your comment. See response to comment 90.

						publication as a recent example – when will this feed into the NICE recommendation?	
158	STH	Royal Cornwall Hospitals NHS Trust	12			We try to obtain feedback or a view from the requesting Consultant on whether the drug they applied for and which was agreed has delivered the claimed benefits. This request usually occurs about 9-12 months after agreeing the drug, and we try to track drug uptake in primary and secondary care as well. Some of the 'audit' responses we receive are helpful and well considered, others tend to be of an anecdotal nature. We see this as work in progress but the idea of trying to ascertain whether the drug was worth agreeing in the first instance could be part of your guidance for decision making groups.	Thank you for your comment. See response to comment 24.
159	STH	UCB Pharma Company Limited	1	General		As members of the ABPI and the European Medicines Group we would like to support the submissions from these organisations and also make some additional general and specific comments (below).	Thank you for your comment. No response required.
160	STH	UCB Pharma Company Limited	2	General		We would like to support the implementation of the guidance as a positive contribution towards the uptake of innovative medicines which would help to reduce variation of healthcare. If implemented it may enhance the relationship with the pharmaceutical industry and represents an opportunity to provide further guidance to all parties in pursuit of a productive relationship.	Thank you for your comment. No response required.
161	STH	UCB Pharma Company Limited	3	1.1	4	This section states that the guidance does not intend to provide information on the implementation or performance management of local formularies. This does create the risk that in the current environment nothing will therefore change. The document would be enhanced by	Thank you for your comment. Please see response to comment 24.

						including clear expectations for implementation and performance management.	
162	STH	UCB Pharma Company Limited	3	4.3.3	12	Proposals for standards of governance, e.g. terms of reference, would make these bodies more transparent and raise the standards of conduct which as the report points out are variable currently, at best. Terms of reference should also include expectations on the communication of formulary decisions, the reason behind the decision, and the format and place of publication, emphasising that the communication should be in the public domain.	Thank you for your comment. Section 4.14 covers these points. Please see recommendations 2.12.1 and 2.14.1.
163	STH	UCB Pharma Company Limited	4	4.7.1	14	We would support the consistent development of opportunities for manufacturers to engage with the formulary process and to have the ability to present appropriate or new information.	Thank you for your comment. Please see recommendations 2.4.1 and 2.5.5 and appendix C.
164	STH	UCB Pharma Company Limited	5	4.12	18	This section could provide much more emphasis, clarification and guidance on the value of medicines beyond consideration of the acquisition cost. A strong link with the QIPP programme could reinforce the need for medicines to be considered in the context of the whole patient pathway and the value of identifying potential cost savings downstream, highlighting that drug costs may actually increase but with the benefit that overall costs may reduce. This links with point 5, below, in that a more productive relationship with manufacturers, stressing a desire to work in partnership for the benefit of improved patient outcomes at reduced cost.	Thank you for your comment. See section 4.10.
165	STH	UCB Pharma	6	4.17.2	21	Publication of formulary decisions would	Thank you for your comment. See

		Company Limited				enhance transparency for both patients and manufacturers and against the growing tendency to keep these decisions private. The wording in the current consultation does not make explicit whether the decision and the rationale for the decision should be made publicly available. This would enhance transparency. There is no justification why either formulary committees workings or decisions made should be treated as a Part II item.	section 4.14.
166	STH	Royal College of Nursing	1	General	General	The Royal College of Nursing welcomes proposals to develop this good practice guidance. It is timely. The document seems comprehensive.	Thank you for your comment. No response required.
167	STH	Pfizer Ltd	1	General		We welcome the opportunity to comment on this important first draft of the NICE Good Practice Guidance for the development and updating of Local Formularies. **Innovation, Health and Wealth: Accelerating Adoption and Diffusion in the NHS (IHW)** One of the key recommendations from the IHW report from Sir David Nicholson states that NHS organisations should make available NICE approved technologies. We support this report and subsequent letter of intent from Dr. Keith Ridge to all Chief Pharmacists and Prescribing Leads in England (Gateway reference 17880), which detailed aspects of the IHW report relevant to this group of health care professionals. It would be helpful to reference this letter at the start of the	Thank you for your comment. See section 1.6.

						document. There should be no local barriers to accessing technologies recommended in NICE appraisals, beyond a clinical decision relating to an individual patient. We do however want to stress the crucial link between access (availability on the formulary) and uptake (use of the medicine in the right patients). It is fundamentally important once a medicine is made available on a formulary that its uptake is encouraged for the right patients through a protocol or care pathway. Formularies and protocols need to work synergistically to ensure the right patients get the right medicines at the right time. See recommendation 13 below. Appropriate uptake of medicines, as well as access via the formulary, should ultimately improve outcomes, reduce health inequalities and drive quality.	Please see sections 4.1, 4.2, 4.6 and 4.13.
168	STH	Pfizer Ltd	1	General		**<u>Medicines Optimisation</u>** Medicines management traditionally focussed on cost, efficiency and safety, but there often tended to be a failure to address public and patient engagement. In addition, there was often insufficient intra- and inter-professional engagement. As a consequence, developing and updating formularies was often poor, resulting in poor adherence to the formularies plus poor concordance with medicines within them. This guide has an opportunity to place a strong emphasis on the need for better engagement across these groups.	Thank you for your comment. Please see section 4.3.

						Keith Ridge, Chief Pharmaceutical Officer for England, has said that Medicines optimisation is likely to be one of the key focuses of the NHS Commissioning Board yet this guide makes no real mention of Medicines Optimisation. We believe that any formulary must make reference to the new commissioning structures and processes, and how medicines are accessed and used are a critical part of this. The part medicines optimisation will play as part of this commissioning process should be outlined in this guide. In isolation, there is a risk that formulary development and maintenance act as another barrier to uptake of medicines rather than facilitating access and uptake. We believe this guide should make clear reference to how this initiative fits with and supports other activity in the NHS to drive appropriate access to medicines such as the new commissioning landscape, the various outcomes frameworks and quality standards.	The scope of the good practice guidance covers the systems and processes relating to local formulary development, and not the wider medicines optimisation agenda.
169	STH	Pfizer Ltd	1	General		**Behavioural Change** The guide focuses very much on the process change required for the development and maintenance of local formularies. Whilst it is important to get a process that is effective, efficient and measureable this is unlikely to be maintained over the longer term if some underlying behaviours are not addressed. There is sometimes a mindset that medicines are a necessary expense rather than fundamental part of a patient pathway. Our concern is that for	Thank you for your comment. This is out of scope. The scope of the guidance covers the systems and processes for developing and updating local formularies.

						some healthcare professionals, a formulary is seen as an opportunity to contain or even restrict the medicines budget, rather than one to optimise the value medicines deliver, which can be both in terms of better patient outcomes and economies across a patient pathway. We believe it is necessary to include detail on how the behaviours required to support this perspective will be embedded. The Innovation Health & Wealth report is a good example of an initiative that attempts to tackle both the processes and behaviours within the NHS. We would want this consultation to have a similar view.	
						We believe that this guide should make a stronger reference to the points and tone of the IHW report and how it applies to development of local formularies.	Thank you for your comment. The GDG agreed that the guidance and recommendations clearly reflect the Innovation, Health and Wealth report in relation to developing and updating local formularies.
						When developing local formularies there is a need to appreciate the balance between short term benefits derived from medicines with the longer term and wider benefits both to the individual and population. A well produced, maintained and implemented formulary should contribute to the short, medium and long term health of the population. It is important for a formulary development group to have a mindset that formularies can and should be viewed as an opportunity to maximise the value of medicines in delivering improved patient outcomes, reductions in hospitalisations, and delivering economies along the patient	Thank you for your comment. This comment reflects the principles of this guidance.

						pathway.	
170	STH	Pfizer Ltd	1	General		**Measurement & success** Throughout the guide there are recommendations to address the issues raised when developing and maintaining local formularies, yet there does not appear to be much sign posting to, or examples of, best practice where users can observe how best practice is implemented. We would recommend that as a theme throughout the document this approach is adopted where possible in all sections. We would also recommend that any formulary has measures of what success looks like. These should not necessarily be confined to adherence metrics to the formulary, but we believe should be broader and consider the patient impact. We hope our comments are helpful in supporting this piece of work and would be happy to provide detail on anything as requested	Thank you for your comment. See response to comment 24.
171	STH	Pfizer Ltd	2	1.1	4	The scope of the guide does not include suggested methods for implementation and performance management of the local formulary. For example, it would be helpful here to reinforce the tools available on the NICE web site to support implementation of NICE appraised medicines on the formulary. There should also be a comment about how uptake of non NICE apprised medicine can be monitored.	Thank you for your comment. See response to comment 24.
172	STH	Pfizer Ltd	3	1.3	4	This section lists a number of benefits to local	Thank you for your comment. See

						formularies. One of the most fundamental ones omitted here is improving the management and health of patients. We believe this should be added to this list.	response to comment 19.
173	STH	Pfizer Ltd	4	4.1.2	11	The number of organisations and indeed individuals involved with the development of local formularies needs to be large enough to ensure robust, credible and accurate processes are in place whilst small enough so it does not become cumbersome and counter-productive. Having the wrong mix and number of individuals involved will lead to decision making being difficult and additionally it is a waste of resource that could be better deployed elsewhere to improve patient care. We believe this perspective is important when reviewing membership as described in 4.4.1 on page 13 of the guide.	Thank you for your comment. Please see response to comment 146 and recommendations 2.3.2 and 2.3.3.
174	STH	Pfizer Ltd	5	4.3.3	12	Under the terms of reference we believe it should also include a section on how frequently the formulary will be updated to reflect new innovative medicines and also license amendments to current medicines. This will support the processes described in the recommendation 4.19 on page 22.	Thank you for your comment. Recommendation 2.16.1 outlines the principles for reviewing and updating the local formulary. The GDG concluded it was inappropriate to include specific reference to frequency of updating as this was dependent upon the scope of the formulary and its relevant evidence base.
175	STH	Pfizer Ltd	6	4.4.1	13	We acknowledge the recommendation for inclusion of patients and the public as members of the decision-making group supporting ‘no decision about me, without me.’ This is an important step in effectively ensuring the end user can express a view on matters affecting	Thank you for your comment. No response required.

						their health management and is engaged early on in the process.	
176	STH	Pfizer Ltd	7	4.5.1	13	We believe recognising the need to address resourcing issues for this process is important. This is especially so for the ongoing work required ensuring the formulary is kept up to date and fit for purpose to reflect the changing health needs of the population being served and the treatments available. There needs to be clear information on what is required in terms of resource and frequency for updating formularies. It is also important to describe in detail the skills required by each member of any formulary group. It would be useful to have additional skills and knowledge around engagement, communication and service redesign for example. A full list of the roles and responsibilities required would help to ensure the right mix of skills are present to develop and update local formularies.	Thank you for your comment. The GDG agree that resourcing of the local formulary and ensuring the local formulary decision-making group has the appropriate range of skills and expertise is important (see section 4.3).
177	STH	Pfizer Ltd	8	4.7.1	14	We believe engagement with stakeholders during the process is paramount and it is important to clearly set out what this engagement will look like. There needs to be a recommendation in this guide to clearly set out a process by which stakeholders are able to input. This should not be simply a one off opportunity to comment, but rather a systematic process allowing input and subsequent feedback at several stages during development. Please see comments on 4.17.3 below.	Thank you for your comment. See recommendations 2.2.1, 2.3.2, 2.4.1, 2.4.2, 2.7.1, 2.14.1 and 2.16.2.
178	STH	Pfizer Ltd	9	4.8.1	15	Across the NHS there are numerous examples	Thank you for your comment. The

						of duplicated reviews of technologies whether at a local, regional and sometimes national level. This often places additional hurdles to patients accessing medicines, offers no additional value and is effectively a waste of resource in terms of money and personnel, which could be better redirected to other areas of the NHS.	recommendations within sections 4.1 and 4.8 cover avoiding duplication of effort.
179	STH	Pfizer Ltd	10	4.8.2	15	Automatic inclusion of medicines with a positive appraisal from NICE is a minimum standard of any formulary and is rightly expressed in this guide. We believe this point needs further explanation in terms of what this actually means in practice. For this guide to be fit for purpose and avoid instances where trusts try to minimise the impact of a positive appraisal, this section needs to be absolutely clear in the directive it is giving. It is unacceptable for doctors to seek to persuade the patient to have an alternative treatment based on cost whilst reserving the NICE appraised treatment only if the initial treatment proves unsuccessful. This should be stated in the guide. It is also unacceptable for commissioners to encourage doctors to persuade patients to pursue this course. This point should also be stated in the guide. Commissioners must make available funding for treatments in accordance with a NICE technology appraisal for any patient who comes within the categories of patients identified in the technology appraisal.	Thank you for your comment. The GDG concluded that the expected approach for adopting a positive NICE technology appraisal is clear and unambiguous throughout the good practice guidance. Please also see the response to comment 4. Thank you for your comment. Please see the response to comment 24.

