



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

Consultation document

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

Consultation document

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Executive Summary

The PPRS 2009 stated that '*subject to discussion with affected parties, the Department of Health will introduce generic substitution in primary care. This will enable pharmacists and other dispensers to fulfil a prescription for a branded medicine by dispensing an equivalent generic medicine. 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*'.

Further to engagement with national stakeholders during 2009, the Department is consulting on three options for the implementation of generic substitution in England:

- (1) Do nothing
- (2) Introduce dispensing flexibility but with specific exclusions, so that the arrangements do not apply to a selected group of products on an exempt list.
- (3) Introduce dispensing flexibility but limiting the scheme in such a way that the arrangements only apply to a selected group of products on a select list.

Options (2) and (3) also both need to give prescribers the ability to apply their clinical autonomy to tailor prescribing to their individual patients' clinical needs. This could be achieved by the prescriber either 'opting in' or 'opting out' the prescription from the arrangements, which in turn could be implemented by either a tick box system or an endorsement applied by the prescriber to the prescription.

The Department of Health's preferred approach is Option 3, with an opt out endorsement. The reasons for this preference are provided in detail, but include considerations relating to patient safety and clinical need, savings to the NHS and manageability of implementation for clinicians and prescription infrastructure providers. At this point, the Department is only considering drugs (not appliances) dispensed by pharmacies (not dispensing doctors) for inclusion within the arrangements.

Views are sought in response to 10 detailed questions relating to the options and implementation approach.

This consultation runs from 5 January 2010 to 30 March 2010. Please see page 23 for directions on how to respond to the consultation.

Introduction

1. The Pharmaceutical Price Regulation Scheme (PPRS) is a voluntary scheme agreed by the Department of Health and the Association of the British Pharmaceutical Industry (ABPI). It is a mechanism used to control the prices of branded medicines sold to the NHS by regulating the profits that companies can make on these sales. It seeks to achieve a balance between reasonable prices for the NHS and a fair return for the industry to enable it to research, develop and market new and improved medicines.
2. The NHS spends about £9 billion a year on branded prescription medicines in the UK. The 2009 PPRS, 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. The measures include a price cut of 3.9% in February 2009 with a further price cut of 1.9% in January 2010 and, subject to discussion with affected parties, the introduction of generic substitution.
3. The 2009 PPRS paragraph 7.6.ii states that *'Subject to discussion with affected parties, the Department of Health will introduce generic substitution in primary care. This will enable pharmacists and other dispensers to fulfil a prescription for a branded medicine by dispensing an equivalent generic medicine. 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'*.
4. 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. Therefore, there is provision for either the Department or the ABPI to request a review to be undertaken with a view to adjustments being made to correct any under or over delivery of the savings.
5. The intention of the generic substitution proposal was that a dispenser would be able to dispense a generic version of medicine when a brand has been prescribed, unless the prescriber has indicated otherwise. It was made in order to maximise the savings to be delivered by the PPRS agreement, releasing resources for improved patient care, whilst ensuring patient safety and addressing industry's concerns that savings ought to be targeted at where drugs had gone off patent. In England in 2008 (in primary care)¹:
 - 83% of prescription items were prescribed generically, made up of:
 - 65% of prescription items that could be dispensed generically; and
 - 18% of prescription items although prescribed generically, were only available as a branded product so they were dispensed as the brand.
 - The remaining 17% of prescription items were prescribed and dispensed by the brand name. The great majority of these drugs are available only as a branded

¹ *Prescriptions Dispensed in the Community, Statistics for 1998 to 2008: England* (July 2009), The Information Centre for Health and Social Care)

product, but 5% of prescription items were prescribed by brand where the drug concerned is available as a generic.

Therefore potentially the generic prescribing rate could have potentially been 88% (ie 83% plus this additional 5%) assuming there were no clinical reasons why the patient needed a specific manufacturer's product. Closing this 5% gap is the key driver behind the implementation of 'generic substitution'. Furthermore, realisation of savings will be most significant in relation to products that have very recently come off patent, when prices fall.

