National Institute for Health and Clinical Excellence

Dyspepsia/GORD
Guideline Consultation Comments Table
10 May – 11 June 2012

Stakeholder	Order No	Section No	Questions to Stakeholders	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
British Society of Gastroenterology	**1**		1	We are concerned that this new guideline will completely replace CG17, as there are some areas not covered in the new proposed guidance. We would like to see the areas **not covered** in the new guideline and which have been addressed in CG17 remain available.	Thank you for your comment. It has now been agreed that discrete sections of the original guideline (CG17) that are not to be updated at this time will be incorporated into the final product and clearly signposted.
British Society of Gastroenterology	**2**		2	No comment	Thank you for your comment.
British Society of Gastroenterology	**3**		3	One of the key areas to consider is whether there is evidence available to make any recommendations on screening risk populations for Barrett's oesophagus and on surveillance. We are pleased that this remains a key area for the new guideline, even though it may be that there is not enough robust evidence currently to make firm recommendations. There is much public concern over these issues among Barrett's and GORD support groups.	Thank you for your comment. The review questions 4.5 b) and h) aim to tackle these ongoing areas of clinical doubt. In the absence of any high level evidence such as RCTs the developers will have to consider using evidence from less robust study designs and will do this in discussion with the guideline development group.
British Society of Gastroenterology	**4**		4	No comment	Thank you for your comment.
British Society of Gastroenterology	**5**	Section 4.3.1 a-f		These are key areas and we are pleased they remain in the scope of the guideline, especially criteria for endoscopy in suspected GORD and Barrett's, as well as updating H pylori management which has moved on	Thank you for your comment and highlighting this very recent publication which will be useful for cross referencing to ensure that we have identified all the relevant data in this area for analysis.

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				since CG17. This new information about optimal treatment for H pylori is summarized in a recent international expert consensus document recently published in GUT (Malfertheiner P, Megraud F, O'Morain CA, et al for the European Helicobacter Study Group. Management of Helicobacter pylori infection--the Maastricht IV/ FlorenceConsensus Report. Gut. 2012 May;61(5):646-64)	
British Society of Gastroenterology	**6**	Section 4.3.2 c		We are disappointed that the guideline will not cover the specialist diagnosis of GORD (pH monitoring etc), as mis-diagnosis of 'functional heartburn' (ie GORD-like symptoms but NOT due to acid reflux) is key to proper selection of patients for specialist (eg surgical) management, and identification of patients who will not benefit from prolonged PPI therapy (studies indicate that this is likely to account for the majority of 'PPI failures' found in about a quarter of patients with apparent GORD).	Thank you for your comment. The specialist diagnosis of GORD was not considered to be a priority for this guideline, amongst the range of competing aspects of care considered for inclusion. We will consider the impact of inappropriate patient selection when considering the review question 4.5 f) on fundoplication.
British Society of Gastroenterology	**7**	Section 4.3.2 o		While understanding that functional heartburn (FH) management may be beyond the scope of this guideline, correct diagnosis is key to specialist management of GORD and differentiation of this from FH (a condition already poorly appreciated by many even in specialist secondary care) should be an important area to be looked at by the CGD in our view.	Thank you for your comment. The diagnosis of functional heartburn is a highly specialist area and was not considered to be a priority for this guideline, amongst the range of competing aspects of care considered for inclusion.
British Society of Gastroenterology	**8**	Section 4.4 i		The inclusion of outcomes from oesophageal function testing seems at variance with the decision not to include diagnosis of FH in points 4 and 5 above, as this is principally a diagnosis of exclusion.	Thank you for your comment. We agree that this outcome is no longer relevant to the reduced scope and will remove

