National Institute for Health and Clinical Excellence

The development and updating of local formularies

Stakeholder Comments

Please enter the name of your stakeholder organisation below.

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Stakeholder Organisation:	Royal Pharmaceutical Society
Name of commentator:	Heidi Wright, Practice and Policy Lead, England

Order number *(For internal use only)*	**Section Number** **Number only** (do not write the word 'section'). Alternatively write **'general'** if your comment relates to the whole document.	**Page Number** **Number only** (do not write the word 'page/pg'). See example in cell below	**Comments** **Please insert each new comment in a new row.** **Please do not paste other tables into this table, as your comments could get lost – type directly into this table.**
Example	4.2	12	Our comments are as follows ……
Proformas that are not correctly submitted as detailed in the line above may be returned to you			
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.
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.
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 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.
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).
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.
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.
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.
8	4.6.1-4.6.2	14	We agree with the recommendations.
9	4.7.1	14	We agree with the recommendations.
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.
11	4.8.6-4.8.8	16	We agree with the recommendations.
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 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
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.
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.
15	4.12.1	18	We agree with this recommendation.
16	4.13.1-4.13.3	19	We agree with the recommendations.
17	4.14.1	19	We agree with this recommendation.
18	4.15.1	20	We agree with this recommendation.
19	4.16.1	20	We agree with this recommendation.
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.
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 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.
22	4.19	22	We agree with the recommendations.
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
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.
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.
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.
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.

Please add extra rows as needed

Please email this form to: LocalFormularies@nice.nhs.uk

Closing date: 5pm on 8th October 2012

PLEASE NOTE: The Institute reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion or the Institute, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.