6. There are reasons other than cost as to why it is good practice for a prescriber to prescribe generically where there are no clinical reasons for the patient needing a specific manufacturer's product:
 - a. dispensing flexibility- prescribing generically provides dispensers with greater flexibility on the products they dispense to patients so patients may obtain their medicines more quickly and less stock has to be held by the pharmacy (which in turn leads to savings for the NHS);
 - b. treatment recognition- prescribing generically also tends to give greater certainty amongst healthcare professionals treating a patient (when for example patients move between care providers on discharge from hospital) as to the patient's treatment regime. Prescribing by generic name tends to remind clinicians of the therapeutic action of the drug so they are less likely to prescribe a drug of similar action unintentionally resulting in duplication or prescribing of a second medicine which is incompatible with the first.
7. That said, we recognise that for clinical reasons there will always be occasions where it is important that patients are maintained on a specific manufacturer's product. Therefore, whilst Government policy has been to promote generic prescribing, prescriber clinical autonomy has always been upheld. This principle has been retained in the development of these proposals.
8. The Department is consulting on the implementation of generic substitution in England. Implementation in Northern Ireland, Scotland and Wales is a matter for the Devolved Administrations.

Stakeholder Engagement

9. During 2009, the Department of Health 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. We have also received written representations from a number of other stakeholders, such as individual manufacturers and patient groups, for example those representing people with epilepsy.
10. A significant number of views have been expressed; key issues include:
 - concerns over the extra workload for clinicians arising from a need to advise and explain any change to patients.
 - doubts over whether introducing generic substitution will achieve anything - the system works well now, with a high generic prescribing rate;
 - the need to exclude certain categories of medicines, such as anti-epileptic drugs, for clinical reasons.
11. These discussions and representations have informed the development of the three options outlined below. They have also informed our decision to hold a full public consultation. Patient views, in particular, need to be appropriately sought and considered. Both representative groups and individuals need an opportunity to comment on this issue, which has already raised interesting and varied debate.

Proposed Changes

Legislative framework

12. The dispensing (supply) of medicines in the NHS in England is governed by the Medicines Act 1968 and the NHS Act 2006. The Medicines Act requires that, where a prescription only medicine is prescribed by a prescriber via a prescription, that medicine must be dispensed in accordance with that prescription. In the main, this has been interpreted as meaning that what is dispensed by or under the supervision of a pharmacist should be exactly what is written on the prescription and so, for example, in the case where a branded product is prescribed, the substitution of that brand by an equivalent generic product is not permitted without the prior agreement of the prescriber. The NHS (Pharmaceutical Services) Regulations 2005 and the NHS (Local Pharmaceutical Services etc.) Regulations 2006, made under the NHS Act, require the dispensing of the medicine that is ordered – and this obligation has similarly been interpreted as requiring the dispensing of a branded product, if that is what is written on the prescription.
13. The Department is not looking to change primary legislation to achieve the implementation of the PPRS commitment.

Options – ruled out

14. In assessing the options available to meet the objectives of the generic substitution commitment, one approach DH has given some consideration to is to prohibit the prescribing of branded products where generic products are available.
15. In providing NHS services, there is already a list of products which primary care prescribers cannot prescribe, listed in Schedule 1 of the NHS (General Medical Services Contracts) (Prescription of Drugs etc) Regulations 2004, and reproduced at Part XVIII A of the Drug Tariff. Under this approach, all branded products where generic products are available would be added to this list. This would not be generic substitution, but a complete ban on these branded drugs being prescribed on the NHS.
16. This would maximise the savings that could be made for the NHS as there would be maximum coverage. Whilst this broad approach would be relatively straightforward to implement, prescribers and dispensers would need to spend additional time with all patients to explain the changes. The most significant disadvantage of this option is that it would not fully allow for prescriber clinical autonomy to tailor prescribing to their individual patients' clinical needs.
17. The Department of Health considers that the lack of clinical flexibility outweighs any benefits identified and so is not consulting on this approach.

Options – for consultation

18. Three options for consultation are considered below:

Option 1 – Do nothing

19. This is the simplest option. Patients would not be impacted and dispensers and prescribers would not need to do anything differently from the present. However, this would preclude the savings identified in the 2009 PPRS through 'generic substitution' being realised and impact on the level of resources available for other areas of NHS care.

Option 2 - Introduction of dispensing flexibility but with specific exclusions, so that the arrangements do not apply to a selected group of products on an exempt list

20. Under this option, a rubric would be included in the standard formats for NHS prescriptions (electronic as well as manual) so that it was clear that if a prescriber wrote the name of a branded version of a medicine on the prescription, the prescriber meant that either the branded version or a generic could be dispensed, unless the name of the medicine was on the 'exempt list' of products that were exempt from the arrangements. It is proposed that this list would be presented in the Drug Tariff.

21. For example, pre-printed on every paper prescription and added to every e-prescription could be the text: *'If the product mentioned in this prescription is referred to by a brand name, the prescriber intends that either it or a generic equivalent may be dispensed, unless the product is listed in the exempt list found at Part XVIIID of the Drug Tariff'*. This would need to be supplemented by the list of 'exemptions' which would be published in the Drug Tariff, ie specific drugs that were not subject to substitution.