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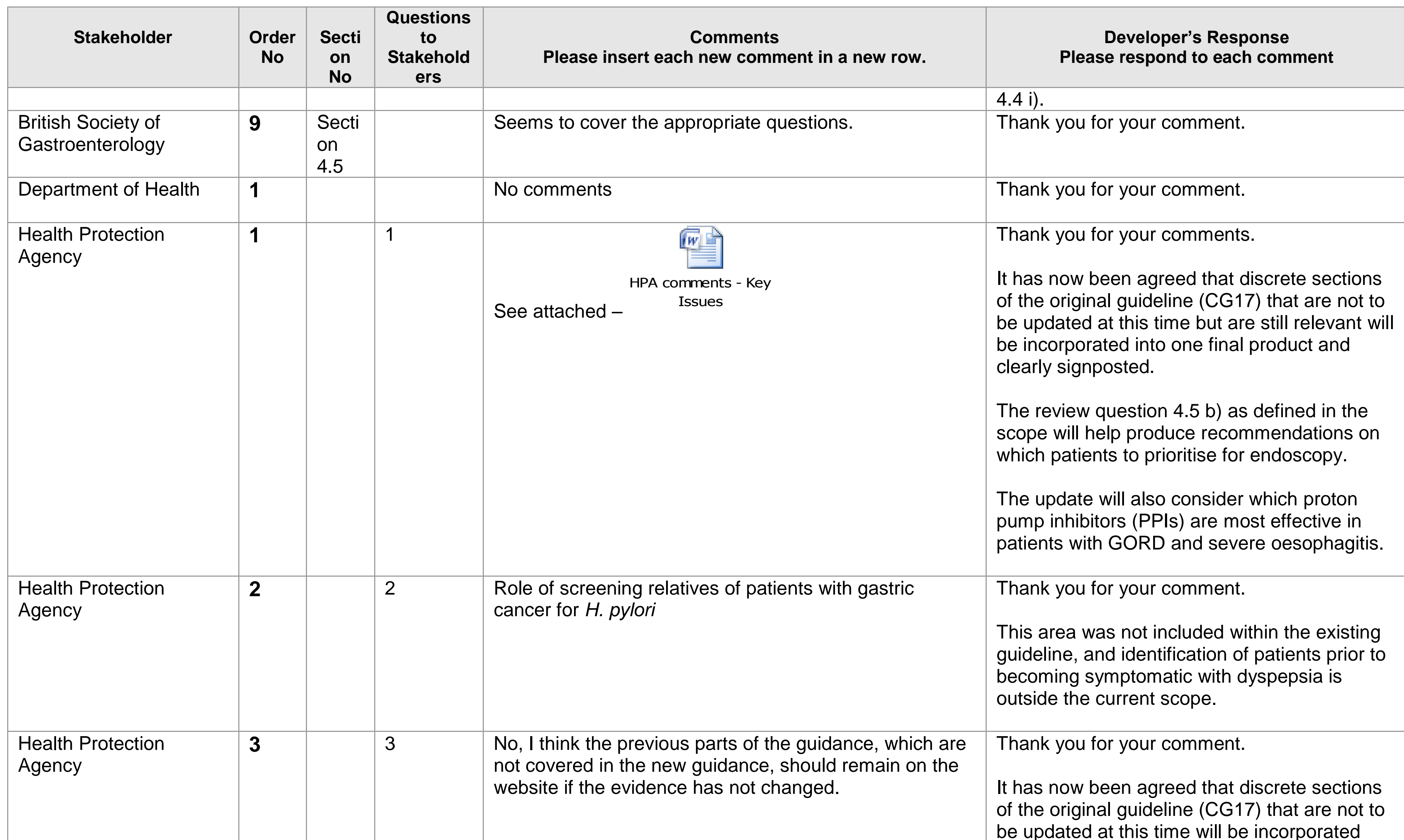
					4.4 i).
British Society of Gastroenterology	**9**	Section 4.5		Seems to cover the appropriate questions.	Thank you for your comment.
Department of Health	**1**			No comments	Thank you for your comment.
Health Protection Agency	**1**		1	See attached – 	Thank you for your comments. It has now been agreed that discrete sections of the original guideline (CG17) that are not to be updated at this time but are still relevant will be incorporated into one final product and clearly signposted. The review question 4.5 b) as defined in the scope will help produce recommendations on which patients to prioritise for endoscopy. The update will also consider which proton pump inhibitors (PPIs) are most effective in patients with GORD and severe oesophagitis.
Health Protection Agency	**2**		2	Role of screening relatives of patients with gastric cancer for *H. pylori*	Thank you for your comment. This area was not included within the existing guideline, and identification of patients prior to becoming symptomatic with dyspepsia is outside the current scope.
Health Protection Agency	**3**		3	No, I think the previous parts of the guidance, which are not covered in the new guidance, should remain on the website if the evidence has not changed.	Thank you for your comment. It has now been agreed that discrete sections of the original guideline (CG17) that are not to be updated at this time will be incorporated