180	STH	Pfizer Ltd	11	4.8.4	15	Decommissioning and withdrawing use of a medicine that is not recommended by NICE is appropriate within a care pathway provided patient care is not compromised. It may also be appropriate to review the 'Do Not Do' list on the NICE web site, which highlights inappropriate treatments. Disinvestment from these should free up resource to invest in other cost effective medicines.	Thank you for your comment. Please see the response to comment 2.
181	STH	Pfizer Ltd	12	4.9.1	17	To support the planned and timely adoption of NICE recommended medicines by the formulary groups, we recommend advice included in the guide that there should be regular ongoing reviews of the literature to horizon scan what NICE technology appraisals are planned. This should be a standing order of business.	Thank you for your comment. Please see recommendation 2.5.1.
182	STH	Pfizer Ltd	13	4.12	18	Ensuring appropriate uptake of a medicine aligned to inclusion on a formulary is paramount. We would recommend more information here detailing the types of tools to facilitate and ensure uptake of medicines such as protocols and pathways. It would also be helpful to consider best practice examples here that demonstrate how best to implement appropriate uptake.	Thank you for your comment. Please see the response to comment 24.
183	STH	Pfizer Ltd	14	4.11.3	18	Where no NICE technology appraisal exists, the need for early engagement with the manufacturer is even more important. We believe this should be strongly reflected in the activity recommended for local formulary groups.	Thank you for your comment. The guidance covers the process and outlines explicit criteria for identifying, prioritising and selecting medicines for consideration, including medicines not subject to a NICE technology appraisal.

							See recommendation 2.5.4. Engagement with relevant stakeholders is covered in section 4.4.
184	STH	Pfizer Ltd	15	4.13.3	19	We believe it is also important that the chair ensures the drivers for decision making are uniformly understood and considered by all members of the formulary development group to reach a decision. Allied to this it is also very important to document how decisions have been reached and the processes taken. This documentation must be transparent and easily accessible to ensure confidence in decisions and also allow challenge if appropriate – see comments below 4.18.1	Thank you for your comment. Please see recommendations 2.12.1 and 2.14.1. The GDG recognised the importance of the chair and section 4.11 lists some characteristics of effective chairmanship.
185	STH	Pfizer Ltd	16	4.17.3	21	Ensuring all stakeholders are updated with revisions to the formulary is extremely important, both to help maintain credibility of the formulary and act as a further checking mechanism. We believe there should be a recommendation for including a pro-active, transparent and robust process for sharing this information. Similar to NICE consultations, this should be a pro-active process to inform registered stakeholders of any updates along with an invitation to feed back comments. There also needs to be a transparent process where comments received by stakeholders are shared and made publically available.	Thank you for your comment. The GDG concluded that recommendations 2.14.1, 2.14.2 and 2.14.3 represent good practice in relation to communication for local formulary decision-making groups and that recommendations 2.4.1 and 2.4.2 represent good practice for stakeholder engagement.
186	STH	Pfizer Ltd	17	4.18.1	21	Having clearly defined grounds for appeal is very important for the credibility of the process. In addition to the comment about due process not being followed, we believe the statement	Thank you for your comment. The recommendations have been reworded. See recommendations 2.16.1 and 2.16.2.

						‘significant new evidence’ is unhelpful. This guide should be more explicit to also included the following: 1) factual inaccuracy in the formulary or evidence considered by the formulary group 2) Substantive change to evidence used to appraise the technology since publication of the formulary - Important and relevant new clinical evidence. - Change in price of treatment or overall cost (especially important to medicines not appraised by NICE 3) New guidance or regulations. 4) If a guideline or treatment pathway identifies a particular cohort of patients that will be different to the patient group on which the original recommendation was based (especially for non NICE appraised medicines) 5) Inconsistency with a NICE TA 6) Existing similar treatments appraised differently resulting in a substantially a different outcome.	
187	STH	European Medicines Group	1	General comments		This guidance is very timely and represents a major opportunity to help raise the standard of local NHS medicines decision-making and improve patients’ access to medicines in a system where adoption is low and slow and often resistant to innovation. Medicines are an essential element of NHS care and good use of medicines supports the NHS in improving patient outcomes and generating efficiencies, for example by reducing unplanned or inappropriate use of secondary care. The guidance offers the opportunity to clearly state the value that	Thank you for your comment. No response required.

						medicines can bring, encourage uptake and appropriate and effective use, and raise standards from a base which, as outlined in the draft, is often low and subject to significant variation. Too often, local medicines decision-making is based upon containment of a discrete medicines budget, resisting new developments, rather than evaluation of the contribution of individual medicines in generating improved outcomes and efficiencies along the whole patient pathway. These issues and maximising value in the system through the use of medicines are recognised by the new efficient **medicines optimisation** agenda. Whilst we welcome the references to policy arising from the NHS Constitution and *Innovation Health and Wealth*, we are extremely disappointed to see that no reference to the concept or ambitions of medicines optimisation is made in the draft. We believe this is a significant omission and our view is that the whole document should be couched in the context of medicines optimisation. Failure to do this would undermine the initiative and run the risk of reinforcing outdated behaviours. Nor does the document appear to recognise its part in supporting the government's policy of improving adoption of innovation in the NHS. The draft therefore, in our view, represents a significant missed opportunity. Specifically: • The purpose of local formularies is couched in very limited terms ('managed introduction,	Thank you for your comment. While the GDG recognised the importance of medicines optimisation, it concluded that this good practice guidance is concerned with systems and processes relating to local formulary development, and it was not appropriate to include a detailed approach to medicines optimisation. To do so would be outside scope. However, the GDG agreed that optimising the use of medicines to improve patient care may be a potential benefit of a local formulary and this has been incorporated into the guidance. This is outside the scope of the guidance.

						utilisation or withdrawal of healthcare treatments') and misses the opportunity to state the contribution that medicines make in delivering improved health and services, their role in enabling efficiencies along care pathways and the role of the formulary in maximising these contributions and in improving patients' access to medicines. The guidance should state that looking at the medicines budget in isolation is contrary to good practice and is not a good use of NHS resources. • The draft sets out eloquently the broad variation in practice from one health economy to another, but in many areas does not set out what best practice is, implying that good practice should be defined locally; this risks reinforcing the current variations in practice. We would suggest that the guidance would benefit from clear statements on what is good practice, supported by live examples in each of the areas covered. • Practical advice on management issues around building and maintaining a formulary would be valuable, e.g. deploying appropriate resources, ensuring that they are adequate to the task, competency and skill requirements. This might be an area where some practical tools could be offered. • Over recent years the National Prescribing Centre has produced a number of useful publications to help support best practice in local decision making about medicines, and we would urge that every opportunity be	Thank you for your comment. The GDG concluded that the purpose of the good practice guidance was to set out key principles. Details of process are necessarily for local consideration and determination. Thank you for your comment. Please see response to comment 24. Thank you for your comment. Please see sections 1.6, 2, 4.3, 4.7 and 4.15.

						taken in this document to reinforce their availability and appropriate consideration. • We would recommend that the writing style is more consistent with that used in previous good practice guides issued by the National Prescribing Centre, most recently the Local Decision-making Competency Framework published earlier this year. The succinct coverage of the content, supported by diagrams, tables and bullet points, is a more accessible read for hard-pressed managers, with the key points easy to assimilate. In addition, we would recommend that the contextual information is separated from the recommendations so that the latter stand out and have maximum impact. Whilst the comments above are critical of the current draft, we would like to state our wholehearted support for the delivery of good practice guidance on the development and maintenance of local formularies. Such guidance is sorely needed, especially at this time of significant organisational upheaval, and represents an opportunity to inculcate good practice into the system when so many organisations are reviewing their structures and processes. We would urge NICE to issue a new draft that is mindful of these significant organisational challenges, which is written in the context of the medicines optimisation and innovation agendas, and which is aimed at being a 'must-have' for all relevant organisations.	Thank you for your comment. This guidance has been produced in accordance with the NICE interim process statement for the production of good practice guidance.
188	STH	European Medicines	2	1.1	4	Whilst the outline of good-practice systems and processes is welcome, we believe that the	Thank you for your comment. Please see response to comment 24.

		Group				guidance would be enhanced considerably by the addition of guidance on implementation and performance management. The latter is fundamental as it provides an important management tool for the clear definition of the role of the formulary, its aims and measurable success criteria. We hope that these will be the subject of further guidance in the near future.	
189	STH	European Medicines Group	3	1.2	4	We believe the definition given for a formulary is very limited and misses the opportunity to outline its role in providing patients with timely access to medicines; also to state the contribution that medicines make in delivering improved health and services and the role of the formulary in maximising that contribution. A key aim of a formulary should be to consider the value of medicines from the perspective of the whole patient pathway - the guidance should state that clearly. It should also make clear that looking at the medicines budget in isolation is contrary to good practice as it can lead to poor decision-making and inefficient use of NHS resources. We are disappointed that there is no reference to medicines optimisation in the document and in particular to aligning the definition of a local formulary to the aims and ambitions of medicines optimisation and the efficient use of medicines to enable the most effective use of NHS resources along the care pathway.	Thank you for your comment. The GDG concluded that the definition used for local formularies within the guidance was appropriate. The benefits of a local formulary are described in section 1.4. Please also see the response to comment 19. Thank you for your comment. While the GDG recognised the importance of medicines optimisation, it concluded that this good practice guidance is concerned with systems and processes relating to local formulary development, and it was not appropriate to include a detailed approach to medicines optimisation. To do so would be outside scope. However, the GDG

							agreed that optimising the use of medicines to improve patient care may be a potential benefit of a local formulary and this has been incorporated into the guidance.
190	STH	European Medicines Group	4	1.3	4	The draft outlines the 'potential benefits' of a formulary. We believe the guidance should state what good practice indicates is the key purpose of a formulary, and that this should refer to its role in ensuring timely access for patients to medicines and to optimising the use of medicines (i.e. aligned with the medicines optimisation agenda as stated in 1.2 above). A further purpose, and important benefit of a formulary, is the provision of a vehicle via which transparency can be achieved about accessibility of medicines. It should be clearly stated that a formulary should fundamentally be looking to seek where best to utilise a medicine, rather than how best to block a medicine.	Thank you for your comment. Section 1.4 describes the purpose of a local formulary. See the response above in relation to medicines optimisation. Please see the response to comment 19. The GDG concluded that section 1.4 states the benefits and purpose of a local formulary clearly.
191	STH	European Medicines Group	5	1.4	5	Examples of effective decision-making groups, their composition, terms of reference and ways of working would be useful to guide local NHS managers.	Thank you for your comment. Please see the response to comment 24.
192	STH	European Medicines Group	6	1.5	5	We welcome the clear statements outlining the policy context for local formularies. The statement in the NHS Constitution on the rights of patients to treatments recommended by NICE is included, along with the associated statutory	Thank you for your comment. The GDG concluded that section 1.6 outlines the policy context for local formularies clearly. Please see the reworded section 4.14.

						funding responsibility, though further emphasis on the importance of transparency in decision making processes is required. We also welcome the reference to *Innovation Health and Wealth* in the context of measures to improve the implementation of NICE technology appraisal guidance and the resulting obligations on all NHS organisations. We are disappointed, however, in the absence of any reference to efficient medicines optimisation, which is central to improving the standards of local medicines decision-making. We recommend that a root and branch review of the guidance be undertaken to align it with the aims and ambitions of medicines optimisation.	Thank you for your comment. While the GDG recognised the importance of medicines optimisation, it concluded that this good practice guidance is concerned with systems and processes relating to local formulary development, and it was not appropriate to include a detailed approach to medicines optimisation. To do so would be outside scope. However, the GDG agreed that optimising the use of medicines to improve patient care may be a potential benefit of a local formulary and this has been incorporated into the guidance.
193	STH	European Medicines Group	7	3	8	The process to develop the guidance has been comprehensive and thorough according to practice operated by NICE in other areas. The search for published evidence is to be applauded and the finding of the extent of lack of published evidence is a useful insight. The trawl for additional evidence from local NHS organisations will have been useful input and the insights into the large variations in current	Thank you for your comment. No response required.