22. This option means that where a drug (eg an anti-epileptic) is not suitable for generic substitution, it would be added to the exempt list. This option should also deliver financial savings for the NHS. There are however two major difficulties with this approach. The first relates to the exempt list: One of the most significant problems is that the exempt list would potentially be very long and likely to get longer as it is regularly updated to reflect new drug developments. Drugs would remain on the list for different amounts of time, some probably forever, while others could be removed over time depending on the development of generics. Also, because a product must actively be placed on the exempt list for it to be excluded from the arrangements, it is likely to lead to a greater scope of products included in the arrangements, even if only temporarily, while there is an administrative lag (or error) to place the product in the exclusion list. Further, prescribers and dispensers would have to continually familiarise themselves with this list, which could be frequently changing as new products go off patent.

23. Secondly, unless we were only going to allow substitution of products with an identical formulation and strength, this approach would require a legal definition of "generic equivalent" that could in practice be very difficult to settle.

24. If substitution were limited to copies of drugs that were identical in all respects to the original, this would be unlikely to achieve the anticipated savings as most generic equivalents are not absolutely identical products. A requirement that the products be identical would also carry with it a risk of the producers of the original version making unnecessary changes to the formulation of their product, simply in an attempt to avoid generic substitution.
25. However, assuming that it is accepted that the generic substitute product need not be absolutely identical to the original version - for example it may have different inactive ingredients or it may be a different salt of the original version - the issue arises as to how different it can be and how the test for acceptable difference could be captured in the relevant legislation. There is a long history of legal dispute over generic equivalence for the purposes of granting marketing authorisations. Some products that would be considered "generic medicinal products" for the purposes of article 10(2)(b) of Directive 2001/83 (the standard definition of a generic for the purposes of granting marketing authorisations) may be acceptable substitutes but not others.
26. All these difficulties would need to be addressed before this option could be pursued.

Option 3 - Introduction of dispensing flexibility but limiting the scheme in such a way that the arrangements only apply to a selected group of products on a select list

27. This option is effectively the inverse of Option 2. The rubric included in the standard formats for NHS prescriptions would be amended so that it was clear that if a prescriber wrote the name of the branded version of a medicine on a prescription, the prescriber meant either the branded version or a generic could be dispensed, if the product was identified in the select list of products for which substitution arrangements were permissible.
28. Unlike Option 2, the scope of drugs to be defined as suitable for generic substitution can be a lot narrower. This means that formulating a definition of "generic equivalent" for the purposes of implementing generic substitution becomes a more manageable task. It is proposed that a list is formulated (see later at paragraph 57 for how the products would be selected) where drugs are referred to by their Recommended International Nonproprietary Name published by the World Health Organization or by their British Approved Name given in the British Approved Names Book (ie by their rINN or BAN). If a drug is prescribed by its proprietary name (a "reference product"), but its rINN or BAN is in the list, the generic equivalent could be supplied. Generic equivalent in this case could be defined as a drug that has the same pharmaceutical form and strength as the reference product, and—
- (i) its active substance has the same rINN or BAN as the reference product, or
 - (ii) its active substance is a salt of the reference product and is a permitted alternative salt included in the select list. To be a permitted alternative salt, the salt will have to have a modified International Nonproprietary Name (INNM) or a British Approved Name Modified (BANM) which relates to the rINN or BAN for the reference product – unless the rINN covers the salt.
29. Under this option, the rubric to be included in the standard formats for NHS prescriptions (electronic as well as manual) could be along the lines of *'If the drug*

mentioned in this prescription is referred to by a brand name and the drug is listed in Part XVIII of the Drug Tariff, the prescriber intends that either it or a generic equivalent may be dispensed. For these purposes, a product is a generic equivalent if it has the same rINN or BAN as the proprietary version or it is a permitted alternative salt mentioned in Part XVIII of the Drug Tariff'.

30. Under this option, all prescriptions would be dispensed as written except for products identified on the select list. The list could be kept short by focussing on the drugs that will yield the biggest financial savings, for example those that have very recently come off patent, are commonly prescribed, and are still subject to relatively high brand prescribing rates even though generic products are available. 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. While the list would need to be dynamic to reflect changes in prescription volumes and patent status, we can determine how often it is changed. It is envisaged that the list would be changed a maximum of four times a year and in reality it is unlikely to need changing more than once or twice a year, with one or two products being added and removed each time. This would strike a balance between achieving cost savings and not creating a significant increase in workload for prescribers and dispensers.