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					into the final product and clearly signposted.
Health Protection Agency	**4**		4	If some areas are not covered, users should be signposted to the old guidance or other sources of guidance listed above.	Thank you for your comment. It has now been agreed that discrete sections of the original guideline (CG17) that are not to be updated at this time will be incorporated into the final product and clearly signposted.
Heartburn Cancer Awareness & Support	**1**		1	The Scope looks appropriate.	Thank you for your comment.
Heartburn Cancer Awareness & Support	**2**		2	We would query the removal of pharmacy provision of information and management. Since OTC medications for heartburn/dyspepsia are so freely available and commonly used one concern is that advice re. when to refer for endoscopy needs to be made clear through every possible route and not only through GP's we therefore feel that this should be covered.	Thank you for your comment. It has now been agreed that discrete sections of the original guideline (CG17) that are not to be updated at this time will be incorporated into the final product and clearly signposted. The evidence review that will be undertaken for review question 4.5 b) will consider prognostic factors to identify characteristics of patients that would suggest referral for endoscopy. The focus of this question will not be setting specific, so recommendations in this area will be of equal interest to pharmacists and general practice.
Heartburn Cancer Awareness & Support	**3**		3	No comment	Thank you for your comment.
Heartburn Cancer Awareness & Support	**4**		4	No comment	Thank you for your comment.
NHS Direct	**1**		1	Yes	Thank you for your comment.

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NHS Direct	**2**		2	No	Thank you for your comment.
NHS Direct	**3**		3	No comment	Thank you for your comment.
NHS Direct	**4**		4	No comment	Thank you for your comment.
Oesophageal Patients Association	**1**		1	Yes	Thank you for your comment.
Oesophageal Patients Association	**2**		2	Notwithstanding the careful and methodical charting of responses and intentions, we are not sure that the significance of diagnosing (as distinct from monitoring) Barrett's Oesophagus from heartburn / GORD symptoms, particularly in patients under the age of 55 years has been explicitly mentioned. In an area where some aspects of a GORD condition happen to be a pre-cursor to adenocarcinoma, it is important that we do not fall into any gap left between CG17 and CG27.	Thank you for your comment. Review question 4.5 b) will consider prognostic factors to identify characteristics of patients that would suggest referral for endoscopy to determine cause. Alarm signs for immediate endoscopy will be addressed by the update of guideline CG27 'Referral for suspected cancer' which is currently being scheduled for development.
Oesophageal Patients Association	**3**		3	No comment	Thank you for your comment.
Oesophageal Patients Association	**4**		4	One priority may be the consequences of lack of referral for specialist diagnosis.	Thank you for your comment. The specialist diagnosis of GORD was not considered to be a priority for this guideline, amongst the range of competing aspects of care considered for inclusion.
Reckitt Benckiser Healthcare (UK) Ltd	**1**		1	Overall, Reckitt Benckiser Healthcare (UK) Ltd is happy with the focus of the proposed scope of the guideline. We are in agreement that the previous scoping document covered a very broad and mostly undefined	Thank you for your comment.

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				therapeutic area so appreciate that the comments received from stakeholders have addressed the need to re-focus the new guideline more specifically in the areas of Dyspepsia and GORD. We hope there will be an opportunity for relevant bodies to review the prescribing bulletin proposed to cover the appropriate use of Proton Pump Inhibitors before this document is published alongside the new Dyspepsia guideline.	It has now been agreed that the original guidance in CG17 on the use of PPIs in the community will be incorporated into the update. The scope will be expanded with review question 4.5 d) covering the use of PPIs to treat patients with severe erosive reflux disease.
Reckitt Benckiser Healthcare (UK) Ltd	**2**		2	Reckitt Benckiser Healthcare (UK) Ltd believes it is still important to consider the inclusion of extra-oesophageal syndromes arising as a result of gastric reflux within the scope. As acknowledged by Vakil (VAKIL et al. *Am J Gastroenterol* (2006) 101: 1900-1920), the working group considered that GORD could be sub classified into oesophageal and extra-oesophageal syndromes, which included the recognition of laryngitis, cough, asthma, and dental erosions as possible GORD syndromes. For this reason, these extra-oesophageal manifestations which form part of the spectrum of disease complicit with GORD should be reviewed for inclusion in the new guideline.	Thank you for your comment. The focus of the population to be considered within the guideline is specifically limited to oesophageal reflux. While the developers acknowledge that there is some cross over to other conditions, and that some evidence may include patients with multiple pathologies, these additional conditions may respond differently to the interventions being considered within this guideline, and therefore outcomes relating to these will not be considered.
Reckitt Benckiser Healthcare (UK) Ltd	**3**		3	We agree that this new guideline should completely replace the existing guideline. If the 2 were to run in parallel, it is clear that there would be significant overlap and repetition which would be confusing and	Thank you for your comment. It has now been agreed that discrete sections of the original guideline (CG17) that are not to

