The proposals to implement ‘Generic Substitution’ in primary care, further to the Pharmaceutical Price Regulation Scheme (PPRS) 2009

Response to the Consultation

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Contact Details	Beth Foster Medicines Pharmacy & Industry Department of Health 456D Skipton House
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Response to the Consultation

Prepared by: Medicines, Pharmacy and Industry - Pharmacy Policy

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Executive Summary

1. The 2009 PPRS stated that subject to discussion with affected parties, the Department of Health (DH) would introduce generic substitution in primary care. Generic substitution would enable pharmacists and other dispensers to fulfil a prescription for a branded medicine by dispensing an equivalent generic medicine.

2. A public consultation on the proposals to implement generic substitution took place from 5 January to 30 March 2010. Three options were put forward for consultation:
    - to do nothing
    - to introduce dispensing flexibility (ie generic substitution), but with specific exclusions, so that the arrangements do not apply to a selected group of products on an exempt list.
    - to introduce dispensing flexibility (ie generic substitution), but limiting the scheme in such a way that the arrangements only apply to a selected group of products on a select list.

3. In total, 423 organisations and individuals submitted written responses. In addition, 107 delegates attended DH listening events, and their comments were recorded as part of the consultation.

4. Greenstreet Berman, an independent social research company, was appointed to analyse the responses on behalf of the DH following a competitive tender process run by the Central Office of Information (COI).

5. The analysis of responses showed no clear consensus with regards to a preferred option going forward. Three key points were apparent:
    - There is a strongly held perception by respondents that generic substitution posed a threat to patient safety. If the proposals were to be implemented, these concerns would arise in the frontline delivery of NHS services, impacting on the workload of health care professionals.
    - The position on the cost-effectiveness of generic substitution implementation is inconclusive. There is a strong sense that the effort involved in implementing a formal generic substitution scheme was simply too great for the potential gain.
    - Other, less nationally prescriptive mechanisms for further supporting the use of generic medicines can be explored.

6. The Coalition Government intends to stand by the 2009 PPRS agreement, which expires at the end of 2013. However, in the light of the public consultation findings, the DH will not be progressing any further the implementation of generic substitution. Instead the DH will be looking at further ways to support the use of generic medicines in a way that is acceptable to patients, recognising that there are still some savings that can potentially be delivered in this area.

Background

7. The NHS spends about £9 billion a year on branded prescription medicines in the UK. The 2009 Pharmaceutical Price Regulation Scheme, a five-year voluntary agreement negotiated between Government and the pharmaceutical industry, includes measures aimed at reducing NHS expenditure on branded medicines by an average of 5% a year over the lifetime of the scheme.

8. The 2009 PPRS stated that subject to discussion with affected parties, the Department of Health (DH) would introduce generic substitution in primary care. Generic substitution would enable pharmacists and other dispensers to fulfil a prescription for a branded medicine by dispensing an equivalent generic medicine.

9. Due to the need to consider the generic substitution arrangements with stakeholders, the arrangements were not finalised at the time of agreeing the PPRS and the precise effect of the generic substitution arrangements on NHS expenditure on drugs was unknown.

10. During 2009, the DH undertook a series of meetings with key national stakeholders, representing general practitioners, community pharmacists and manufacturers, to discuss the commitment in the PPRS agreement in England. Written representations were received from a number of other stakeholders, such as individual manufacturers and patient groups, for example those representing people with epilepsy. These discussions and representations informed the development of the three options consulted on and the decision to hold a full public consultation, which would enable, in particular, patient views to be appropriately sought and considered.

11. The consultation ran from 5 January to 30 March 2010. The consultation document can be found at: http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/consultations/liveconsultations/DH_110517. Respondents were able to respond via a DH questionnaire containing 10 questions online or in writing, write in letters or freeform responses. Five listening events in London (2), Leeds (2) and Bristol also took place.

12. Three options were put forward for consultation:
    - to do nothing
    - to introduce dispensing flexibility (ie generic substitution), but with specific exclusions, so that the arrangements would not apply to a selected group of products on an exempt list.
    - to introduce dispensing flexibility (ie generic substitution), but limiting the scheme in such a way that the arrangements would only apply to a selected group of products on a select list.

13. The consultation document presented the third option as the DH's preferred option, on the grounds that it provided the best balance between cost savings and manageability. The DH also provided a Partial Impact Assessment on the costs, benefits and equality issues. Further, during the consultation the Department published an additional list of references to research that had been used during the development of the Partial Impact Assessment.

Analysis of Responses

14. Greenstreet Berman, an independent social research company, was appointed to analyse the responses to the consultation on behalf of the DH following a competitive tender process run by the Central Office of Information (COI).

15. Their report is published on the DH website alongside this document.

16. The Department would like to thank the 423 organisations and individuals who submitted written responses and the 107 delegates who attended DH listening events, whose comments were recorded as part of the consultation. The responses came from a wide variety of respondent types, as shown by the tables below.