Prescriber autonomy- the ability to opt-in or out of the arrangements

31. Whilst Options 2 and 3 give the flexibility to create a list of drugs that is either exempt from any arrangements or included in any arrangements, these two options also need to be able to maintain prescribers' clinical autonomy to tailor prescribing to their individual patient's clinical needs. Two ways of achieving this have been identified:

- the prescriber could be asked to indicate whether the prescription item is to be subject to the dispensing flexibilities - opting in, so they would need to indicate, where appropriate, when they prescribe by brand, whether dispensing of a generic is acceptable.
- the prescriber could be asked to indicate if the prescription item is to be exempt from the dispensing flexibilities – opting out so they would need to indicate, where appropriate, when they prescribe a brand whether dispensing of a generic is not acceptable.

32. Opting in or opting out could be achieved in one of two ways.

(i) A tickbox system

33. In addition to the requirements of options 2 and 3, every NHS prescription could include a further statement as to whether the prescription item should be included or exempt from the arrangements and the prescriber should tick a box to indicate.

34. For example, under Option 2, for opting in to the arrangements, the rubric to be included in the standard formats for NHS prescriptions (electronic as well as manual) could be something along the lines of the following: '**Where indicated by the prescriber by ticking the box**, if the product mentioned in this prescription is referred to by a brand

name, the prescriber intends that either it or a generic equivalent may be dispensed, unless the medicine is listed in the exempt list found at Part XVIIID of the Drug Tariff.'

35. In this scenario, the dispenser can only supply a generic product against a prescription for a brand where the product is not in the exempt list and the prescriber has ticked the box to indicate that substitution may take place.
36. Alternatively, for opting out of the arrangements the rubric to be included in the standard formats for NHS prescriptions (electronic as well as manual) could be something along the lines of the following: *'If the product mentioned in this prescription is referred to by a brand name, the prescriber intends that either it or a generic equivalent may be dispensed, unless **the prescriber has ticked the box below or the medicine is listed in the exempt list found at Part XVIIID of the Drug Tariff**'.*
37. In this scenario, the dispenser can supply a generic product against a prescription for a brand where the product is not in the exempt list and the prescriber has not ticked the box.
38. Similar arrangements could be made under Option 3 using the tick box to enable the prescriber to opt in or opt out of the arrangements for each prescription item. For this option, for opting in to the arrangements, the product would need to be on the select list and the box would need to be ticked. For opting out of the arrangements where the product was on the select list, the box would not need to be ticked.
39. For paper prescriptions, to reduce the possibility of the box being completed by someone other than the prescriber, the tick box would need to be either completed electronically as part of prescribing via an electronic system and printed, or, if done by hand it would need to be counter signed by the prescriber.
40. The advantage of using a tick box is that it would clearly remind the prescriber that there is a choice to opt in or opt out of the arrangements. This arrangement would also satisfy current legislative requirements that dispensing must be in accordance with the prescription.
41. However, this method could present problems where there is more than one item on the prescription as there would be insufficient room for multiple tick boxes. It would therefore require a separate prescription form for each item to accommodate the tick box. This would result in a patient having to pay additional prescription charges (unless they are exempt) where two different strengths of the same product presentation are prescribed on different prescription forms. It would lead to inconvenience for GPs and increased costs to PCTs of providing additional forms. The prescribing system suppliers of NHS Electronic Prescription Service (EPS) prescriptions would also need to include this line on each EPS prescription item. A further complication is that NHS Prescriptions Services, the NHS organisation that processes prescriptions for payment, would need to re-engineer their scanners and business processes in order to recognise whether the prescription item was in or out of the arrangements depending on whether there was or was not a mark in the relevant tick box.