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				unnecessary.	be updated at this time will be incorporated into the final product with the aim of eliminating overlap and repetition. These sections will be clearly signposted to avoid confusion.
Reckitt Benckiser Healthcare (UK) Ltd	**4**		4	We have no further comments regarding prioritisation of outstanding areas.	Thank you for your comment.
Royal College of General Practitioners	**1**		1	Yes	Thank you for your comment.
Royal College of General Practitioners	**2**		2	No	Thank you for your comment.
Royal College of General Practitioners	**3**		3	Yes	Thank you for your comment. It has now been agreed that discrete sections of the original guideline (CG17) that are not to be updated at this time will be incorporated into the final product and clearly signposted to avoid confusion.
Royal College of General Practitioners	**4**		4	Primary Care Management	Thank you for your comment. It has now been agreed that discrete sections of the original guideline (CG17) that are not to be updated at this time will be incorporated into the final product and clearly signposted to avoid confusion. This may include recommendations relating to initial treatment options in primary care. Additionally a new review question 4.5 d) will consider the use of PPIs in severe reflux oesophagitis.

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Royal College of Nursing	**1**		1	In view of recent national Awareness Campaign Pilot, it may be remiss to exclude signs and symptoms of Oesophago-gastric (OG) cancer (much of which focuses on pharmacy management of over the counter (OTC) medications).	Thank you for your comment. Review question 4.5 b) will consider prognostic factors to identify characteristics of patients that would suggest referral for endoscopy. Alarm signs for immediate endoscopy will be addressed by the update of guideline CG27 'Referral for suspected cancer' which is currently being scheduled for development.
Royal College of Nursing	**2**		2	Signs and symptoms of OG cancer.	Thank you for your comment. Review question 4.5 b) will consider prognostic factors to identify characteristics of patients that would suggest referral for endoscopy. Alarm signs for immediate endoscopy will be addressed by the update of guideline CG27 'Referral for suspected cancer' which is currently being scheduled for development.
Royal College of Nursing	**3**		3	Yes as previous guideline was cumbersome and subjective	Thank you for your comment. It has now been agreed that discrete sections of the original guideline (CG17) that are not to be updated at this time but still relevant will be incorporated into the final product using the current guideline template with the aim of eliminating overlap and repetition These sections will be clearly signposted to avoid confusion.
Royal College of Nursing	**4**		4	Signs and symptoms of OG cancers	Thank you for your comment.

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					Review question 4.5 b) will consider prognostic factors to identify characteristics of patients that would suggest referral for endoscopy. Alarm signs for immediate endoscopy will be addressed by the update of guideline CG27 'Referral for suspected cancer' which is currently being scheduled for development.
Royal College of Paediatrics and Child Health	**1**			No comments	Thank you for your comment.
Royal College of Physicians	**1**		General	The RCP is grateful for the opportunity to respond to the above draft scope consultation. We would like to endorse the comments submitted by the BSG. We have also received comments from an expert who attended the scoping workshop for the guideline as an RCP representative. At that stage the expert expressed strong reservations that not enough new scientific evidence existed to justify an update to the guideline at this time. They have reviewed the amended scope and feel strongly that the Guideline should be placed on hold until important ongoing studies (which address the eight questions of the guideline) report.	Thank you for your comment. NICE has been instructed by the Department of Health to provide updated guidance in this area. It is anticipated that useful recommendations for the NHS will be developed within the guideline.
Royal Pharmaceutical Society	**1**		1	The Royal Pharmaceutical Society are disappointed that the role of pharmacists will not be covered in these guidelines, however agree with the other areas that NICE propose to cover.	Thank you for your comment. It has now been agreed that discrete sections of the original guideline (CG17) that are not to be updated at this time will be incorporated into the final product and clearly signposted to avoid confusion.
Royal Pharmaceutical	**2**		2	The scope omits information about the role of	Thank you for your comment.