						practice are most valuable in identifying the issues that have to be addressed. The inclusion of industry representatives on the Guidance Development Group has been welcomed by the EMG. However, we believe that this methodology has led to draft guidance that is anchored in current practice, rather than seeking to move practice forward according to leading edge examples and medicines optimisation. This is a significant missed opportunity. We would recommend that the guidance be reviewed in the light of the medicines optimisation agenda and include examples of good practice as a marker to others of what is achievable. The document rightly highlights the statutory responsibility to make funding available within three months for a NICE approved medicine. It needs to be made clear that local formulary status and processes should not to be used as mechanisms to restrict this.	Thank you for your comment. Please see the response relating to medicines optimisation within comment 192 above. Thank you for your comment. The GDG concluded that the expected timeline for adopting a positive NICE technology appraisal is clear and unambiguous throughout the good practice guidance. Please also see the response to comment 4.
194	STH	European Medicines Group	8	4	10-22	The introductory sections cover nine pages of contextual information. This section contains further context and although this is very useful information, we believe readability would be enhanced if the contextual information was shortened and separated from the recommendations, or that the presentation of the information is such that the recommendations stand out more so that they have more impact. We do not believe that the recommendations	Thank you for your comment. The guidance is produced in line with the interim process statement for good practice guidance. The recommendations have all been included in a separate section. See section 2. Thank you for your comment. Please

						articulate good practice. In many areas, they set out options based on current practice and there is not enough emphasis on saying what best practice looks like. Live examples of such good practice would enhance impact and understanding. As currently drafted there is a danger that unwanted variations in practice will be continued.	see response to comment 24.
195	STH	European Medicines Group	9	4.1.1-4.1.2	11	This section would benefit from some guidance on the most effective number and mix of decision-making groups and how to engage them. We welcome the statements here about development of local integrated pathways and positioning medicines within those pathways and recommend that this aspect of formulary decision-making is emphasised in other sections. The emphasis on the importance of clinician involvement is also welcome.	Thank you for your comment. Please see the response to comment 26. Thank you for your comment. No response required.
196	STH	European Medicines Group	10	4.2	11-12	The Guidance Development Group found no evidence to indicate that one formulary scope was any more appropriate than another. However, we believe the guidance would benefit from some practical advice as to the considerations for one scope vs. another, e.g. the challenges in terms of resourcing of coverage of a very large population, economies of scale, etc. It would be a shame if lack of evidence led to lack of practical and commonsense advice. We fully support the statement that a 'simple list	Thank you for your comment. Please see the response to comment 26. Thank you for your comment. No

						of medicines may not be suitable to ensure that the formulary integrates with local care pathways'.	response required.
197	STH	European Medicines Group	11	4.3	12	As said above we believe some examples of good practice would be welcome here. In particular the lack of any guidance on performance management in the document means that sections such as this one lack specificity and direction on good practice.	Thank you for your comment. Please see the response to comment 24.
198	STH	European Medicines Group	12	4.4	13	The local decision making competency framework mentioned is excellent. As 'membership' is such a fundamental issue we would welcome more pointers on direction and good practice in this section. For example, we believe there should be greater emphasis on patient groups. Attempts to ensure patient and public interest groups should be encouraged and best practice advice offered to help secure regular membership. Open / public meetings might aid regular membership. Representation from patient and public groups varies and good practice standards could encourage better engagement with these groups. We also believe there must be clinical representation from the appropriate clinical specialty. And we would support the consideration of industry representation for membership. The weighting of views needs to be balanced, such that formulary decisions represent a broad	Thank you for your comment. The GDG concluded that recommendations 2.3.3 and 2.4.1 provide appropriate, explicit guidance in this area. Thank you for your comment. Please see response 45. Thank you for your comment. Please see recommendation 2.3.2.

						decision, rather than one driven by any inappropriate pharmacist bias.	
199	STH	European Medicines Group	13	4.5	13	The subject of resourcing is absolutely critical to the successful development and implementation of a formulary. The recommendations merely state that attention should be paid to resourcing requirements and the possible value of collaboration with other organisations where the formulary scope is narrow. We believe this section should be strengthened with much more detail on the nature of the resources required and what this means in terms of competency, skills requirements, manpower and budget. Again examples of good practice would add value.	Thank you for your comment. The GDG concluded that recommendations outlining the principles for resourcing of the local formulary decision-making group were appropriately devised, but the details are for local consideration and determination. Also see recommendation 2.3.3.
200	STH	European Medicines Group	14	4.52	13	We strongly agree with this recommendation.	Thank you for your comment. No response required.
201	STH	European Medicines Group	15	4.6	13/14	This section would benefit from a greater emphasis on the need for external transparency, as well as the welcome emphasis on accountability to corporate governance bodies.	Thank you for your comment. Please see the response to comment 6.
202	STH	European Medicines Group	16	4.7	14	This section would benefit from greater emphasis on communication planning as a critical element of engagement activity.	Thank you for your comment. The GDG concluded that recommendations 2.14.1, 2.14.2 and 2.14.3 provide clear guidance on communications.
203	STH	European Medicines Group	17	4.7.1	14	We welcome inclusion of engagement with the relevant manufacturers of medicines within the recommendations but would like to see this more strongly mandated. This in our opinion is a critical element of the	Thank you for your comment. The GDG concluded that recommendations 2.4.1 and 2.4.1 provide clear guidance on engaging with all stakeholders. Manufacturers are included as a

						process, to ensure the committee has access to all the available evidence. Companies have the most information on the medicines they develop and market and are able to add insights to interpretation of evidence. We believe that companies should also be able to review draft evidence summaries and decisions for factual accuracy. It may be helpful to readers to give some idea of priorities for engagement of different groups.	source of information on medicines in the good practice guidance. See recommendation 2.8.2. See response to comment 6. The GDG concluded that priorities for engagement would vary according to topic or locality and in addition identifying a priority group could be potentially prejudicial to good practice.
204	STH	European Medicines Group	18	4.8.1-4.8.5	15	This section gives a clear steer on good practice for incorporating information and guidance from horizon scanning organisations, NICE, the MHRA, etc. Other sections would benefit from a similar style and statement of good practice.	Thank you for your comment. No response required.
205	STH	European Medicines Group	19	4.8.2	15	To help ensure compliance with recent directives from the NHS Chief Executive and Chief Pharmaceutical Officer, we recommend the wording be changed from 'should' to 'must.' Emphasis on the expected timelines is needed.	Thank you for your comment. The recommendation has been reworded to ensure consistency. See recommendation 2.6.1.
206	STH	European Medicines Group	20	4.8.5	15	We would recommend that one of the criteria for prioritising treatments not subject to NICE appraisal should be value in improving management of, or outcomes from, the patient pathway.	Thank you for your comment. Recommendation 2.5.4 gives guidance on the criteria that should be included when prioritising medicines not subject to a NICE technology appraisal. This list is not meant to be exhaustive and a final list would be down to local determination. See also

						We would encourage inclusion of a statement about working with the manufacturer during consideration of treatments not subject to a NICE appraisal.	recommendation 2.7.1. Thank you for your comment. Recommendation 2.8.2 has been reworded and manufacturers are included in the list of organisations in appendix C.
207	STH	European Medicines Group	21	4.8.7	16	We welcome the encouragement of transparency and engagement. We would recommend that all paperwork, including minutes of the meeting and pertaining to decisions, are made public.	Thank you for your comment. Please see response to comment 6.
208	STH	European Medicines Group	22	4.8.8	16	While it is implied in the descriptions, being specific about 'outcomes' as a measure would be useful. We would recommend that applications for healthcare treatments should also include consideration for improving management of, or outcomes from, the patient pathway. A specific section considering Health Economics and Outcomes Research (HEOR) along the patient pathway is recommended. This will also link into resource impact.	Thank you for your comment. These considerations are out of scope for this guidance.
209	STH	European Medicines Group	23	4.9	17	We would encourage making explicit recommendations on making NICE recommended medicines available, without the need for further assessment.	Thank you for your comment. See recommendation 2.8.1.
210	STH	European Medicines Group	24	4.9.1	17	We endorse the statement that local formulary processes should support the planned and timely adoption of medicines recommended by NICE. Though this statement would benefit from	Thank you for your comment. See recommendation 2.6.1

						specifics about timelines.	
211	STH	European Medicines Group	25	4.9.2	17	We would draw the authors' attention to the recent decision by NICE to clarify the meaning of 'option' in its guidance (paragraph 5.2 of technology appraisal guidance). This should be referenced in the guidance. This seeks to clarify that 'option' means an option for clinicians and not for funding. We would assert that the place in treatment of a medicine recommended as an option by NICE should be clear from NICE guidance and that the need for decision-making groups to assess the place in treatment is likely to be duplicative and create barriers or delays to implementation.	Thank you for your comment. Please see response to comment 7. Thank you for your comment. Recommendations 2.6.1 and 2.6.2 have been reworded.
212	STH	European Medicines Group	26	4.10	17	We welcome the plan to offer best practice guidance in the final published document. Consistency, transparency, quality and clarity of decision making should be enhanced by the adoption of best practice guidance.	Thank you for your comment. No response required.
213	STH	European Medicines Group	27	4.10.1	17	The guidance recommends use of a multi-criteria decision tool. We believe the guidance would be enhanced by suggestions as to the best available tools and specific examples of good practice. MPC guidance can offer advice on how the capability can be built, enhanced and accessed and we urge the authors to take the opportunity to reinforce this. The decision criteria should include the potential of the medicine to improve management of, or outcomes from, the care pathway.	Thank you for your comment. Please see response to comment 24.

						An emphasis on the need for transparency of the criteria would also be welcomed.	
214	STH	European Medicines Group	28	4.11	17-18	Further review of evidence in the case of NICE approved medicines should be for exceptional reasons only, and these should be documented. A key part of evidence and information gathering should be liaison with the manufacturer who may have evidence that is not readily available to formulary developers.	Thank you for your comment. See recommendation 2.8.1. Thank you for your comment. Recommendation 2.8.2 has been reworded and manufacturers are included in the list of organisations in appendix C.
215	STH	European Medicines Group	29	4.11.1	18	We welcome the recommendation that where there is no NICE technology appraisal nationally available evidence summaries should be considered.	Thank you for your comment. No response required.
216	STH	European Medicines Group	30	4.11.2	18	As competency and skills will be a key issue, we recommend referral to the best practice materials available from the MPC which help in the identification and development of these. In reviewing evidence, the need for accuracy and balance should be stresse.d.	Thank you for your comment. Please see sections 1.6, 2, 4.3, 4.7 and 4.15. Thank you for your comment. See section 4.11 and recommendation 2.3.3.
217	STH	European Medicines Group	31	4.12	18	The language in this section is potentially confusing. The terms 'financial impact' and 'clinically and cost effective' are used in a way that implies they mean the same thing. A clear distinction should be made between cost effectiveness and budget impact – a medicine can be cost effective even if it increases the size of the medicines budget. It is here that impact	Thank you for your comment. This section has been clarified. See section 4.10.

						and value across the pathway are particularly important, as use of a medicine that increases the medicines budget may well lead to savings in other budgets, such as reductions in referrals and use of secondary care facilities.	
218	STH	European Medicines Group	32	4.13	19	This section would benefit from more explicit recommendations and examples of what is good practice rather than merely 'considering' how to reach final determinations. For example, guidance on how to deal with considering positioning new medicines in light of generic comparators should be considered.	Thank you for your comment. Please see response to comment 24. Thank you for your comment. Please see section 4.7.
219	STH	European Medicines Group	33	4.14	19	Examples of good practice would be useful. The recommendation should make explicit the need for all documentation relating to decisions to be easily publically available / suitable for review by patient groups.	Thank you for your comment. Please see response to comment 24. Thank you for your comment. Please see response to comment 6.
220	STH	European Medicines Group	34	4.15.1	20	This recommendation should be more explicit on the timelines for decision-making according to good practice, i.e. what is meant by 'timely' and what is an unacceptable delay to patients having access to the medicines deemed appropriate for them.	Thank you for your comment. Recommendations 2.3.4, 2.6.1, 2.13.1 and 2.13.2 have been reworded. The GDG concluded it should not set explicit recommendations regarding timelines for decision-making as these will vary dependent on the decision being made locally.
221	STH	European Medicines Group	35	14.6	20	Recommendations on best practice timings to reach a decision should be provided.	Thank you for your comment. Please see response to comment 220.
222	STH	European	36	14.7	20	EMG believes that all formularies should be in	Thank you for your comment. Please

		Medicines Group				the public domain. Further, all documentation relating to decisions should be publically available such as processes for submission, updating, around membership and terms of reference, meetings summaries, decisions including reasons for inclusion / exclusion and appeal.	see response to comment 6.
223	STH	European Medicines Group	37	14.7.1	21	While the emphasis on NICE recommended medicines is welcome, transparency about all medicines included in a local formulary should be the overall goal. The good practice from some organisations of full disclosure, recognised by the authors, should be the expected norm.	Thank you for your comment. Please see response to comment 6.
224	STH	European Medicines Group	38	14.7.2	21	Formulary recommendations should be communicated to the manufacturer.	Thank you for your comment. Please see response to comment 6.
225	STH	European Medicines Group	39	4.18	21-22	The inclusion of a section on an appeal process is welcome. However, the guidance does not make clear if an appeal process is recommended in line with good practice, merely the factors to be taken into consideration if there is one. The addition of recommended grounds for appeal and examples of good practice would add value. There is also no guidance on whether an appeal process should be accessible to patient groups. In addition to the two appeal circumstances listed, the 'due process' statement should be expanded to include a reference to a lack of 'full and balanced consideration of the application'.	Thank you for your comment. The section has been clarified. See section 4.16.

						As the authors eloquently point out there is considerable variation in process and standards deployed around the country. Until best practice across the board is guaranteed, an assumption that there is automatically a 'due process' may be premature.	
226	STH	European Medicines Group	40	4.19	22	This section recognises the importance of keeping a formulary up to date in an area where the evidence base is constantly changing. There is no recommendation, however, of good practice in terms of appropriate intervals for review. The emphasis on transparency is welcomed.	Thank you for your comment. Please see response to comment 12.
227	STH	Health and Social Care Board Northern Ireland	1	**4.9.2**	17	**4.9.2 Where a NICE technology appraisal states 'option for treatment' the medicine should be adopted onto the local formulary and decision-making groups should assess its place in the local pathway.** It is our view that this depends on the remit of the local formulary. We are in the process of developing a regional formulary for Northern Ireland. The remit is to provide prescribers with guidance on first and second line choices only. It is therefore focused on non-specialist prescribing choices. Therefore we will not be adopting all drugs where a NICE technology appraisal states 'option for treatment' onto the NI Formulary. This will not affect patient access to 'non-formulary' treatments where clinically appropriate.	Thank you for your comment. The clear remit in England is the automatic inclusion of the approved medicines where clinically appropriate in the local formulary. This is in line with the Department of Health document 'Innovation, Health and Wealth'. Arrangements such as those described may however be in line with recommendation 2.6.1.