(ii) An endorsement

42. A second possibility is that prescribers add an endorsement on the face of the prescription, next to each prescription item as appropriate, using an acronym to indicate to the dispenser whether the prescription item is to be included in the arrangements or not.
43. For example, for Option 3, for opting in to the arrangements the acronym could be 'GS' for 'Generic Substitution', the rubric to be included in the standard formats for NHS prescriptions (electronic as well as manual) could be something along the lines of the following: ***'Where indicated by the prescriber marking the prescription item with GS if the drug mentioned in this prescription is referred to by a brand name and the drug is listed in Part XVIIID of the Drug Tariff, the prescriber intends that either it or a generic equivalent may be dispensed. For these purposes, a product is a generic equivalent if it has the same rINN or BAN as the proprietary version or it is a permitted alternative salt mentioned in Part XVIIID of the Drug Tariff.'***
44. In this scenario, the dispenser can only supply a generic against a prescription for a brand where the product is in the select list and the prescriber has marked the item GS on the prescription form. If the prescriber has not marked GS against the item, the generic substitution arrangements would not apply.
45. For opting out of the arrangements the acronym could be 'NGS' for 'Not for Generic Substitution' and the rubric to be included in the standard formats for NHS prescriptions (electronic as well as manual) could be something along the lines of the following: ***'If the drug mentioned in this prescription is referred to by a brand name, and the drug is listed in Part XVIIID of the Drug Tariff, the prescriber intends **unless the item has been endorsed 'NGS'** that either it or a generic equivalent may be dispensed. For these purposes, a product is a generic equivalent if it has the same rINN or BAN as the proprietary version or it is a permitted alternative salt mentioned in Part XVIIID of the Drug Tariff.'***
46. In this scenario, the dispenser can supply a generic against a prescription for a brand where the product prescribed is in the Drug Tariff list and the prescriber has not marked the item 'NGS' on the prescription form. If the prescriber marks the item 'NGS' regardless of whether the product is in the list, the substitution arrangements would not apply.
47. Similar arrangements could be made for Option 2 using the same acronyms. To enable opt in, where the product is not on the list, if the prescriber is content for substitution to occur they would need to endorse the item 'GS'. To enable opt out, where the product is not on the list, if the prescriber was not content with substitution they would need to endorse the item 'NGS'. Otherwise the dispenser would have flexibility as to which manufacturer or supplier's product they supplied.
48. Using an endorsement would mean that more than one item per prescription form could be accommodated. GPs' systems already allow for endorsements to be added, so it would only require the addition of a new endorsement rather than a new function. It has the additional advantage that NHS Prescriptions Services would not need to re-engineer their scanners, but they would however need to review their business processes to

recognise the endorsement. However as with GP systems this would not be a new function.

Scope of the proposals

49. At this point, the Department is only proposing considering drugs, and not appliances, for inclusion within the arrangements. Therefore, amendments to dispensing appliance contractors' terms of service is not necessary.
50. In addition, the Department is not proposing to apply these arrangements to dispensing doctors because dispensing doctors are generally dispensing against their own prescriptions, so it is unlikely that additional dispensing flexibilities would make a significant practical difference. Therefore, amendments to the terms of service of dispensing doctors – whether they provide pharmacy services as a dispensing doctor on a PCT's dispensing doctors list or as part of arrangements with a PCT for the provision of primary medical services - are not necessary.

Summary of proposals

51. We could maintain the present situation (option 1), make generic substitution the rule except for a list of drugs which are exempt (option 2) or make generic substitution the rule for a select list of drugs (option 3). For these last two options we can maintain the prescriber's ability to apply their clinical autonomy to tailor prescribing to their individual patients' clinical needs by providing them with the means to decide whether the prescribed item should be subject to the arrangements by enabling opt in or opt out by adopting a tickbox system or an endorsement. This arrangement would also satisfy current legislative requirements that dispensing must be in accordance with the prescription. The Department's preferred choice is for Option 3 and using an endorsement to enable the prescriber to opt the prescribed item out of the arrangements.

Why Option 3 and an opt-out endorsement

52. In the Department's view, Option 3 is the most proportionate implementation approach, which will be most acceptable to both patients and clinicians. It is not generic substitution of all drugs, but generic substitution for a specific list of drugs. Further, the prescriber will have the ability to opt a particular prescribed item out of the arrangement if it is not suitable for a particular patient.

53. The key benefits of this approach are:

- patients can continue to receive a specific manufacturer's product where their treating clinician judges that there is a clinical need;
- it ensures value for money is obtained and the savings to the NHS under the 2009 PPRS are maximised;
- while it will require either new NHS paper prescriptions or system suppliers to add the required wording on the electronic prescription form, the use of the endorsement is a more limited, and more practical, change than the use of a tickbox;
- the proposed list can be kept manageable and thus more easily recalled by prescribers and dispensers;
- implementation can be phased so that on the first day of implementation prescribers and dispensers are not required to consider whether a generic can be dispensed for all prescriptions still written as a brand where a generic is available.