17. Over half of the written responses to the consultation came from private individuals. Many of the responses from private individuals came from two identifiable campaigns:
    - 51 responses used a template for a campaign initiated by Epilepsy Action, and more responses clearly drew on the issues raised by the Epilepsy Action campaign, although they did not use the same template.
    - 103 responses used a template for a campaign initiated by LIVErNORTH.

18. Of the 269 individually developed responses (not part of the above mentioned campaigns), the respondent types were as follows:

Respondent type – written	**Number of**	
Pharmaceutical company	34	170 organisations
NHS organisations	33	
Local pharmaceutical committee (LPC)	26	
Third sector	21	
Professional and/or regulatory body	15	
Community pharmacy	12	
Trade body	10	
Other organisation	19	
Epilepsy patient or carer	41	99 individuals
Doctor	15	
Individual pharmacist	9	
Other individual	34	
Total	**269**	

19. The listening events were attended by 107 people, representing 81 organisations and nine individuals. Some organisations were represented by more than one delegate.

Respondent type – listening events	Number of respondents	
NHS	28	81 organisations (some represented by more than one delegate)
Pharmaceutical company	12	
Community pharmacy	8	
Trade body	6	
Media and PR companies	6	
Patient groups and third sector	6	
Local pharmaceutical committee (LPC)	5	
Other organisation	9	
Individuals	10	9 individuals
Total	**90**	

20. Please refer to the Greenstreet Berman document for the analysis of responses.

Discussion

21. The DH considers that Greenstreet Berman has carried out a thorough analysis of the consultation responses, and has presented these findings in a comprehensive report. In making its decision regarding next steps, the DH took account of all of the report's findings.

22. The consultation showed no clear consensus with regards to a preferred option going forward. Within the overall responses, there are three key points that emerged:

a) The perception strongly held by consultation respondents that generic substitution posed a threat to patient safety.

23. The DH's greatest concern in considering the analysis of the consultation responses was the 'general and wide-ranging' (p 18 of the analysis report) perception that generic substitution posed a threat to patient safety. There were 225 comments on patient issues, the majority of which related to:
    - Patient safety and wellbeing
    - Epilepsy drug patient safety concerns
    - Patient confusion, anxiety and non-compliance

24. Generic substitution seemed to represent 'a step too far' for patients, particularly those patients needing drugs where there are clinical or patient safety concerns with regards to interchange between different manufacturer's products. Of particular concern was the finding that 76% of those who answered the consultation said that generic substitution posed equality risks to groups including those who might be confused about drug changes, including the elderly, learning disabled, mental health patients, non-English speaking patients and those with low levels of 'health literacy'.

25. However:
    - The PPRS 2009 document had said '*Provision will be made to allow the prescriber to opt out of substitution where, in his clinical judgment, it is appropriate for the patient to receive a specific branded medicine. In these circumstances, the named brand must be dispensed. Provision may also be made to exclude certain categories of medicines for clinical reasons in the interests of patient safety.'* This was followed up by various references to the importance of patient safety in the consultation document, including the fact that anti epileptic drugs would be unsuitable for substitution, and drugs where there are any general clinical or patient safety concerns with regard to interchange between different manufacturer's products could be specifically not included in the list.
    - It should be noted that 83% of prescriptions are already written generically and so patients already manage a degree of interchangeability if their dispenser fulfils their generic prescription through different manufacturers' products at different times depending on market availability etc.

26. Therefore, whilst the concerns raised by consultation respondents may not take account of the safeguards proposed, nor the fact that the majority of patients already manage a

degree of interchangeability, the existence of these worries and fears clearly demonstrates the complex and contentious nature of the generic substitution policy proposal, and the potential for it to cause worry and confusion. Were the DH to go ahead with the implementation of generic substitution, it considers it likely there would be a significant knock on effect of such concerns from patients onto health professionals. Dealing with such concerns and questions at the service delivery level would also impact on their workload.

b) Cost effectiveness

27. At the time of the PPRS, the precise effect of the generic substitution arrangements on NHS expenditure on drugs was unknown. The Department's Partial Impact Assessment attempted to address this gap in knowledge by modelling the net savings that could be achieved. It indicated that if we moved to the preferred option, then there could be some net annual savings, in the region of £19m, (which does not include the one-off implementation costs of around £3.8m).

28. However, consultation respondents strongly challenged the Partial Impact Assessment. To quote Greenstreet Berman's report (p.50) "Overall, respondents were sceptical about the DH assessment of costs and benefits presented in the Partial Impact Assessment. Many made general comments about the overall cost effectiveness, asserting that either the costs would be substantially higher than the DH anticipated, or that the benefits would be less, or both." Issues that came into play included the impact on health practitioners' workload and the impact on the pharmaceutical industry.