						There is a distinction between not including a drug on a local formulary and denying patients access to NICE approved medicines where clinically appropriate. We would like this issue to be reflected in the NICE guidance.	
228	STH	Aneurin Bevan Health Board (NHS Wales)	1	general		The document is surprisingly interesting!	Thank you for your comment. No response required.
229	STH	Aneurin Bevan Health Board (NHS Wales)	2	1.1	4	This document will give our organisation the opportunity to measure and compare its formulary management processes against accepted NICE standards. The standards give a good balance between being not too specific, and not so general as to be meaningless.	Thank you for your comment. No response required.
230	STH	Aneurin Bevan Health Board (NHS Wales)	3	4.18.1	21	Provision of an independent panel to assess appeals may not be practically/economically viable in some NHS organisations. If the suggestion to collaborate with neighbouring groups (in 4.18.2) is based on established practice it would be useful to cite examples or provide more detail here.	Thank you for your comment. See section 4.15. Please see the response to comment 24.
231	STH	Aneurin Bevan Health Board (NHS Wales)	4	General on sections 4.11-4.13	17 - 19	These sections could help update the terms of reference for the MTC, and encourage the formulary to be owned and more integrated into other local decision making groups.	Thank you for your comment. No response required.
232	STH	Aneurin Bevan Health Board (NHS Wales)	5	1.5	5	The NHS Constitution for England is quoted as the context for these draft good practice recommendations however this constitution does not apply in Wales (although 3 month statutory funding requirements for TAGs do).	Thank you for your comment. Wording in the final guidance relating to the status of the guidance in Wales was agreed with the GDG's member from Wales. See section 1.

						As the guidance will apply in Wales it would be useful to refer to the remit of the All Wales Medicines Strategy Group (AWMSG) with regard to appraisal of medicines in Wales, the fact that there is the same statutory obligation for Health Boards to implement AWMSG recommendations within 3 months and the relationship of the guidance to NICE, ie AWMSG guidance is interim to NICE guidance should this be subsequently published.	
233	STH	Aneurin Bevan Health Board (NHS Wales)	6	4.11.1	18	Local formulary groups should us nationally available evidence summaries – examples would be helpful here. If these should be limited to UK the wording should state “ensuring the summary is relevant to the medicine, indication and healthcare setting being considered.”	Thank you for your comment. Please see response to comment 34.
234	STH	Aneurin Bevan Health Board (NHS Wales)	7	4.9.1	17	4.9.1 Local formulary processes should support the planned and timely adoption of medicines recommended by a NICE technology appraisal. So it does not specify the 3 months limit. Our wordings may be something like local prescribing committees should support and develop a planned and timely adoption of medicines recommended by a NICE technology appraisal. In developing a planned and timely adoption of NICE recommended medicines, it may be reasonable to take the immediate financial impact into consideration. Whenever possible, NICE recommended medicines should be adopted into local formularies within 6 to 12 months. The 3 months approval limit was fine when funding was much	Thank you for your comment. Recommendation 2.6.1 now clearly states within ‘3 months’ in line with statutory responsibilities.

						less of a problem but we are in a very difficult economic climate and it will get worse.	
235	STH	Aneurin Bevan Health Board (NHS Wales)	8	4.8.2	15	Not withstanding the comment above, it may be better to say that “medicines with a positive NICE technology appraisal should be included in a local formulary within 3 months of the issue date” rather than including the word “automatically”. Whilst there will be an element of advanced planning for new TAs, there will always need to be further discussion on publication with clinicians to plan the managed entry and budget implications.	Thank you for your comment. Please see the response to comment 234.
236	STH	Aneurin Bevan Health Board (NHS Wales)	9	general		It would be useful if the good practice guidance included some specific advice on the status of medicines recommended in NICE Clinical Guidelines and the requirement for formulary inclusion. Clearly when a particular medicine is endorsed within a guideline this raises the expectation for formulary inclusion. This has been an issue locally with the use of pregabalin and the positioning of this within local pathways. Another example is where a class of drugs is mentioned within a clinical guideline eg DDPP-4 inhibitors (sitagliptin, vildagliptin) but it would not be appropriate or necessary to include all within a formulary.	Thank you for your comment. The criteria for prioritising medicines not subject to a NICE technology appraisal are in recommendation 2.5.4.
237	STH	Aneurin Bevan	10	4.5	13	“The GDG found that resource levels should be	Thank you for your comment.

		Health Board (NHS Wales)				proportionate to the tasks undertaken" again more detail would be helpful here. In addition to the technical, analytical and financial skills the significant requirement for a decision-making group to have adequate administrative support should be recognised in the recommendations.	Recommendation 2.3.3 recommends using the local decision-making competency framework which contains sufficient detail.
238	STH	GlaxoSmithKline	1	1.1	4	We need to ensure these local arrangements have a level of consistency. We support the ABPI's position that information on how this guidance will link to NIC, innovation scorecards and organisational performance against implementing NICE would be useful.	Thank you for your comment. Please see response to comment 24.
239	STH	GlaxoSmithKline	2	1.3	4	GSK would welcome the mention of how patient flows would feature here. The aim to ensure consistent patient care across NHS organisations should be paramount when considering formulary processes to enable patients to be managed effectively across health economies.	Thank you for your comment. This is out of scope.
240	STH	GlaxoSmithKline	3	4.1.1	11	The size of a local formulary should depend on patient demographic rather than geography alone, the engagement across health economies as suggested by NICE shouldn't take the decision too far away from patient and the ability of local economies to make decisions - the formulary must still serve purpose at a local level in line with the statutory responsibilities set out by the H & SC Act (2012). Engagement should be sufficient to ensure patients can obtain consistent care across neighbouring economies, but should not state that these formularies must be the same. Clear guidance on stakeholder mapping and processes would be helpful.	Thank you for your comment. Please see response to comment 26. The GDG concluded that it should not make explicit recommendations regarding the optimum number and type of stakeholders. This should be for local consideration and determination, depending on the size and scope of the formulary and a number of other factors.

						However, GSK believe the risk stratification tool used should be down to local choice and accountability. Funding flows need to be made clear and links to PBR tariff.	
241	STH	GlaxoSmithKline	4	4.1.2	11	How do we make sure clinicians are adequately involved? This needs to happen across all care settings.	Thank you for your comment. Please see response to comment 24.
242	STH	GlaxoSmithKline	5	4.2.1	12	Again it is important to reconsider the objective of local formularies as stated in 4.1.1. Clear definition of who the stakeholders are would be beneficial. GSK support the ABPI's point that a reminder of the purpose and background of a local formulary would sit well here.	Thank you for your comment. Please see response to comment 45 and section 4.4.
243	STH	GlaxoSmithKline	6	4.4	12	Which patient groups are going to be contacted? GSK suggest national therapy expert patient groups are contacted to facilitate communications on medicines, whereas local health watch will then be drawn upon to look at implementation at a local level. A clear process and incentive for involving patient groups should be outlined. How will they know about the formulary etc? Consideration of industry membership to bring the latest evidence and knowledge on the medicine similar to the way AWMSG has industry input as part of the group would strengthen this part of the guidance.	Thank you for your comment. Please see response to comment 45. Manufacturers are included as stakeholders within recommendation 2.4.1. Section 4.14 on communication and dissemination emphasises the importance of communication with stakeholders and dissemination of formulary information. There is a recommendation for local formulary decision-making groups to publish all relevant local formulary information online, in a clear, simple and transparent way, so that patients, the public and stakeholders can easily understand it. This includes formulary policies, minutes of meetings, decision outcomes and associated decision outputs (see recommendation 2.14.1).
244	STH	GlaxoSmithKline	7	4.4.1	13	We agree with the scope of the formulary group and public representation (DH guidance on good	Thank you for your comment. The GDG agreed that local formulary

						practise). GSK do not think it wise to have these meetings entirely in public as proposed by the ABPI and would suggest that the discussions around budget allocation are held in private, much like the meetings at a national level, the structure, organisation and outcomes of the meetings is more appropriate to be made public.	decision-making groups should publish all relevant local formulary information online, in a clear, simple and transparent way, so that patients, the public and stakeholders can easily understand it. This includes formulary policies, minutes of meetings, decision outcomes and associated decision outputs (see recommendation 2.14.1). However, given the different functions and forms of local formularies, the GDG concluded that it should not currently be prescriptive about public meetings, whilst recognising the need for transparency. The decision whether to hold meetings in public, or in private, should be for local consideration and determination.
245	STH	GlaxoSmithKline	8	4.5	13	No local cost-effective assessment should take place which undermines the purpose of national NICE assessments and duplicates effort unnecessarily. In line with recommendations in the IHW document (Dec 2012) medicines recommended in a NICE TA should be automatically included in relevant formularies, meaning that at a local level only the pathway and funding flow needs to be determined, which must be done within the 90 day funding direction period.	Thank you for your comment. See recommendation 2.8.1.
246	STH	GlaxoSmithKline	9	4.5.2	13	Recommending larger formularies does not seem in line with NHS re-forms which are pushing for localised accountability and commissioning, but may be beneficial in some localities for patient outcomes and consistent care. The size of geography covered goes back	Thank you for your comment. The guidance does not define an optimum population size or number of provider organisations involved in developing and updating local formularies. The recommendations for practice allow

						to comments on section 4.1.1. Links to patient flows and clarity of decision makers in line with NHS reforms would make this piece of the guidance more impactful.	organisations to balance the risks and benefits of different models locally.
247	STH	GlaxoSmithKline	10	4.6	13	GSK strongly support the ABPI's suggestion to change this last sentence to "and financial flows agreed in standard national contracts."	Thank you for your comment. Please see response to ABPI comment 290.
248	STH	GlaxoSmithKline	11	4.7.1	14	Standard procedure for gathering the latest evidence on a medicine should be to come to the manufacturer. A clear communications plan for stakeholders would be helpful.	Thank you for your comment. The GDG concluded that local formulary decision-making groups should utilise a range of high quality information sources, including those produced by national and regional horizon scanning organisations and manufacturers. Please see appendix C. The need to develop a local communication framework, in consultation with stakeholders is included within the guidance (see recommendation 2.14.3).
249	STH	GlaxoSmithKline	12	4.8.2	15	We need to emphasis the proper adoption of NICE national care pathways as well as just the usage of medicines. GSK would suggest a 3 month timelines needs to be made more mandatory in order to have effect. It must be considered that some protocols are based on the use of a specific medicine in a pathway, and so guidance on the placement of a medicine in an existing pathway is crucial. In addition to whether a medicine is on formulary there should also be tracking on its level of usage and in how many appropriate patients. We would suggest a local health outcomes analysis where NICE haven't reviewed a medicine with a thorough consideration of the implication for service	Thank you for your comments. Please see response to comment 9. The GDG agreed that linking formulary decisions within care pathways is important and this is referred to throughout the guidance. See sections 4.1, 4.2, 4.6 and 4.13. The GDG concluded that the expected timeline for adopting a positive NICE technology appraisal is clear and unambiguous throughout the good practice guidance.

						delivery. GSK agree with the ABPI in reference to the latest communications from Keith Ridge and David Nicholson, suggesting the wording of this section needs to be made more directive, "must" instead of "should/could".	Tracking the level of usage is out of scope. See response to comment 24. The latest communications from Dr Keith Ridge and David Nicholson are included within the guidance (see section 1.6).
250	STH	GlaxoSmithKline	13	4.8.4	15	Who should this discussion be with? Again a clear stakeholder map and process needs to be put in place for clarity here. Clinicians should still have right to prescribe medicines not on the formulary where they feel appropriate. The flow diagram at the back of the guidance needs to add in more detail and more information on what constitutes proper engagement. The role of specialist centres which may be acting on a more regional level should be considered.	Thank you for your comment. In the context of the document, the recommendation relates to the discussions of the local formulary decision-making group. The GDG concluded that it should not make specific recommendations regarding the optimum number and type of stakeholders. This should be for local consideration and determination, depending on the size and scope of the formulary. The flowchart summarises the core elements of the local formulary process clearly and concisely.
251	STH	GlaxoSmithKline	14	4.8.5	15	A clear timeline should be set in place for this. This should not be prioritised over adoption of NICE approved meds.	Thank you for your comment. The GDG concluded that the expected timeline for adopting a positive NICE technology appraisal is clear and unambiguous throughout the good practice guidance. In the guidance, other medicines are prioritised according to criteria (see recommendation 2.5.4).
252	STH	GlaxoSmithKline	15	4.8.6	16	This has been mentioned previously and may appear repetitive in the guidance. Appropriate engagement with stakeholders should be outlined in a clear consistent process, both for	Thank you for your comment. The reactive identification of medicines is only considered in this section. Manufacturers are included as

						following positive nice guidance and following no/negative guidance. Manufacturers should be involved in evidence gathering and contacted in writing when a medicine is being considered for a formulary or removed from formulary.	stakeholders within recommendation 2.4.1. Section 4.14 on communication and dissemination emphasises the importance of communication with stakeholders and dissemination of formulary information.
253	STH	GlaxoSmithKline	16	4.8.7	16	This may benefit from further guidance on how long the application should be, a suggestion would be somewhere between including sufficient information on placement in pathways and links to medicines optimisation, but not so as to make the application itself become a barrier.	Thank you for your comment. A recommendation is made regarding the content of application forms (see recommendation 2.5.7). The GDG recognised the barriers to applications for new medicines to be considered and this is reflected in the document (see recommendation 2.10.2).
254	STH	GlaxoSmithKline	17	4.8.8	16	Good formularies should be more than a simple list of medicines but involve placement in care pathways and funding flows. Ideally there will be clear links to how this would be implemented; an example of good practice would be the Bristol North Somerset & South Gloucesterhsire (BNSSG) placement of Prolia in the care pathway http://www.bnssgformulary.nhs.uk/66-Drugs-affecting-bone-metabolism/ which shows good links to further information on the medicine, and also guidance around implementation.	Thank you for your comment. This is out of scope. See response to comment 24.
255	STH	GlaxoSmithKline	18	4.9.1	17	GSK suggest a 3 Month timeline in line with the timelines suggested by NICE for adoption of approved medicines.	Thank you for your comment. The GDG concluded that the expected timeline for adopting a positive NICE technology appraisal is clear and unambiguous throughout the good practice guidance.
256	STH	GlaxoSmithKline	19	4.10.1	17	Duplication of effort if NICE approved.	Thank you for your comment. See recommendation 2.8.1.