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Society				community pharmacist in the management of patients with dyspepsia symptoms, provision of patient information, recording of adverse events, and particularly, the use of over-the-counter drugs, antacids, or alginates. Community pharmacists are well placed to offer initial and ongoing advice to patients with dyspepsia and GORD symptoms. They are able to identify when patients should be referred to their GP e.g. when alarm symptoms are present; provide advice about over-the-counter treatments for dyspepsia; and provide appropriate lifestyle advice to help patients manage their symptoms. Community pharmacists can additionally provide medication use reviews and additional advanced services (e.g. new medicines service), which provide opportunities to identify medicines that may cause dyspepsia or GORD symptoms and offer appropriate advice to patients. Pharmacists have also been involved in a pilot of dyspepsia clinics which have improved patient access to screening, advice and access to medication, and patients' overall quality of life.	It has now been agreed that discreet sections the original guidance in (CG17) that will not be updated at this time, for example that relating to the community pharmacy, will be incorporated into the final product.
Royal Pharmaceutical Society	**3**		3	We agree that a new guideline should replace the existing guidelines as they were developed many years ago and new community pharmacy services, and over-the-counter and pharmacy only medicines for the treatment of reflux symptoms and dyspepsia have become available.	Thank you for your comment. In order to provide a comprehensive guideline with the resources available we are proposing to carry forward discrete sections of the original guideline (CG17) into the update. We recognise that community pharmacy treatment in these conditions has expanded since the

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					existing guidance was published, and the new guidance will aim to be as generic as possible when it comes to care settings.
Royal Pharmaceutical Society	**4**		4	We believe that it is important to highlight the role of community pharmacists as they provide the first point of contact for dyspepsia and GORD sufferers and can help patients to manage their symptoms. As experts in medicines, pharmacists can also offer advice on how to take medicines, adverse effects, possible interactions and cautions, to raise patients' awareness and increase their understanding of their condition and therapy, which will encourage medicines adherence and empower self-care.	Thank you for your comment. It has now been agreed that the original guidance in CG17 for the community pharmacist will be incorporated into the update.
United Kingdom Clinical Pharmacy Association (UKCPA)	**1**		1	Yes	Thank you for your comment.
United Kingdom Clinical Pharmacy Association (UKCPA)	**2**		2	We note that the primary care pharmacological management of dyspepsia and GORD (such as PPIs, H2 receptor antagonists) will not be covered in the new guideline, to be replaced by a NICE prescribing bulletin on GORD. If the prescribing bulletin focuses purely on GORD this will leave a gap in the useful guidance on doses and recommended length of treatment for PUD , undiagnosed dyspepsia and non ulcer dyspepsia in the current dyspepsia guideline.	Thank you for your comment. It has now been agreed that discrete sections of the original guideline (CG17) that are not to be updated at this time will be incorporated into the final product and clearly signposted to avoid confusion.
United Kingdom Clinical Pharmacy Association (UKCPA)	**3**		3	Yes as long as point 2 is addressed above.	Thank you for your comment. It has now been agreed that discrete sections of the original guideline (CG17) that are not to be updated at this time will be incorporated

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					into the final product and clearly signposted to avoid confusion.
United Kingdom Clinical Pharmacy Association (UKCPA)	**4**		4	Guidance on h.pylori eradication is important to address because of concerns with changing resistance patterns	Thank you for your comment. The developers will consider local resistance to certain antibiotics when developing recommendations for eradication of H Pylori. Variation many make interpretation of the published data particularly difficult in this area.

