

Consultation Reply Form

Closing date for responses: 30th March 2010

Please fill in the appropriate response.

Response form	
Name[s] : Nigel Morley M.R.Pharm.S, Joe Forshaw M.R.Pharm.S and G Bull BaHons, Russ Brookbanks,	
Contact address including postcode : 7 Prospect Court Courteenhall Road Blisworth Northants NN7 3DG	
Organisation representing (if appropriate) : Dispex Buying Group	
Email : victoria@surelines.com	

If you are responding on behalf of an organisation, please indicate which type of organisation you represent:

NHS	
Social Care	
Private Health/Independent Sector	
Third Sector	
Regulatory Body	
Professional Body	Yes
Education	
Trade Union	
Local Authority	
Trade Body	
Other (Please give details)	

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Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes. The relevant legislation in this context is the Freedom of Information Act 2000 (FOIA) and the Data Protection Act 1998 (DPA).

If you want the information that 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 amongst 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.

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. However, the information you send us may need to be passed on to colleagues within the UK Health Departments and/or published in a summary of responses to this consultation.

Consultation Questions

The Department welcomes comments and views from all interested parties on the proposals to implement 'Generic Substitution' in primary care.

We would particularly welcome views on the following questions:

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?

- a) No
b) See answer c) below
c) We would prefer option 1 [do nothing] as most prescriptions are already written by generic name and the only time an item is prescribed by its branded [proprietary] name is when there is an issue over clinical bioavailability or patient compliance. This decision is therefore best left to the prescriber to decide and not the dispenser.

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?

We do not agree that there should be any change to the current way in which a prescription is written by the prescriber and supplied by the dispenser and so using the rINN or BAN as the criteria to regulate the same named product is unnecessary and irrelevant.

Question 3

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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?

a) No as we do not agree that there should be any change to the current legislation regarding prescription writing and dispensing and therefore the inclusion of different salts is not needed and is therefore irrelevant.

b) No we do not agree that there should be any change to the current legislation regarding prescription writing and dispensing and therefore the proposed wording (paragraph 56b) to be included within the rubric of NHS prescriptions is not needed.

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?

a) No – there is no need to have a list of items which are suitable for substitution as the prescriber, at the point of prescribing has already made a conscious decision to prescribe a brand in all cases where a branded [proprietary] drug is chosen to be written on the prescription for that specific brand to be dispensed to the patient.

b) No – It is inappropriate for the Drug Tariff to contain a list of any medicines suitable for substitution as this will lead to confusion, more dispensing errors, slow down the dispensing process and generally add another level of administration to the NHS BSA Prescription Services which is unnecessary and difficult to implement or police.

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?

As we prefer option 1 – do nothing – we do not believe there is any need to produce such a list and therefore there is no criteria which we believe should be considered for the production or amendment of any such list.

Question 6

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

As we prefer option 1 – do nothing – we do not believe there is any need to produce such a list and therefore we have no comment to make on the proposed list as we do not believe there should be any such list in the first place.

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?

We prefer option 1 – do nothing and so there is no point in commenting on the inclusion of appliance contractors or dispensing doctors in the scope of these new arrangements as we do not believe any new arrangements should be made.

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.

We disagree there will be any significant savings to the NHS, as the proportion of prescriptions written by brand is already extremely low and is due to concerns over patient compliance and issues around bioavailability rather than for any other reason. Generic prescribing has been the norm in primary care for the past twenty years and there will be no significant change in current prescribing patterns due to these proposed changes to legislation [option 2 or option 3]. We in fact believe there will be an increased burden upon the NHS as a whole to introduce either option 2 or option 3 as a consideration of the increased cost of recalling all prescriptions currently in circulation, the cost of printing new prescription forms, the increased time in processing prescriptions by NHS BSA Prescription Services staff, upgrading current prescription processing software and hardware, the increase in cost by having to educate both prescribers and dispensers to the new system. The general increase in the administration burden of prescription writing, dispensing and processing will far out weigh any potential savings made via any form of generic substitution. The impact on the income of retail pharmacy should also seriously be considered as not only will retail pharmacists potentially lose money unnecessarily, slow down the dispensing process and the administration and checking burden upon them will be increased. Also please see our answer to question 9 a) below.

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?

- a) Older people are more likely to be confused by changes in their supplied medication on a more regular basis [than under the current arrangements] as recognised brands are substituted for unrecognised generics more often and this will lead to lower patient compliance through confusion and subsequently higher costs to the NHS as more patients are admitted to secondary care due to them not taking their medication. i.e. Poor compliance.
- b) Only option 1 – no change – provides any opportunity to promote equality as the decision to prescribe by brand is left to the prescriber who prescribes by brand for a particular reason already.

Further comments

Question 10

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

In summary we do not believe this is a rational use of NHS money as prescribers already make the maximum use of generic prescribing and only prescribe by brand where there is an issue as we have mentioned already. The increased cost to the NHS and burden placed upon prescribers and dispensers makes both options 2 and 3 both unwanted and unworkable and in practice will cost the DH more money than it is possible to save from the very small percentage of prescriptions that will be substituted via either method.

Fundamentally, any change of medicine determined as appropriate by the prescriber must carry with it a transfer of liability from the prescriber to the person effecting the change.

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Without such a transfer of liability the principle of generic substitution is likely to meet opposition from prescribers and indeed from those effecting the medicine change.

Where liability of this sort lies requires absolute clarity and may require defining in law?