257	STH	GlaxoSmithKline	20	4.11.1	18	Clear guidance to contact the manufacturer would help ensure the latest evidence is available to clinicians to make informed decisions.	Thank you for your comment. Recommendation 2.8.2 has been reworded and manufacturers are included in the list of organisations in appendix C.
258	STH	GlaxoSmithKline	21	4.12.1	18	This process may form a barrier in itself, it would be ideal to see these meetings pre-launch, in line with good horizon scanning.	Thank you for your comment. See section 4.10.
259	STH	GlaxoSmithKline	22	4.14.1	19	A proactive approach to contacting the medicines manufacturer would benefit the process and ensure the latest evidence is available. Clear documentation at each stage of the formulary process should give indications of the rationale for choices - this should be made available in public domain as long as no mention of pre-launch medicines. This ensures transparency of the process for any appeals and gives patients an idea of the reasons for local formulary decisions and options for IFR's. This documentation should be in line with the standard of NICE documentation (if resource at a local level permits).	Thank you for your comment. See section 4.14.
260	STH	GlaxoSmithKline	23	4.15.1	20	Engage Pharma pre-launch – horizon scanning to check for pipeline products and latest trials.	Thank you for your comment. The GDG agreed that horizon scanning was an important consideration. See recommendation 2.5.1.
261	STH	GlaxoSmithKline	24	4.16.1	20	How frequent are these going to be?	Thank you for your comment. The GDG concluded that the frequency of local formulary decision-making group meetings should be for local consideration and determination.
262	STH	GlaxoSmithKline	25	4.17.1	21	Published formularies should be more than just a simple list of medicines but should contain information on funding flow, suggested placement in care pathways, and links provided	Thank you for your comment. See section 4.13. The GDG concluded that the frequency

						to gain more info about the product (cannot rely on Pharma to be promoting). Published formularies should be reviewed on a quarterly basis as a minimum (horizon scanning is therefore essential) fitting in with the 3 month period NICE suggest for inclusion of positively appraised new meds. The 'process' itself should not be a reason for delay.	of formulary review should be for local consideration and determination, depending on the size, scope and geographical coverage of the formulary.
263	STH	GlaxoSmithKline	26	4.17.3	21	How will public/patients know this is available?	Thank you for your comment. See response to comment 6.
264	STH	GlaxoSmithKline	27	4.18.1	21	We need to set timelines for appeals, perhaps bigger appeal geography – aligned at regional office of NHSCB? Clear guidance on who can appeal. In addition to a) and b), should include c) if inaccurate info is used.	Thank you for your comment. See section 4.15. The GDG concluded that the timeline for an appeal should be determined locally.
265	STH	GlaxoSmithKline	28	4.18.2	22	GSK agree and support NICE that this is the best way forward.	Thank you for your comment. No response required.
266	STH	GlaxoSmithKline	29	General		GSK are in support of the comments made by the ABPI; any supplementary comments have been captured in the following response document. In summary, GSK would like to see the following 5 points adhered to when developing local formularies: 1. The size of a local formulary should depend on patient demographic rather than geography alone, and the engagement across health economies as suggested by NICE shouldn't take the decision too far away from patient. Aggregating up to too large a geography could impact the ability of local economies to make decisions in line with their statutory responsibilities under the H & SC Act (2012). Engagement should be sufficient to ensure patients can obtain consistent care across	Thank you for your comments. Thank you for your comment. The guidance does not define an optimum population size or number of provider organisations involved in developing and updating local formularies. The recommendations for practice allow organisations to balance the risks and benefits of different models locally.

						neighbouring economies, but should not state that these formularies must be the same. 2. A clear process map for engagement with stakeholders should be put in place, following both positive and negative/no NICE guidance. Definitions of who these stakeholders are, and how they should be approached needs to be defined. Increased dialogue with manufacturers of the medicines will enable optimal evidence gathering on a product. 3. The end product of following a robust formulary process should be more than a simple list of medicines but involve placement in care pathways and funding flows. Ideally this guidance will include clear links to how this would be implemented and any shared savings agreements, although not going in to detail which is out of scope of the Good Practice Guide. 4. Medicines with positive NICE guidance should be prioritised locally to gain a formulary position as quickly as possible. A process should be put in place to asses medicines with no NICE guidance but this should not take priority over adoption of NICE approved medicines, e.g. the MPC new medicines service. 5. Clear documentation at each stage of the formulary process should give indications of the rationale for choices and this should be made available in public domain. This ensures transparency of the process used for any appeals and gives patients an idea of the reasons for local formulary decisions and options for IFR's. This local documentation	Thank you for your comment. The GDG concluded that it could not make explicit recommendations regarding the optimum number and type of stakeholders. This should be for local consideration and determination, depending on the size and scope of the formulary. Manufacturers are included as stakeholders. Thank you for your comment. Implementation of the guidance is out of scope. See response to comment 24. Thank you for your comment. See response to comment 251. Thank you for your comment. See response to comment 259.

						should be in line with the standard of current NICE documentation (if resource at a local level permits). Overall, GSK would like to see that the finalised NICE guidance reflects accurately the objectives of local formularies and medicines optimisation. Where formularies are applicable they should aim to help manage the medicines budget, give guidance around shared care protocols, and control the number of different medicines stocked by pharmacy, overall ensuring that local patient outcomes are a priority.	Thank you for your comment.
267	STH	ABPI	1	1.1	4	As the scope of the guidance is defined as <u>not</u> relating to performance management or implementation, we need to know who will be responsible for defining both these areas since this is fundamental in measuring success. We would also be keen to know how this guidance will link to e.g. the NICE Implementation Collaborative, innovation scorecards and quality reports. We would be interested to know how a member of the general public will be able to see what a health economy is doing with regard to access to medicines. How will benchmarking be undertaken and variation addressed? We hope that all these key topics will form part of future guidance.	Thank you for your comment. Please see response to comment 24.
268	STH	ABPI	2	1.2	4	There is no mention of medicines optimisation and that the fundamental purpose of a formulary is to improve patient outcomes.	Thank you for your comment. The scope of the good practice guidance covers the systems and processes relating to local formulary development, and not the wider medicines

							optimisation agenda. Section 1.4 has been reworded.
						The comment regarding definitions depends on what is meant by definitive. There are many references on this subject, as well as clear dictionary definitions, and we have included some at the end of this form.	Thank you for your comment. The GDG agreed the definition provided within section 1.3 as no suitable published definition of a local formulary could be found.
						We would encourage publication of how this Guideline was derived in detail, including the literature search.	Thank you for your comment. The good practice guidance was produced in line with the NICE interim process statement for good practice guidance. Information relating to the literature search is included within appendix B.
						The prescriptive definition chosen does not include maximising the value of medicines in a patient pathway, and moving away from silo based budgeting. Surely a key strategy in formulary management is to optimise medicines usage?	Thank you for your comment. See section 1.4.
269	STH	ABPI	3	1.3	4	We are concerned to see there is no mention of patients. A crucial element of quality care should be to ensure that patients who move from one NHS organisation to another have their medicines managed consistently and in turn their health outcomes maintained. A formulary should be about access and uptake, not blocking.	Thank you for your comment. Please see section 1.6.
270	STH	ABPI	4	1.4	5	Further examples of different decision making groups could be provided in an appendix, as well as suggestions for e.g. strong governance, good terms of reference, inclusive membership,	Thank you for your comment. Please see response to comment 24.

						performance management measures etc. The NICE website has some examples and this should be referenced in a way that inculcates best practice rather than accepting unmeasured heterogeneity.	
271	STH	ABPI	5	1.5	5, 6	We would welcome reference to the NHS Constitution, Innovation, Health and Wealth strategy (IHW) and financial flows. The NHS Constitution is being revised in autumn 2012. We would like to know how the further changes will be taken into account, with regard to formulary design. There is also no reference to the Secretary of State's Direction on local and transparent decision making from 2009. http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Directionsfromthesecretaryofstate/index.htm We believe this should be added to the text under statutory responsibility. Guidance should be in line with all statutory and legal obligations. In particular, the costing templates produced by NICE should be published at the same time that the NICE guidance is released, with no time lag between the two. These should be consistent, in line with the technology appraisal, undergo rigorous independent review and provide costs from Year One.	Thank you for your comment. The GDG concluded that section 1.6 outlines fully the policy context for local formularies. Thank you for your comment. This is outside the scope of the guidance. Thank you for your comment. The guidance reflects the comprehensive approach contained in the NHS Constitution Thank you for your comment. This is outside the scope of this guidance.
272	STH	ABPI	6		6	From the IHW recommendations, we would like to know if the entire T&F group comments are included here. The text reads as incomplete.	Thank you for your comment. Implementation is outside of scope for this guidance. Please see response to

						We agree with adoption of innovation but would also argue that the uptake of more established products at all stages of their life cycle equals medicines optimisation. A suggestion to NHS organisations on how to bring together disparate but related work streams e.g. responding to David Nicholson's letter regarding NICE guidance would have been helpful. There is also no mention of the standard national contract and use of pass through/ innovation payments for PbR excluded drugs. Or indeed of e.g. new HRGs for patient access schemes, IFR variation orders and so on. Explaining the mechanics of how to run a good formulary by joint working between clinicians and the accountants would go a long way towards making it clear what people have to do in practice to improve their local arrangements. The NPC did this in their competency assessments via their regional LDM facilitators and it would be good to see this work bought together in this document. This would make it more forward looking, rather than a summary of variable current practice.	comment 24.
273	STH	ABPI	7	2	7	We would welcome much more detail on how implementation priorities are to be decided in this section, possibly based on statistical analysis of a national survey. We would also encourage clear guidance on how this will be scored, possibly through working in partnership with NHS IC to develop effective metrics.	Thank you for your comment. Please see response to comment 24.
274	STH	ABPI	8	3.1	8	As the scope of this guidance currently does not cover implementation and management,	Thank you for your comment. Please see response to comment 24.

						something more robust than a reference to "parallel work streams overseen by the DH" would be helpful, particularly during a time of significant organisational turbulence. Good practice is not sufficiently articulated.	
275	STH	ABPI	9	3.2	8	We would welcome more details here with regard to workshop structure and attendees, which should be referenced given the importance of the work that this group has undertaken in the development of this guidance. We would like to know the detailed outcomes of the workshop. We would also welcome a more detailed analysis of the relative advantages and disadvantages of different types of formularies, so that NHS staff can plan for improvement.	Thank you for your comment. Please see appendix A. The guidance has been developed in line with the NICE good practice guidance interim process statement.
276	STH	ABPI	10	3.3	8	As in point 9 we would encourage publication of more details of the GDG.	Thank you for your comment. Please see appendix A.
277	STH	ABPI	11	3.4	8	This section is very light on detail. We would like to see far more details of the literature searches undertaken. There is no reference to which databases were used, what definitions were used, what search terms were included, or the timeframes within which the searches were performed. It would be helpful if this information was included in an appendix.	Thank you for your comment. Information relating to the literature search is included within appendix B.
278	STH	ABPI	12	3.5, 3.6, 3.7	8, 9	Reference is made to several important issues, but they are not listed in detail anywhere. We believe that this should be published, as they may have the potential to affect the content of the final guidance document. We are concerned at the lack of statistical analysis and the apparently low number of responses (less than half of the number of	Thank you for your comment. An invitation was distributed to 9278 individuals on the NICE medicines and prescribing database asking for the submission of information they felt might be useful in the development of the good practice guidance. It was not a direct survey of all local formulary

						formularies, assuming that each large acute trust has one).	groups and analysing the 'response rate' is inappropriate. There is no definitive list of local formulary decision-making groups and therefore the total number of local formularies is not known. Some formularies cover a larger number of organisations, and therefore trusts, than others. The GDG concluded that the methodology was appropriate given the available literature.
279	STH	ABPI	13	4.1	10	This section lacks examples and does not set out clearly what good practice looks like. We would also encourage the recommendation of particular best practice rather than stating "it depends" – a re-focus on quality and patient flows and experience between services would be useful. This would also help the new NHS architecture in planning resources and in reducing duplication and increasing consistency. We would like to see a diagram of taxonomies, e.g. a secondary care led D&T, through to a more inclusive APC showing joint working across health sectors. The diagram would also benefit from inclusion of interactions with e.g. clinical networks, CDF, the pharmaceutical industry and so on. This section needs to be a lot more detailed and visual.	Thank you for your comment. Please see response to comment 24.
280	STH	ABPI	14	4.1.1	11	An explanation of how to map stakeholders and processes is needed and should not be assumed. We are in agreement that the formulary needs integration with other groups but this section also needs tightening up, e.g. which risk stratification tool? (traffic lighting systems can	Thank you for your comment. This is outside the scope of this guidance.

						vary from one trust to the next). Again, a best practice example would help to illustrate this more clearly.	
281	STH	ABPI	15	4.1.2	11	We would suggest that referencing management literature on e.g. the maximum number of people at a meeting for it to be effective, corporate governance regarding accountability from the recent H&SC Bill would be beneficial. Otherwise there is the potential for groups to say they cannot agree because their membership is large, or by going in the other direction, they will not engage everyone they need to, so they become inert and ineffective. Perhaps a way to address this is by defining a clear annual work programme that should be signed off by trust Boards. Again, good examples will add value.	Thank you for your comment. The GDG concluded that the guidance should not be specific about the size or composition of the local formulary decision-making group. Optimising this is dependent on a large number of local factors.
282	STH	ABPI	16	4.2	11	We would support the provision of more background information – the explanation why the NHS moved from the BNF to local formularies plus some examples from international literature on benefits, e.g. wide use in US managed care. We welcome the inclusion of engaging with pharma, as manufacturers have the most information about their products. Perhaps this information would be better in a background reading section and included in the references.	Thank you for your comment. The GDG concluded that the succinct background section sufficed. Thank you for your comment. Manufacturers are included in section 4.4, recommendations 2.4.1 and 2.5.5 and appendix C.
283	STH	ABPI	17	4.2.1	12	This section must be more specific and relate directly to commissioners and providers.	Thank you for your comment. The GDG concluded that it should outline the principles for the scope of the local formulary. The details of the scope are for local consideration and determination.