These stakeholder were approached but did not comment;

Abbott Laboratories

Airedale NHS Trust

Alder Hey Children's NHS Foundation Trust

Association of Anaesthetists of Great Britain and Ireland

Association of British Healthcare Industries

Association of Surgeons of Great Britain and Ireland

Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland

Astrazeneca UK Ltd

Barrett's Oesophagus Campaign

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Boehringer Ingelheim

Bolton Hospitals NHS Trust

Boston Scientific

Bradford District Care Trust

British Acupuncture Council

British Association for Psychopharmacology

British Dietetic Association

British Geriatrics Society - Gastro-enterology and Nutrition Special Interest Group

British Medical Association

British Medical Journal

British National Formulary

British Nuclear Medicine Society

British Pain Society

British Psychological Society

British Society for Antimicrobial Chemotherapy

British Society of Paediatric Gastroenterology Hepatology and Nutrition

BUPA Foundation

Cambridge University Hospitals NHS Foundation Trust

Camden Link

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Capsulation PPS

Care Quality Commission (CQC)

Coeliac UK

Dako UK Ltd

Department of Health

Department of Health, Social Services and Public Safety - Northern Ireland

Digestive Disorder Foundation

DO NOT USE

Dorset Primary Care Trust

Eisai Ltd

Eli Lilly and Company

Equalities National Council

Faculty of Dental Surgery

Faculty of Public Health

Fighting Oesophageal Reflux Together

General Medical Council

George Eliot Hospital NHS Trust

GlaxoSmithKline

Gloucestershire LINk

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Great Western Hospitals NHS Foundation Trust

H & R Healthcare Limited

Hafan Cymru

Hammersmith and Fulham Primary Care Trust

Health Quality Improvement Partnership

Healthcare Improvement Scotland

Hertfordshire Partnership NHS Trust

Hindu Council UK

Humber NHS Foundation Trust

Independent Healthcare Advisory Services

Institute of Sport and Recreation Management

Integrity Care Services Ltd.

Janssen

Johnson & Johnson Medical Ltd

Joint Speciality Committee in Gastroenterology and Hepatology, Royal College of Physicians and British Society of Gastroenterology

KCARE

Lancashire Care NHS Foundation Trust

Liverpool Primary Care Trust

Luton and Dunstable Hospital NHS Trust

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Maidstone and Tunbridge Wells NHS Trust

Medicines and Healthcare products Regulatory Agency

Mendip Primary Care Trust

Ministry of Defence

National Cancer Action Team

National Childbirth Trust

National Clinical Guideline Centre

National Collaborating Centre for Cancer

National Collaborating Centre for Mental Health

National Collaborating Centre for Women's and Children's Health

National Institute for Health Research Health Technology Assessment Programme

National Patient Safety Agency

National Public Health Service for Wales

National Treatment Agency for Substance Misuse

Neonatal & Paediatric Pharmacists Group

NHS Ashton, Leigh and Wigan

NHS Connecting for Health

NHS Gloucesterhsire & NHS Swindon Cluster

NHS Plus

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NHS Warwickshire Primary Care Trust

Norgine Limited

North Essex Mental Health Partnership Trust

Nottinghamshire Healthcare NHS Trust

Novartis Pharmaceuticals

Pancreatic Cancer Action

Peckforton Pharmaceuticals Ltd

PERIGON Healthcare Ltd

Pfizer

Pharmaceutical Services Negotiating Committee

Primary Care Society for Gastroenterology

Proprietary Association of Great Britain

Public Health Wales NHS Trust

Royal Berkshire NHS Foundation Trust

Royal Bolton Financial NHS Trust

Royal College of Anaesthetists

Royal College of General Practitioners

Royal College of General Practitioners in Wales

Royal College of Midwives

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Royal College of Obstetricians and Gynaecologists

Royal College of Paediatrics and Child Health , Gastroenetrology, Hepatology and Nutrition

Royal College of Psychiatrists

Royal College of Radiologists

Royal College of Surgeons of England

Royal Society of Medicine

Scottish Intercollegiate Guidelines Network

SEE Pfizer - DO NOT USE Wyeth Pharmaceuticals

Sheffield Teaching Hospitals NHS Foundation Trust

SNDRi

Social Care Institute for Excellence

Society and College of Radiographers

Society for General Microbiology

South East Coast Ambulance Service

South West Yorkshire Partnership NHS Foundation Trust

South Western Ambulance Service NHS Foundation Trust

Sutton1in4 Network

Teva UK

The Association of the British Pharmaceutical Industry

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The British In Vitro Diagnostics Association

The Gut Trust

The Rotherham NHS Foundation Trust

Torax Medical Inc.

UK Pain Society

Welsh Government

Welsh Scientific Advisory Committee

Western Cheshire Primary Care Trust

Westminster Local Involvement Network

Wirral University Teaching Hospital NHS Foundation Trust

Worcestershire Acute Hospitals Trust

York Hospitals NHS Foundation Trust

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