54. The key risks are:

- the costs of implementation could be disproportionate to the savings;
- that prescribers may use the opt-out functionality unnecessarily;
- the difficulty of efficiently maintaining the Select List;
- the possibility of compromising patient safety:- Paper prescriptions without the additional wording will be circulating in the NHS for some time; for patients this may mean that they may receive a brand when the statement is not on the form, and then a generic when the necessary words are on a subsequent form and then possibly back to brand. One way of mitigating this (but at cost) is to recall prescriptions in use and for all prescriptions from a certain date to contain the required rubric.

55. However, on balance Option 3 best meets the objectives of continued prescriber autonomy to meet clinical need and maintain patient safety, increased financial efficiency, and a manageable increase in workload for prescribers and dispensers.

Implementation

56. As outlined in paragraph 12, in implementing generic substitution, we are governed by primary legislation in the Medicines Act 1968, which requires that a medicine is dispensed in accordance with the prescription. As outlined in Option 3, we are therefore aiming to achieve flexibility in which a manufacturer's product is dispensed by explicitly outlining the dispensing flexibility on the front of the prescription form (paper or electronic). It is proposed that to do this:

a) Changes to secondary legislation are needed, namely to NHS Pharmaceutical Services Regulations and NHS Local Pharmaceutical Services Regulations, making generic substitution part of pharmacist's terms of service. This will need to outline the dispensing flexibility that is allowed so long as the prescriber has not opted the prescribed item out of the arrangements. The Regulations would need to give the Secretary of State the power to establish and maintain the list of drugs for generic substitution. The changes will also need to include any service provision such as explanations to patients. It is expected that any cost implications are taken into account in funding for the community pharmacy contractual framework.

b) The rubric in the standard formats for NHS prescriptions (electronic as well as manual) would need to include:

If the drug mentioned in this prescription is referred to by a proprietary name and the drug is listed in Part XVIIID of the Drug Tariff, the prescriber intends unless the item has been endorsed 'NGS' that either it or a generic equivalent may be dispensed. For these purposes, a product is a generic equivalent if it has the same rINN or BAN as the proprietary version or it is a permitted alternative salt mentioned in Part XVIIID of the Drug Tariff.'

With paper prescriptions this wording could either be added in advance or it could be a requirement of prescribing system suppliers. We suggest that pre-printing the wording onto paper prescriptions, in advance, is the preferable approach.

c) While paper prescriptions can be written by hand and even a computer generated paper prescription can have an endorsement added by hand with a counter signature, most prescribers will be looking to their system suppliers to add the 'Not for Generic Substitution (NGS)' endorsement to the list of available prescriber endorsements on their prescribing systems.

d) A list of the products affected needs to be published and maintained (as referred to in (a) above).

e) Changes will need to be made to EPS systems by I.T. systems suppliers to accommodate the new endorsement. Prescribers will probably also want their systems to automatically identify to which products the arrangements will apply, unless they opt out if required.

Selection of Products

57. It is proposed that the list from which flexible dispensing is allowed will be short and focussed on products which will contribute the most to savings. The criteria for the list, and any revisions to it, will take account of:
- the percentage of generic prescribing for the product
 - the ready availability of generic versions
 - whether there are any general clinical or patient safety concerns with regard to interchange between different manufacturer's products
 - the cost savings to be made by allowing generic substitution.
58. The Department of Health will apply these criteria and review the list on a regular basis. A proposed list of products which could form the first list for generic substitution can be found at [Annex A](#) on page 25.
59. The initial list containing just under 40 products is likely to have only a few new products added no more than four times a year. As generic prescribing of individual products increases and the savings to be made from the flexibilities reduce, products could be removed.
60. Often the biggest savings will be made early on when a product comes off patent and generics become available. Due to the complexity of product patents, there is often not that much notice as to when generics will be available. Therefore it is not intended that the Department will publicly consult on the amendments to the list in order that it can quickly be amended to reflect the market. However, a balance needs to be struck to give prescribers and dispensers advance warning as to whether the arrangements now apply to a product. It is therefore proposed to give one month's notice in the Drug Tariff (which is published monthly, both in paper and online) before an addition or deletion is made to the list. No amendments to the list will have legal effect until the publication of the revised list in the Drug Tariff, at the end of the notice period.

Costs/Benefits

61. Details of the costs and benefits of these proposals are set out in the accompanying draft Impact Assessment.

Views sought

62. Views are sought on all aspects of the arrangements, but in particular:

Implementation approach

Question 1

a) In general do you think that the preferable implementation approach is indeed Option 3, with opt-out endorsement, ie allowing the dispenser flexibility as to which manufacturer's product to supply if a product is listed unless the prescriber specifically opts out?

(b) If so, do you have any particular comments regarding its workability for patients, prescribers and dispensers?