284	STH	ABPI	18	4.2.2	12	We would encourage the Terms of Reference (TORs) and work plan to be ratified by NHS Boards.	Thank you for your comment. Please see response to comment 24.
285	STH	ABPI	19	4.3	12	We would encourage consideration of providing good examples for people to see, which shares best practice and innovation, and avoids unnecessary repetition of work. Medicines not subject to NICE appraisal should be assessed for improvement of outcomes and we would encourage a statement about the need to consult with manufacturers since they have the most information about their products.	Thank you for your comment. Please see response to comment 24.
286	STH	ABPI	20	4.4	12,13	We believe that far more emphasis on patient groups is required here, particularly since all the policy drivers like 'No Decision About Me, Without Me' puts patients at the centre of everything we do. We agree with and support the referenced framework, which is excellent, but it may benefit from a review of the communication strategy. We would also support consideration of industry membership, similar to the way AWMSG has industry input as part of their group.	Thank you for your comment. The GDG concluded that the guidance was clear on the need to engage with patients and the public. Please see recommendations 2.4.1 and 2.14.1. Please see response to comment 6.
287	STH	ABPI	21	4.4.1	13	We would be interested to know whether local groups, if they are going to include members of the public, can hold formulary meetings in public. The Coalition Government has a very clear agenda on openness and transparency in Government and there are also the Nolan principles of public life. We would also recommend that all stakeholders are involved in decisions and that these are not made in the absence of the key clinician. These decisions should be a balanced view of the Committee and not dominated by the pharmacist	Thank you for your comment. Please see response to comment 244.

						view as is often the case at present.	
288	STH	ABPI	22	4.5	13	We believe that this section needs to be far more robust. With reference to all the guidance on CCG and CSS authorisation, where there are sections in both on medicines optimisation, this could be included in order to give the NHS a more practical guide.	Thank you for your comment. This is outside the scope of this guidance.
289	STH	ABPI	23	4.5.2	13	We reference to the previous comment. This section could link to the guidance above and reflect patient flows. There is plenty of management literature that shows what level of decision making is effective and what is considered to overly extend transaction time. There needs to be a connection between this and CCGs and the rest of the new NHS architecture.	Thank you for your comment. This is outside the scope of this guidance.
290	STH	ABPI	24	4.6	16	We would encourage the last sentence of this section to include 'and financial flows agreed in standard national contracts.'	Thank you for your comment. The GDG concluded the wording in this section was sufficient.
291	STH	ABPI	25	4.6.1	14	We believe this section must include the word "annually" and be combined with 4.6.2	Thank you for your comment. The GDG concluded that the guidance should not be specific about when reviews should take place. Some local formulary decision-making groups could need reviewing earlier than annually and equally reviewing groups which do not require reviewing annually would be inefficient.
292	STH	ABPI	26	4.7	14	This whole section simply lists who to talk to and would benefit enormously from providing advice on how to develop a clear communications plan.	Thank you for your comment. The GDG concluded that the section contains sufficient detail to be helpful without being overly prescriptive.
293	STH	ABPI	27	4.8	15	We would encourage reference to policies on ethical decision making in this section. The revised NHS Constitution will focus on this when	Thank you for your comment. See section 4.7 and comment 24 regarding implementation.

						it is published. The NHS Confederation has also written some good papers in this area, by (Dr) Daphne Austin. This section would also benefit from having more examples set out in the appendix of e.g. a well-designed IFR form.	
294	STH	ABPI	28	4.8.1	15	We would recommend that the summaries referred to here are given in a link.	Thank you for your comment. Please see response to comment 34.
295	STH	ABPI	29	4.8.2	15	We would refer the GDG to recent letters from Keith Ridge and David Nicholson on this subject, and change the words 'should/ could' to must, which would help ensure compliance.	Thank you for your comment. This section has now been reworded. Please see section 4.6.
296	STH	ABPI	30	4.8.3	15	We would recommend the same action here as in the point above.	Thank you for your comment. Please see response to comment 295.
297	STH	ABPI	31	4.8.4	15	We suggest there may be benefit in having a partnership with the manufacturer in this process.	Thank you for your comment. Please see recommendation 2.5.5.
298	STH	ABPI	32	4.8.5	15	We would encourage inclusion of a statement about working in partnership with pharma as well as a recommendation that this is done once nationally, otherwise there is a risk of re-creating mini regional HTAs that duplicate effort and waste valuable resource.	Thank you for your comment. Please see response to comment 163 and recommendation 2.8.2.
299	STH	ABPI	33	4.8.6	16	We would agree with evidence gathering by the pharmaceutical industry to support prescriber development and ownership of a formulary submission.	Thank you for your comment. No response required.
300	STH	ABPI	34	4.8.7	16	In line with the recommendations from IHW, and the letters from Keith Ridge and David Nicholson, we would support publication of all paperwork, whether formulary applications or minutes of meetings into the public domain.	Thank you for your comment. Please see response to comment 6.
301	STH	ABPI	35	4.8.8	16	We would recommend including good examples in the appendix.	Thank you for your comment. Please see the response to comment 24.
302	STH	ABPI	36	4.9	16, 17	The current guidance on adoption of NICE recommended medicines is clear. We would	Thank you for your comment. Please see section 4.6 and recommendations

						encourage that this section should be explicit in its recommendations on making NICE approved medicines available to all patients who would benefit from them through local formularies, without further local assessment.	2.6.1 and 2.8.1.
303	STH	ABPI	37	4.10	17	The inconsistency in decision making is a major concern. It is not acceptable to state that as long as the methodology is set out, variation is acceptable. It is not.	Thank you for this comment. Local decision-making is legitimate. See 'Supporting rational local decision-making about medicines (and treatments)', produced by the National Prescribing Centre (2009).
304	STH	ABPI	38	4.11	17	We believe that this section contradicts a recent letter from David Nicholson, and the experience of the pharmaceutical industry with regard to local appraisal of NICE approved medicines. However there is a difference between reproducing the work of NICE and service planning, e.g. working out where a new treatment sits in an algorithm. We would encourage a strong statement here, backed up by facts and statistics. There is no need for further local or regional review of a NICE approved medicine once it has been assessed nationally.	Thank you for your comment. The GDG concluded that the wording within section 4.8 reflects the evidence found. Recommendation 2.8.1 makes it clear where there is a NICE technology appraisal there should be no further duplication of the NICE evidence assessment, or challenge to an appraisal recommendation.
305	STH	ABPI	39	4.11.1	18	We would encourage that this section is worded to be far more specific. Clear guidance and templates on what local appraisal for a medicine without NICE HTA approval would provide localities with practical support.	Thank you for your comment. Section 4.8 and 4.9 provide more detail.
306	STH	ABPI	40	4.11.2	18	We agree that localities will need appropriate skills and competencies to undertake a high quality appraisal. Some indication of what the level of resource may be would be useful. It is not appropriate use of NHS resource for every formulary group to attempt to carry out mini	Thank you for your comment. Please see the response to comments 178 and 199.

						QALYs.	
307	STH	ABPI	41	4.12	18	The ABPI strongly agrees with the fact that clinically and cost effective treatments positively impact healthcare budgets. We would encourage the inclusion of more references on cost benefit analysis here. We would also encourage some mention of the year of care pilots and Patient Level Information Costing (PLICS)	Thank you for your comment. This is out of scope. Please see response to comment 24.
308	STH	ABPI	42	4.12.1	18	We believe that financial and commissioning agreements need to be in place and set as a standard part of formulary decision making processes.	Thank you for your comment. See section 4.10.
309	STH	ABPI	43	4.13	19	Rejecting branded medicines when there is a significant generic market is not always in the best interests of patients. Therefore we would welcome a clear and transparent process for reviewing therapy areas in a formulary that does not focus solely on price but that also includes the latest clinical and other data from the manufacturer.	Thank you for your comment. See recommendation 2.16.1 which encompasses responding to all important new evidence in formulary reviews.
310	STH	ABPI	44	4.14	19	We would encourage the citing of examples of good practice, and reference to appropriate training and support	Thank you for your comment. Please see response to comment 24.
311	STH	ABPI	45	4.14.1	19, 20	There should be some mention of the Freedom of Information Act and its relevance to this section.	Thank you for your comment. The GDG concluded that reference to the Freedom of Information Act was not needed within this section. See recommendations 2.14.1 and 2.14.2.
312	STH	ABPI	46	4.15	20	We would encourage the inclusion of a glossary to explain the difference between e.g. protocol and policy, plus publishing examples of good practice in the appendix.	Thank you for your comment. The GDG did not consider it necessary to include a glossary. Key terms are defined within the document and/or referenced. Implementation is out of scope. Please see response to

							comment 24.
313	STH	ABPI	47	4.15.1	20	The meaning of this paragraph is unclear. We would encourage its removal and replace it with a sentence that states the communication policy should be clearly agreed with all relevant parties and that clinicians, patients and manufacturers should know the outcome of decisions made with minimal delay.	Thank you for your comment. We agree with this comment and the recommendations within this section have now been reworded.
314	STH	ABPI	48	4.16	20	We would encourage this section to be far more prescriptive as it is not just about process; it is also about patients waiting for a decision in order to get their medicine. To improve efficiency, it would be advisable to have decision making in a single place, rather than a confusing succession of different committees.	Thank you for your comment. The section on accountability has been reworded, strengthened and clarified following feedback.
315	STH	ABPI	49	4.17	21	Our view is that all formularies and associated documentation relating to medicines should be in the public domain. Re 4.17.2 use NHS brand rules http://www.nhsidentity.nhs.uk/ Communication should include conveying outcomes to the manufacturers.	Thank you for your comment. Please see response to comment 6.
316	STH	ABPI	50	4.18	21	We would encourage the expansion of this section to include clear guidance on what a good appeals process should look like for all relevant parties to include patients, healthcare professionals and industry, particularly if it can be clearly demonstrated that one formulary has accepted a medicine and another has not, and that there are no valid reasons for the difference. A lack of consideration of a full and balanced application should be sufficient grounds for appeal.	Thank you for your comment. This section has been extensively reworded by the GDG post-consultation.
317	STH	ABPI	51	4.18.2	22	We would encourage this section to include far more detail on the constitution of an appeal	Thank you for your comment. Please see response to comment 316 and

						panel, along with examples of good practice.	response 24 regarding implementation.
318	STH	ABPI	53	4.20	23	There seems to be omission of a lot of detail here, for example IFRs (is it a population or an individual approach?), and there is no mention of patients, industry, regulators or commissioners.	Thank you for your comment. The flowchart is intended to summarise the local formulary process clearly and concisely, and does not consider the entirety of local arrangements. Some of these may vary in different localities.
319	STH	ABPI	54			There are a number of gaps: The largest is medicines use in specialised services. How is the managed entry of new products commonly covered by Specialised Commissioning Groups (and from April 2013), the NHS Commissioning Board to be undertaken? Are these to be included on local formularies? There is no mention anywhere in the document about these products. We are aware that work is progressing elsewhere, but none of this is captured in this document, and that is a major and concerning omission. In addition, there is no mention of: • Audit • Measurement – PACT for primary care, what is happening for secondary? Are we still using DDDs and bed days? Or the proportionality of a medicine within a therapeutic group? Lots of work is being done with FCEs and case mix with PharmEx. Scotland use HMUD • No mention of inequalities • How can this support better commissioning? E.g. links to NICE	Thank you for your comment. The developing arrangements for specialised commissioners are not confirmed and cannot be included within this guidance. Many aspects are likely to be out of scope. Audit and measurements – please see response to comment 24. Following the guidance on accountability and reporting arrangements (within 4.3) and