29. In particular, consultation respondents challenged both the 5% generic prescribing increase 'window' (referred to in paragraph 5 of the consultation document) and the 50% assumption (referred to in the Partial Impact Assessment) for the opt-out of generic substitution. A number of respondents asked whether- with a 83% generic prescribing rate – it was realistic to think that further savings could be made. "Branded prescribing is generally intentional on the part of the clinician, said a number of respondents….so prescribers would simply opt out and generic substitution would not release savings.' (p. 50 in the report). Expanding on the issue of opting out, the report highlighted how some respondents had expected the opt-out rate to be higher that 50%, either because prescribers are already aware of the generic medicine options because of good work by PCTs, and have already exercised a clinical choice by prescribing a brand; or prescribers would regularly opt out to avoid taking the time to assess individual cases for the acceptability of generic substitution.

30. There was also a strong sense that the measures that would be needed to implement the arrangements were disproportionate to the debatable savings that the arrangements would deliver. In other words, the effort involved in implementing a formal generic substitution scheme was simply too great for the potential gain; ie 'a sledgehammer to crack a nut'. The DH acknowledge that a number of implementation measures would have been required for the preferred option, which do represent significant changes, for example, ongoing workload implications for healthcare professionals and administrative costs.

31. Overall, the position on cost effectiveness is inconclusive. DH will not be completing a Full Impact Assessment to take account of the issues raised, in view of the decision taken on next steps (see below).

c) Other mechanisms to support the use of generic medicines.

32. A number of respondents suggested alternative ideas for supporting the use of generic medicines, including:
    - Continued encouragement of generic prescribing through
        - PCT medicines management
        - software-driven solutions
    - a pharmacist prescribing intervention scheme whereby pharmacies alert GP practices that a generic is available and prompt GP staff to change repeat medication records so that any future prescriptions are issued using the product's generic name.

33. The Department's recently published guidance *Strategies to achieve cost-effective prescribing: guidance for primary care trusts and clinical commissioning groups*,[1] supports the first of the ideas mentioned above and can assist PCTs and clinical commissioning groups in implementing the Quality, Innovation, Productivity and Prevention (QIPP) agenda.

34. The Department will be considering what it can do to further support the use of generic medicines. This will need to take account of the changing NHS architecture. The NHS White Paper *Equity and Excellence: Liberating the NHS*, sets out proposals for consortia of GP practices, working with other health and care professionals, and in partnership with local communities and local authorities, to commission the majority of NHS services for their patients. Commissioning by GP consortia will bring together responsibility for clinical decisions and for the financial consequences of these decisions.

35. GPs will have opportunities to further consider where a generic, rather than a branded prescription would be more appropriate (assuming of course there is no compromise patient safety) in the light of their close involvement with both patients and their choices, and the financial accountability for prescribing decisions.

[1] available at:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_120214

Next Steps

36. In the light of the strong perception that generic substitution poses a threat to patient safety, the inconclusive position on cost effectiveness and the ability to utilise or explore other mechanisms to support the use of generic medicines, DH will not be progressing any further the implementation of generic substitution. Instead, (as referred to in paragraph 32) the DH will be looking at further ways to support the use of generic medicines in a way that is acceptable to patients, recognising that there are still some savings that can potentially be delivered in this area.

37. The Coalition Government intends to stand by the 2009 PPRS agreement, which expires at the end of 2013. In addition, the Coalition Agreement announced the government’s intention to develop a system of ‘value-based pricing’, which will help to ensure better access to innovative and effective medicines on the NHS while securing value for money. The Cancer Drugs Fund will act as an ‘interim measure’ to improve patient access to key cancer drugs and provide confidence to the wider public that the NHS will be there in their hour of need.

Learning from the consultation process

38. To quote Greenstreet Berman (p 6): 'Some respondents, especially private individuals, noted that they found the DH consultation on generic substitution difficult to understand, because of the technical nature of the questions.'

39. The Medicines, Pharmacy and Industry Group acknowledge that this was a reasonably technical consultation and whilst efforts were made to ensure the consultation document was accessible to all readers, more could have been done, for example signposting key issues within the consultation document.

40. Other concerns were expressed regarding the accessibility of the consultation process, namely the complexity of this internet based process, which some respondents thought discriminated against certain groups of people, namely the elderly and those who find concentrating difficult. Where such comments were made, individual responses were sent to these respondents by the DH, which made the following points:

    - Stakeholders have been able to respond to the consultation in the form of letters and individual submissions - no responses were excluded.
    - Responding was not simply an internet based process. It was possible to write in, or telephone the Department and request a paper copy of the document and response template.
    - The Department of Health also ran a number of listening events across the country where officials listened and recorded the views of a variety of stakeholders, including patients and their representatives, to find out what their views were on the three options. These events were publicised to the National Association of LINks Members (NALM) Steering Group for onward cascading, and to a wide variety of the Department's stakeholders, including third sector organisations representing patients, as well as being highlighted in the more usual communications routes, such as the consultation's Press Notice. The outputs from these events were analysed in full alongside all the other consultation responses.

41. More generally, all Department of Health public consultations, including this consultation, follow the Code of Practice on Consultation. In particular, the Department of Health aims to adhere to the seven consultation criteria contained in the Code of Practice, which can be found at http:www.bis.gov.uk/policies/better-regulation/consultation-guidance.