(c) If not, why not – what is your preferred approach – Option 1/2/3, opt-in/opt-out, tickbox/endorsement or other?

Question 2

Do you agree that using rINNs and BANs, and requiring the generic to be in the same pharmaceutical form as the named product, is the best way to identify products that are subject to the arrangements?

Question 3

a) Do you agree with the proposed scope of the definition of "generic equivalent", to allow for different salts?

b) Do you think that the proposed wording (see paragraph 56b) to be included within the rubric of NHS prescriptions (electronic as well as manual) delivers the definition effectively?

Question 4

a) Do you think a select list of just under 40 rINNs and BANs, plus permitted alternative salts, that is amended via additions and deletions, which in practice will be made no more than four times a year, is an appropriate balance between being flexible enough to reflect changes in the market, while still being workable for prescribers and dispensers?

b) Do you think it is appropriate for this list and the notice of its amendments to be published in the Drug Tariff?

Question 5

Do you have any comments on the proposed criteria that the Department should use to consider whether an addition or deletion should be made to the select list?

Question 6

Do you have any comments on the proposed initial select list in Annex A?

Question 7

Do you have any comments on the proposed scope of the arrangements, namely that dispensing by both appliance contractors and dispensing doctors is out of scope?

Impact Assessment

Question 8

Do you agree with our estimate of the likely benefits and costs? If not, please indicate and provide evidence, where possible, of any areas of disagreement.

Question 9

a) Do you think any of the options present any risks to equality for particular groups of people, people from minority ethnic groups, disabled people, older people, men women and transgender people and people from different faith groups? If so, what are they and what do you think needs to be done to address these risks?

b) Do you think there are opportunities to promote equality in any of the three options? If so, what are these?

Further Comments

Question 10

Do you have any additional comments on any aspect of this consultation?

Timetable for implementation

63. Subject to the outcome of this consultation, there will be a notice period before implementation, to enable preparation. Lead in time for practical implementation will depend on the Option taken forward.

How to respond

Published alongside this document is a template for responses.

Responses should be submitted by 30 March 2010

e-mail: generic.substitution@dh.gsi.gov.uk

or, posted to:

Beth Foster
Generic Substitution Consultation
Department of Health
456D
Skipton House
80 London Road
London SE1 6LH

Criteria for consultation

The consultation follows the 'Government Code of Practice on Consultation'. In particular, we aim to:

- formally consult at a stage where there is scope to influence the policy outcome;
- consult for at least 12 weeks with consideration given to longer timescales where feasible and sensible;
- be clear about the consultation process in the consultation documents, what is being proposed, the scope of influence and the expected costs and benefits of the proposals;
- ensure the consultation exercise is designed to be accessible to, and clearly targeted at, those people it is intended to reach;
- keep the burden of consultation to a minimum to ensure that consultations are effective and to obtain consultees' 'buy-in' to the process;
- analyse the responses carefully and give clear feedback to participants following the consultation;
- ensure officials running consultations are guided in how to run an effective consultation exercise and share what they learn from the experience

Consultation on the proposals to implement 'Generic Substitution' in primary care

The full text of the Code of Practice is available on the Better Regulation website at: www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44420.html

Comments on the consultation process itself

If you have concerns or comments which you would like to make relating specifically to the consultation process itself, please contact:

Consultations Co-ordinator
Department of Health
3E48, Quarry House
Leeds
LS2 7UE

Email consultations.co-ordinator@dh.gsi.gov.uk (Please do not send consultation responses to this address).

Confidentiality of information

We manage the information you provide to us in accordance with the Department of Health's Information Charter.

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004.

If you want the information you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, among other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department of Health.

The Department will process your personal data in accordance with the DPA and, in most circumstances, this will mean that your personal data will not be disclosed to third parties.

Summary of responses to the consultation

A summary of the responses to this consultation will be made available before or alongside any further action, such as laying legislation before Parliament, and will be placed on the Consultations website at:

www.dh.gov.uk/en/Consultations/responsestoconsultations/index.htm

ANNEX A

Proposed list of products for which substitution arrangements are permissible

rINN or BAN of Product Prescribed	Permissible Salts	Strength	Form
Aciclovir	N/A	200mg	Tablets
		400mg	Tablets
		800mg	Tablets
		200mg	Dispersible tablets
		400mg	Dispersible tablets
		800mg	Dispersible tablets
		200mg/5ml	Oral suspension
		400mg/5ml	Oral suspension
		5%	Cream
Alendronic Acid	sodium alendronate	10mg	Tablets
		70mg	Tablets
Amlodipine	besilate	5mg	Tablets
	maleate	10mg	Tablets
	mesilate		
Amoxicillin	trihydrate	250mg	Capsules
		500mg	Capsules
		3g	sachets
		125mg/5ml	Oral suspension
		250mg/5ml	Oral suspension
Atenolol	dihydrochloride	25mg	Tablets
		50mg	Tablets
		100mg	Tablets
Betahistine	Hydrochloride	8mg	Tablets
		16mg	Tablets
Bicalutamide	N/A	50mg	Tablets
		150mg	Tablets
Cetirizine	hydrochloride	10mg	Tablets
		5mg/5ml	Oral solution
Ciprofloxacin	hydrochloride	100mg	Tablets
		250mg	Tablets
		500mg	Tablets
		750mg	Tablets
Citalopram	hydrobromide	10mg	Tablets
		20mg	Tablets
		40mg	Tablets
		40mg/ml	Oral drops
Co-Codamol (Codeine /Paracetamol)	Phosphate (for the codeine)	8/500mg	Dispersible tablets
		8/500mg	Capsules
		15/500mg	Caplets
		30/500mg	Tablets
		30/500mg	Caplets
		30/500mg	Capsules
Co-Cyprindiol (Cyprote)	Acetate (for the	30/500mg	Effervescent tablets
		2mg/35mg	Tablets

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	cyproterone)		
Co-Tenidone (Atenolol/Chlortalidone)	N/A	50/12.5	Tablets
		100/25	Tablets
Diclofenac	sodium	25mg	Tablets
		50mg	Tablets
		50mg	Dispersible tablets
		12.5mg	Suppositories
		25mg	Suppositories
		50mg	Suppositories
		100mg	Suppositories
	potassium	25mg	Tablets
Diltiazem	hydrochloride	60mg	Tablets
Doxazosin	mesilate	1mg	Tablets
		2mg	Tablets
		4mg	Tablets
		4mg	Modified release tablets
		8mg	Modified release tablets
Enalapril	maleate	2.5mg	Tablets
		5mg	Tablets
		10mg	Tablets
		20mg	Tablets
Finasteride	N/A	1mg	Tablets
		5mg	Tablets
Fluconazole	N/A	50mg	Capsules
		150mg	Capsules
		200mg	Capsules
Fluoxetine	hydrochloride	20mg	Capsules
		60mg	Capsules
		20mg/5ml	Oral liquid
Ibuprofen	N/A	5%	Gel
		10%	Gel
		100mg/5ml	Oral suspension
Ipratropium	Bromide	250mcg/ml	Nebuliser solution
		500mcg/ml	Nebuliser solution
Ketoprofen	N/A	50mg	Capsules
		100mg	Capsules
Lisinopril	dihydrate	2.5mg	Tablets
		5mg	Tablets
		10mg	Tablets
		20mg	Tablets
Lisinopril/ hydrochlorothiazide	dihyrate	10mg/12.5mg	Tablets
		20mg/12.5mg	Tablets
Omeprazole	N/A	10mg	Gastro resistant capsules
		20mg	Gastro resistant capsules
		40mg	Gastro resistant capsules
Paroxetine	hydrochloride	20mg	Tablets
		30mg	Tablets
Piroxicam	N/A	10mg	Capsules
		20mg	Capsules
		10mg	Dispersible tablets
		20mg	Dispersible tablets

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		0.5%	Gel
Pravastatin	sodium	10mg	Tablets
		20mg	Tablets
		40mg	Tablets
Ramipril	N/A	1.25mg	Capsules
		2.5mg	Capsules
		5mg	Capsules
		10mg	Capsules
		1.25mg	Tablets
		2.5mg	Tablets
		5mg	Tablets
		10mg	Tablets
Salbutamol	sulphate	100mcg/dose	Aerosol inhaler
		1mg/ml	Nebuliser solution
		2mg/ml	Nebuliser solution
		2mg	Tablets
		4mg	Tablets
		2mg/5ml	Oral solution
Sertraline	hydrochloride	50mg	Tablets
		100mg	Tablets
Simvastatin	N/A	10mg	Tablets
		20mg	Tablets
		40mg	Tablets
		80mg	Tablets
Sodium Chloride	N/A	0.9%	Nebuliser solution
Sodium Cromoglicate	N/A	2%	Eye drops
Sumatriptan	succinate	50mg	Tablets
		100mg	Tablets
Terbinafine	hydrochloride	250mg	Tablets
		1%	Cream