						Commissioning Guides • Is it about driving change in prescribing guidelines or compliance with guidelines?	deliberating and reaching decisions (4.11) would undoubtedly encompass inequality issues. Links to commissioning and guidelines are also explicit in the guidance.
320	STH	Boehringer Ingelheim	1	General		As a manufacturer and supplier of medicines, Boehringer Ingelheim is a stakeholder in the consultation,, and welcomes the opportunity to be part of the development of the Local Formularies Good Practice Guidance. Boehringer Ingelheim welcomes the development by NICE of Guidance on Local Formularies. Boehringer Ingelheim believes in the principles of • Transparency • Consistency • Fairness in the basis for evidence Should these principles be adopted, the current system will be greatly enhanced. Formularies, when adopted and implemented optimally, should allow the NHS to take rational, evidence based decisions about the availability of medicines and technologies – ensuring consistent uptake and diffusion of innovation at local level. **Transparency** Formulary decisions should be transparent, and	Thank you for your comment. No response required. The GDG considers that the guidance is consistent with addressing these comments/issues.

						ensure that when a medicine has been appraised by NICE, that the medicine is available for clinicians to prescribe for all appropriate patients, unequivocally. Should this system be implemented, it will serve to eliminate unwarranted variation in healthcare provision, medicines availability and outcomes for patients. The current situation is significantly far from this in many areas in England. • The formulary process lacks transparency, with Senior Clinicians often being the last to learn of a formulary and its outcome. • Patients and patient advisory groups are also unaware of the existence of a formulary, resulting in a poor understanding and frustration about the lack of availability of a particular medicine. **Consistency** There is no standard formulary process in England, with different trusts and Primary Care Organisations adopting variable processes, which result in post-code prescribing and variation in healthcare provision and outcomes. For example, lack of consistency, currently results in medicines which have been approved	

						as the result of a NICE technology appraisal in England being widely available for prescribing by General Practitioners in some areas. In other areas, the same medicine, and the same TA through a different formulary, results in *secondary care only* prescribing. This significantly restricts access to the medicine, and serves to increase referrals and resulting costs to the NHS. **Fairness in the basis for evidence** Sources of evidence vary from NICE Technology Appraisals being fully utilised as a source of evidence to being totally disregarded in many cases. In the majority of cases, local NHS Formularies do not currently adopt the wording or indeed the spirit of NICE TA's – and regularly place further barriers to the availability of a medicine to clinicians to prescribe. The impact of this is to deny eligible patients access to a medicine which has shown to be *cost effective* and would benefit them. Where evidence **is** used from a NICE TA to support a local formulary decision, there is a strong need for ***good practice*** and ***consistency*** in the supporting critical information in the form of costing templates(CT) – which is also currently lacking.	Responsibilities for prescribing and for administration settings are often a legitimate matter for local determination. The GDG did not see evidence to support the statement that the majority of local formularies do not adopt NICE technology appraisals. This comment relates to NICE costing templates and is out of scope.

						• The costing template should be published with the guidance to ensure commissioners are able to begin the implementation process and hit the 3 month deadline. (Dabigatran CT was published nearly six months after guidance(TA249) and three months after the end of the implementation period) • Costing templates should reflect the technology appraisals and be consistent with each other (not the case with TA249 and TA256 which had different costs for the **same** event) • Costing templates should be developed in parallel with the TA and undergo a rigorous independent review process (e.g. like an ERG) • Costing templates should provide costs from year one. Currently only costs using the default NICE assumptions available from Year 1 despite a recommendation in the CT to use local costs if possible **Summary** Boehringer Ingelheim welcomes the intent of the Good Formulary Guide, and supports its development. In order to be effective, and drive system	

						change, Boehringer Ingelheim recommends 1. A standard formulary process spanning Primary and Secondary Care in the form of a Joint Formulary 2. Automatic adoption of NICE approved medicines onto all formularies resulting in prescribing and patient access to these medicines within the 90 day period. 3. A re-examination of the supporting evidence process surrounding the development and publication of costing templates Finally, in order for the good practice guide to have meaningful traction – Boehringer Ingelheim recommends that the implementation of its recommendations be “hard wired” into NHS systems which drive reward and recognition such as CQINN, the Commissioning Outcome Framework and CCG Authorisation.	Thank you for your comment. Please see response to comment 26. Thank you for your comment. This is covered in section 4.6. Thank you for your comment. This is out of scope. Thank you for your comment. Please see response to comment 24.
321	STH	British Pharmacological Society	1	General		The practical value of the recommendations lack clarity.	Thank you for your comment. The recommendations outline the principles for developing and updating local formularies. The scope of this guidance does not include processes relating to implementation and performance management of local formularies. See response to comment 24.
322	STH	British	2	General		While page 5. Section 1.3 indicates that patients	Thank you for your comment. The

		Pharmacological Society				that meet NICE criteria should routinely be offered the appropriate drugs on the local formulary, this is partly contradicted by Recommendation 4.9.2, page 17 'Where a NICE technology appraisal states 'option for treatment' the medicine should be adopted onto the local formulary and decision-making groups should assess its place in the local pathway.' My own experience (from 8 years service on formulary committees) is that local decision-making groups have in many instances decided that the NICE approved drug has no place in the local pathway due to the expense, or that there are additional local restrictive criteria beyond that suggested by NICE in order to limit availability and numbers of patients eligible. This leads to the perverse situation where drugs are listed on a local formulary, but with different (usually much more restrictive) eligibility criteria than what NICE have originally stipulated. I think the guidance panel needs to be much clearer about what they mean about being adopted on a local formulary, as being listed in formulary per se does not mean that the drug is available to qualifying patients (due to the drug being placed differently in the local pathway from what NICE envisaged).	NICE definition of the term 'option for treatment' is incorporated into the good practice guidance. The corresponding recommendation (2.6.2) has been amended. Recommendation 2.6.1 has also been reworded to say that medicines with a positive NICE technology appraisal should be included within the relevant care pathway(s), in line with NICE recommendations.
323	STH	Astellas Pharma Ltd	1	General		Astellas welcomes NICE's recommendations to strengthen the process of updating local formularies so that it becomes more transparent and systematic. However, without a clear system of oversight and accountability, it is not clear whether the guidance will improve the quality and consistency of local formulary development. Astellas recommends that NICE	Thank you for your comment. Please see response to comment 24.

						develops performance metrics to underpin the final set of recommendations, against which local improvements should be measured.	
324	STH	Astellas Pharma Ltd	2	4.7	14	Astellas agrees with the recommendation that there should be a process of consultation with relevant stakeholders before formulary changes are made. It is important that through this process, formulary groups and committees seek to understand the impact to patients of any formulary changes, and the need to ensure that clinicians working with patients have the autonomy to make the right treatment decisions together – any treatment changes must above all be clinician and patient-led. Astellas calls for recommendation 4.7 to be strengthened so that relevant manufacturers are routinely consulted prior to a decision being made rather than solely at the discretion of the panel – eg in cases where [manufacturers] are deemed to "*offer additional evidence and insight that can assist with decision-making"*. One example of good practice is the Greater Manchester Medicines Management Group (GMMMG) which has developed a clear process for formulary additions/new therapies which is available online: http://www.nyrdtc.nhs.uk/gmmmg The GMMMG recently completed a formulary review on most of the chapters of the BNF using a robust, transparent and fair process. In one of Astellas' therapy areas, the consultation started	Thank you for your comment. No response required. Thank you for your comment. No response required.

						in May 2011 when GMMMG invited manufacturers to attend a stakeholder meeting where they outlined their aims and the process. GMMMG also released a draft formulary on which they invited feedback. This was open to local clinicians and manufacturers, with submissions being made through their website. The process was fully inclusive so that a broad range of evidence could be considered by the group.	
325	STH	Astellas Pharma Ltd	3	4.15		Third sector organisations and manufacturers should be given the opportunity to contribute supportive materials that can form part of the decision outputs such as commissioning care pathways that have been developed as a result of partnership working.	Thank you for your comment. Recommendation 2.13.1 recommends the development of decision outputs with stakeholders. Manufacturers are included as stakeholders in section 4.4.
326	STH	Astellas Pharma Ltd	4	4.17		Astellas supports the recommendation to improve the way that formularies are communicated, and suggests that the guidance also stipulates that as well as information being provided clearly, it should also be provided in a timely way.	Thank you for your comment. Please see recommendation 2.3.4.
327	STH	Lilly UK	1	General		We thank NICE for the opportunity to comment on the draft of this important document and recognise the considerable amount of work that has been put into researching this topic. Please see our detailed comments on the draft guidance below.	Thank you for your comment. No response required.
328	STH	Lilly UK	2	General		Please could NICE clarify the scope of this	Thank you for your comment. The good practice guidance is concerned

						guidance beyond 2014 once Value Based Pricing is in place. Or will this guidance be updated to be available once VBP is finalised?	with systems and processes relating to local formulary development. It is not clear whether updating will be required once Value Based Pricing is in place, but this will be considered.
329	STH	Lilly UK	3	General		We would recommend an Executive summary that clearly states: • Purpose of the guidance • Current policy drivers and the NHS Constitution • Key recommendations We would suggest an Appendix that includes the methodology and some of the discussion around current practices.	Thank you for your comment. As the guidance is published in a web-based format, it was not felt necessary to include an Executive Summary. The bullet points mentioned are all included in sections 1 and 2 of the guidance. Thank you for your comment. The methodology is available in section 3. Planned appendices have now been added to include more information on the GDG (please see appendix A) and the literature search (please see appendix B).
330	STH	Lilly UK	4	General		We would suggest that guidance be given regarding timelines to act on the recommendations or guidance around how long certain decisions should take. This could allow for processes to be implemented now, and be in place by April 2013 to coincide with the Innovation Health and Wealth (IHW) requirements.	Thank you for your comment. This is out of scope. Please see response to comment 24.
331	STH	Lilly UK	5	1.1	4	The document states that it is providing good practice recommendations to ensure 'NHS organisations' develop and update local formularies. Please could the GDG clarify whether this covers England only, or England,	Thank you for your comment. The wording has been clarified.

						Wales and Scotland? The document states that it does not 'seek to define an optimum population size or number of provider organisations'. To assist formulary decision bodies with implementation it may be useful to provide a recommendation about the level at which local formularies should sit and whether this should sit at LAT or Network level, or give guidance on options in different situations.	Thank you for your comment. The GDG agreed that the scope of the formulary should be agreed locally through consultation with all locally defined stakeholders and section 4.2 discusses the variation in the range of healthcare providers covered by local formularies. The recommendations for practice allow organisations to balance the risks and benefits of different models locally.
332	STH	Lilly UK	6	1.3	4	Variation across the country and potential benefits are listed, however we would find it beneficial to more clearly articulate the purpose of a local formulary.	Thank you for your comment. The GDG concluded the level of detail in this section was appropriate.
333	STH	Lilly UK	7	1.5	5	We wonder whether there should be a section that sits under the statutory responsibility section that provides guidance on what the NICE wording of 'option' means? This would be in line with the recent NICE communications whereby: "medicines recommended as an option are an option for clinicians and not for funding". We believe that, as a key driver of appropriate practice, the section on the context and NHS Constitution and IHW could be utilised when describing the definition and purpose of local formulary.	Thank you for your comment. See response to comment 7.
334	STH	Lilly UK	8	4.5	13	We would suggest an additional recommendation be made here about making sure the local formulary is developed at an appropriate level within the NHS to not result in	Thank you for your comment. See response to comment 178.

						any unnecessary duplication of efforts or resource utilisation.	
335	STH	Lilly UK	9	4.7.1	14	We support the clear inclusion of manufacturers as key stakeholders for consultation and engagement.	Thank you for your comment. No response required.
336	STH	Lilly UK	10	4.8	15	We believe this good practice guidance would benefit from the inclusion of processes for how and when to make Individual Funding Requests (IFRs).	Thank you for your comment. Section 4.15 on reconsideration and appeals has been updated following consultation and now makes reference to the IFR process.
337	STH	Lilly UK	11	4.8.4	15	We propose further clarification when a NICE technology appraisal has not been recommended. To address this we would suggest the text be re worded to state:"Where NICE does not recommend a medicine and the local decision has been made not to fund a medicine....". The text could then address decommissioning as part of the work of local formulary groups and to decide locally whether or not to fund drugs that are not NICE approved. We would also suggest that where NICE does not recommend a medicine and the local decision has been made not to fund a medicine, the guidance indicate how this decision will be communicated to patients. An additional sub point discussing situations where a drug with a negative NICE appraisal receives local funding would also seem appropriate. Please could the document also clarify how to develop and update formularies with respect to	Thank you for your comment The GDG agreed that in circumstances where a medicine is not recommended in a NICE technology appraisal, discussions and actions on withdrawing and decommissioning a medicine should be considered in line with NICE recommendations. For example, NICE guidance may state that people currently receiving a medicine within its licensed indication that has not been recommended should have the option to continue therapy until their clinicians consider it appropriate to stop. See recommendation 2.5.3. Local formulary decision-making groups should consider how all formulary information is disseminated (see section 4.14). Thank you for your comment. Arrangements for specialised

						the Cancer Drugs Fund, which specifically addresses oncology treatments for patients who have been unable to access a drug recommended by their oncologist?	commissioning and the cancer drugs fund are changing and due to the current lack of clarity it was considered not possible to include them within this guidance.
338	STH	Lilly UK	12	4.8.8	16	The document states that applications for new healthcare treatments should include cost effectiveness data. Please could the GDG provide guidance where the NHS should access this information in the absence of a published NICE appraisal or SMC recommendation? Or would this only apply to drugs that have either undergone a NICE review or an SMC review?	Thank you for your comment. The GDG felt that cost-effectiveness/ resource impact should be included within standard criteria for decision making. However, cost-effectiveness data will not be available for all medicines.
339	STH	Lilly UK	13	4.9	16	We believe this would be an appropriate place in the document to advise that NICE assessments should not be re done so as to avoid unnecessary costs and resource use to the NHS.	Thank you for your comment. See recommendation 2.8.1.
340	STH	Lilly UK	14	4.9.2	17	As per NICE's decision to proactively clarify the wording 'option' included in publications, would it be useful for the GDG to also add the NICE clarification that medicines recommended as an option are an option for clinicians and not for funding?	Thank you for your comment. See response to comment 7.
341	STH	Lilly UK	16	4.17	21	We feel the document could be extended to include guidance on how to address the rights of patients to have decisions about medicines not funded, following a proper consideration of the evidence, explained to them, as per the NHS Constitution.	Thank you for your comments. The GDG concluded that a clinician is best placed to submit a formal appeal on behalf of their patient population for the inclusion of a medicine within a local formulary. Where a clinician considers an individual patient to be exceptional to a commissioning policy, funding for a

							medicine should be requested through the local individual funding request (IFR) process. The IFR process and other mechanisms for patient's to appeal are not included within this guidance.
342	STH	Lilly UK	17	4.18	22	The document does not appear to address the mechanism for patients to appeal if, as per the NHS Constitution, they have not had the reason for a medicine not being funded explained or they believe proper consideration of the evidence has not taken place. We wonder whether the reader would benefit from some additional guidance around this point?	Thank you for your comment. The GDG discussed the ability of patients or patient groups to appeal a decision made by the local formulary decision-making group. See responses to comments 118 and 341.
343	STH	Lilly UK	18	4.20	23	We felt this flow chart could benefit with inclusion of medicines that are reviewed at launch and pre NICE. The flow chart would be more useful to readers if it covered all of the work of formulary groups. Please could you clarify what is meant by 'managed' adoption into the formulary of medicines that have received a positive NICE recommendation?	Thank you for your comment. Please see response to comment 318. The term 'managed adoption' has been reworded.
344	STH	Northampton General Hospital	1	4.4.1	13	Inclusion of patients and the public on local formulary decision making groups, may not be appropriate	Thank you for your comment. Please see response to comment 70.
345	STH	Northampton General Hospital	2	4.9.2	17	After due consideration of a positive TA, if an alternative NICE approved "option for treatment" is preferred on the formulary, why is it mandatory to add both to the formulary? This creates issues e.g. should we stock the drug though not likely to use it, do we write local	Thank you for your comment. See response to comment 7.

						guidance for options not likely to be used etc	
346	STH	Heatherwood and Wexham Park Hospitals NHS Foundation Trust	1	4.8.2	15	Where there is more than 1 technology appraisal for the same treatment indication, and where the appraisals gives these treatments an equal level of efficacy, it is most appropriate for an organisation to select one of these treatments only to minimise risk of error in practice. This may be reviewed at such a time when there is either evidence of superiority for one of the technologies over the other, or until such a time that a cost advantage is presented of sufficient magnitude to compensate for changes in policies and procedures. An example of this is: TA245 Apixaban for the prevention of venous thromboembolism after total hip or knee replacement in adults TA157 Dabigatran etexilate for the prevention of venous thromboembolism after hip or knee replacement surgery in adults TA170 Rivaroxaban for the prevention of venous thromboembolism Having all products on the shelves on the wards, and separate guidelines for treatment and follow-up increases the risks. How organisations manage this needs to be clear in the final guidance	Thank you for your comment. See response to comment 7.
347	STH	Heatherwood and Wexham Park Hospitals NHS Foundation Trust	2	General		It is not fair to expect organisations to implement NICE TA's when the costing templates have not been published. In fact, this draft expands the need for organisations not only to implement appraisals within the 90 period after publication, but also to plan during the horizon scanning period. Surely, NICE should be publishing the costing templates in time for this exercise to be	Thank you for your comment. This is out of the scope of this guidance.

						carried out. Additionally, NICE guidance should be clear about which treatments should be carried out in Primary and which in Secondary and Tertiary Settings – this again is essential if uniformity of provision is to be attained	
348	STH	AstraZeneca UK Ltd	1	General	1	We recommend that this guidance is titled “Best Practice Guidance” rather than “Good Practice Guidance” to ensure adequate implementation by NHS organisations	Thank you for your comment. The title is consistent with the interim process statement.
349	STH	AstraZeneca UK Ltd	2	General	1	We recommend that there should be a foreword from Sir Andrew Dillon or Sir Michael Rawlins setting out the national importance of this issue, to provide context	Thank you for your comment. Style will be consistent with other NICE guidance which does not include such forwards.
350	STH	AstraZeneca UK Ltd	3	General	7	The key priorities for implementation of this guidance should be included in the scope of this consultation.	Thank you for your comment. The NICE guidance executive recommended that the key priorities for implementation be removed from the guidance. See section 2.
351	STH	AstraZeneca UK Ltd	4	General		The Guideline Development Group should consider using boxes to illustrate examples of best practice which informed the recommendations.	Thank you for your comment. This is out of scope. See response to comment 24.
352	STH	AstraZeneca UK Ltd	5	General	1	To make clear the benefits/incentives of adhering to this guidance in line with Sir Davia Nicholson’s and Dr Keith Ridge’s letters sent to the NHS in August 2012, particularly around publishing implemtnatation of TAGs	Thank you for your comment. Dr Keith Ridge’s letter has now been incorporated. See section 1.6.
353	STH	AstraZeneca UK Ltd	6	4.1.1	11	The role of Area Prescribing Committees and clinical networks are critical but seem to have been omitted from the Guidance.	Thank you for your comment. The guidance does make a number of references to other decision-making bodies and clinical networks. See sections 4.1, 4.2, 4.4, 4.16.
354	STH	AstraZeneca UK Ltd	7	4.3.3	12	Terms of reference should also include targets for funding NICE approved medicines to ensure accountability to the local community	Thank you for your comment. While the guidance does not include ‘targets for funding’ the principle of this comment is

							now covered in section 4.14 and recommendation 2.14.2, in line with the NHS Chief Executive's letter.
355	STH	AstraZeneca UK Ltd	8	4.4	12	We recommend making patient representation mandatory in line with the Government's 'No decision about me; without me' initiative.	Thank you for your comment. Please see response to comment 70.
356	STH	AstraZeneca UK Ltd	9	4.5	13	Under Resourcing, it should be explicitly stated that the decision-making group should not duplicate NICE assessment	Thank you for your comment. Please see recommendation 2.8.1.
357	STH	AstraZeneca UK Ltd	10	4.7.1	14	The manufacturers can also provide information on other formularies appraising the same medicine to ensure appropriate allocation of resource and to avoid duplication of effort within the same region/geographical area..	Thank you for your comment. No response required.
358	STH	AstraZeneca UK Ltd	11	4.8.2	15	We recommend to add 'no duplication of NICE assessment or further restriction on NICE recommendation' in keeping with the IHW report's findings	Thank you for your comment. The recommendation has now been reworded. See recommendation 2.8.1.
359	STH	AstraZeneca UK Ltd	12	4.8.5	15	We recommend adding 'clinical support' and 'level of unmet need'	Thank you for your comment. The specific criteria would be for local consideration and determination. The 'level of unmet need' would be covered within the criteria stated in recommendation 2.5.4.
360	STH	AstraZeneca UK Ltd	13	4.9	16	Please contact Dr Elisabeth George, Associate Director at NICE for a correct definition of 'option for treatment' which can be now be viewed on recent consultation documents and is to be applied retrospectively to previous TAGs from recent communication with Sir Andrew Dillon.	Thank you for your comment. See response to comment 7.
361	STH	AstraZeneca UK Ltd	14	4.10.1	17	We challenge the recommendation to include cost effectiveness . Do decision-making groups have the appropriate knowledge/resource to undertake an independent cost effectiveness analysis?	Thank you for your comment. The GDG concluded that cost-effectiveness should be included within standard criteria for decision making, but recognised that this may require

						Do decision-making groups have the appropriate knowledge to understand 3rd party cost effective analyses and the implications for their local health economy?	technical expertise (as may other prioritisation criteria), as stated in this comment.
362	STH	AstraZeneca UK Ltd	15	4.15.1	20	We should ensure that recommendations are available in the public domain to ensure accountability to the local community	Thank you for your comment. See section 4.14.
363	STH	AstraZeneca UK Ltd	16	4.17.2	21	We should ensure that the notes and minutes are transparent, robust and available on the internet.	Thank you for your comment. See section 4.14.
364	STH	AstraZeneca UK Ltd	17	4.18.1	21	Members of the public should have right of appeal to decisions made.	Thank you for your comment. The GDG concluded that a clinician is best placed to submit a formal appeal on behalf of their patient population. Individual patients have existing mechanisms for appeal. See section 4.15.
365	STH	AstraZeneca UK Ltd	18	4.20	23	Further clarification is required to further explain what the GPG mean by 'managed adoption'	Thank you for your comment. The term 'managed adoption' has been reworded.
366	STH	AstraZeneca UK Ltd	19	4.13	19	We recommend that there should be an opportunity for the Manufacturer to factual accuracy check before publication in the public domain. This is in keeping with current UKMi process.	Thank you for your comment. The GDG felt that the guidance could not make explicit recommendations regarding local quality assurance processes. The recommendations outline the principles for developing and updating local formularies, but the details of the process are for local consideration and determination.
367	STH	AstraZeneca UK Ltd	20	4.10	17	Role of NHS Evidence needs to be clarified.	Thank you for your comment. The role of NHS Evidence is out of scope. NHS Evidence is an important source of information on medicines and is included in appendix C.
368	STH	AstraZeneca	21	4.10	17	The role of Local Action Teams in the updating	Thank you for your comment. The role

		UK Ltd				of local formularies need to be clarified.	of LATs in this area is currently not clear and therefore could not be included.
369	STH	AstraZeneca UK Ltd	22	1.5	5	We recommend the inclusion of the mandate with specific reference to R&D and uptake and implementation of NICE approved medicines.	Thank you for your comment. Please see section 1.6.
370	STH	AstraZeneca UK Ltd	23	4.6	13	Who is accountable for this process within the local decision-making process in terms of seniority? Will they also be accountable for implementation of NICE-approved medicines? Without clear lines of accountability, local NHS organisations will simply dely implementating NICE guidance	Thank you for your comment. Lines of accountability and reporting arrangements should be included within terms of reference for local formulary decision-making groups (see recommendation 2.3.1).
371	STH	AstraZeneca UK Ltd	24	4.20	23	We recommend that It should be made clear on the diagram: “Stakeholder engagement and managed adoption into formulary within three months”	Thank you for your comment. The GDG concluded that the expected timeline for adopting a positive NICE technology appraisal is clear and unambiguous throughout the good practice guidance.
372	STH	NHS Sheffield (Sheffield PCT)	1	1.1	4	It would be of assistance if this section clarifies the level of local formulary. Does the definition “NHS organisations” include a GP practice or groups of practices such as localities or associations, who may develop their own formularies?	Thank you for your comment. The GDG agreed that a formulary operating solely within one organisation is not likely to cover the whole care pathway. This is reflected in the guidance (see section 4.2). However, the scope of the local formulary should be agreed locally through consultation with all locally defined stakeholders (see recommendation 2.2.1). The guidance does not define an optimum population size or number of provider organisations involved in developing and updating local formularies. The recommendations for practice allow organisations to balance the risks and

							benefits of different models locally.
373	STH	NHS Sheffield (Sheffield PCT)	2	4.4.1	13	We have also found difficulty in securing public involvement in formulary development. Patient groups are often focussed on a particular therapeutic area e.g. diabetes.	Thank you for your comment. Please see response to comment 70.
374	STH	NHS Sheffield (Sheffield PCT)	3	4.7.1	14	The recommendation around engagement with specific patient and/or patient representative groups or local communities is a more realistic way of achieving public involvement in formulary development.	Thank you for your comment. No response required.
375	STH	NHS Sheffield (Sheffield PCT)	4	4.8.2	15	There is uncertainty on inclusion of a product where NICE recommends in a TA that it is “an option” or recommends for a particular indication and not others. Some primary care formularies focus on only recommending first and second choices. Secondary care formularies are more restrictive in that they usually cover the products stocked in the pharmacy. They would not wish to include on the formulary and keep in stock a drug option where the consultants have chosen an alternative NICE option for the same indication. The health economics data in NICE TAs can become outdated e.g. where a drug price falls as it becomes available as a generic. The NICE TA may not be updated in a timely manner to reflect this but it may affect a decision at local level. How should this be managed?	Thank you for your comment. Please see response to comment 7.
376	STH	NHS Sheffield (Sheffield PCT)	6	4.11.1	18	How should products recommended in NICE clinical guidelines rather than TAs be treated? Are these to be managed as indicated here for products where there is no NICE TA?	Thank you for your comment. See response to comment 9.

377	STH	NHS Sheffield (Sheffield PCT)	7	4.18.1	21	This indicates that clinicians should have the ability to appeal the decision made. Did the GDG consider whether this right should also apply to patients or patient groups?	Thank you for your comment. The GDG did discuss the ability of patients or patient groups to appeal a decision made by the local formulary decision-making group. See responses to comments 118 and 341.