



**Royal  
Pharmaceutical  
Society**  
of Great Britain

English Pharmacy Board

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25<sup>th</sup> March 2010

Dear Sir/Madam,

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

**RPSGB response**

***Background***

The Royal Pharmaceutical Society of Great Britain is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation. The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy. The Society leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums. Following the publication in 2007 of the Government White Paper Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century, the Society is working towards the de-merger of its regulatory and professional roles. This will see the establishment of a new General Pharmaceutical Council and a new professional body for pharmacy in 2010.

The Society welcomes the opportunity to respond the Department of Health's consultation on generic substitution.

**General comments**

The English Pharmacy Board (EPB) of the Royal Pharmaceutical Society of Great Britain (RPSGB) does not consider any of the options fully acceptable. We recognise that pharmacy has an important role and responsibility when it comes to making the best use of NHS resources. We therefore support the principle of generic substitution and recognise its potential role in better use of NHS resources. However, we do not consider any of the three options proposed to be the best course of action to achieve this.

We believe that generic substitution is a professional matter and our preferred option is that it should be left to the professional judgement of the pharmacist. Under the current proposals there is no opportunity for pharmacists, who are experts in the use of medicines, to be involved in the decision process of when to substitute generically. We believe that additional guidance should be developed to support and inform pharmacists when using their professional judgement

The primary purpose of generic substitution should be patient safety. Pharmacists have a role as educators of the public and have the ability to counsel patients and / or carers appropriately. The secondary purpose of this consultation is the cost of medicines to the NHS. We are not convinced that either option 2 or option 3 would save the NHS any money, as implementation of either option is likely to be bureaucratic and costly. Also, if implemented, these proposals could end up adding to the drugs bill through impaired compliance, wastage and poorer patient outcomes. We are also concerned that, even if the cost of medicines to the NHS reduces, the implementation costs for pharmacists, e.g., additional time for reviewing lists of approved (or not approved) for substitution medicines and providing additional counselling and assurance to patients, will not be appropriately remunerated

There are times when being able to substitute a generic for a branded product without having to consult the prescriber would be of benefit to all involved, especially the patient. An example is when a doctor writes a prescription out of hours, or whilst carrying out a home visit – this is often written as a particular brand. If the pharmacy does not stock that particular brand it would make sense for all concerned if they could substitute with the appropriate generic without having to contact the prescriber, as quite often the prescriber is no longer available. It is referral for clarification on such ‘minor’ issues that causes the most friction between prescribers and dispensers.

Reimbursement issues also need to be considered and there is scarce information on this within the consultation document. If a prescriber were to allow generic substitution but a pharmacist chose not to make that substitution for the clinical benefit of the patient, would the pharmacist be financially penalised for doing that? It has not been made clear how remuneration will be addressed as a result of the proposals in this consultation. Pharmacists should be reimbursed for what they supply as long as they have justification for supplying a particular product.

We are also concerned about the additional workload this could place on pharmacists’ dependent on how the scheme operates in practice as pharmacists will need to explain the process to patients. They will also need to regularly consult the generic prescribing list to ensure they were up to date

with the process. There is also the potential of accusations of misconduct or fraud if a pharmacist fails to notice if a prescriber has opted in or out of the scheme and this would need to be addressed and clarified. Liability is also a concern and again, this has not been clarified in the proposals. If a pharmacist substitutes and causes patient distress or reduction in health benefit because of a different, but recognised, side-effect profile, who would be liable in law?

The proposals outlined in this consultation would, we believe, be operationally extremely complex and there is a huge reliance on prescribers to get it right.

The EPB believes that these proposals for generic substitution are a short term fix and not a long term solution. The longer term solution would potentially require changes in legislation which would mean while the process for change would be more lengthy and involved, the outcomes would be better for all participants

There needs to be a focus on education so that prescribers prescribe generically wherever feasible and appropriate. Pharmacists can have a role in supporting prescribers to do this.

We are concerned that implementation of either option 2 or 3 could damage relations between general practitioners and pharmacists as pharmacists would be labelled as 'accountants of the NHS', and this at a time when we are encouraging collaboration between healthcare professionals.

### **Question 1**

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

As stated above, we do not fully agree with any of the options stated in this consultation and would propose a fourth option, where pharmacists have discretion to substitute generically where appropriate, and after consultation with the patient and / or carer. We are aware that this would require changes in legislation but would see this as a more comprehensive long term solution to the issue.

Clarity is also needed as to whether option 3 would allow a pharmacist to use their discretion to substitute or not. This consultation does not make it absolutely clear if all prescriptions would have to be substituted, or if the pharmacist would have professional discretion as there may be circumstances

where the branded product is appropriate for the patient but this may not be apparent to the prescriber. Patients could experience delays in obtaining vital medicines whilst such queries are being confirmed unless professional pharmacists' discretion was enabled.

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

It would be unacceptable for the pharmacist to have to substitute unless the prescriber endorsed otherwise, since this would indicate that remuneration would be based on the generic being dispensed – the consultation does not clarify the remuneration process. This would not help support the relationship between the pharmacist and the patient or the prescriber.

There is also concern from patients that new patients might be put directly on the generic medicine and accept a side effect without the chance to try the branded equivalent that may not produce the side effect. Prescribers should be required to explain to patients that they have the option of the proprietary brand.

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

Please see comments above. Since the vast majority of prescriptions are generated by computers which can be set to prescribe generically we do not see the need for such a change to the current system. Prescribers need to be educated and supported to prescribe generically where appropriate.

**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?**

If generic substitution was to be implemented it would be helpful to have a list of which medicines were equivalent. This could support both prescribers and dispensers in making appropriate decisions.

There are several medicines where different forms are still bioequivalent and savings can be obtained by the use of one form over another e.g. ramipril capsules vs tablets. In this situation it would not be necessary to use the same pharmaceutical form.

### Question 3

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

Yes, and consideration should be given to including different formulations.

**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?**

We believe that the implementation of the proposals could be overly burdensome and complex with little advantage to the NHS as a whole.

### 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?**

Yes, if this proposal is to proceed. However, the current proposed list would require a review (see answer to question 6).

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

We recognise that the list would need to be updated with some frequency in order for it to be kept up to date and these changes to be effective. This will however come with additional risk and responsibility being placed on both prescribers and dispensers to be up to date to avoid errors occurring. Increased flexibility through more generic prescribing and a greater role for pharmacists in discussing medicines with patients and then making substitution decisions would be a more preferable outcome.

However, if this proposal proceeds then this is the appropriate place to publish such information. It may also be beneficial for the information to be available in the BNF, although this could only be updated every 6 months.

### 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?**

Yes, the criteria should also consider whether a medicine is still available as a branded product, as some branded medicines are discontinued at the point of the generic becoming available. See also the answer to question 10 below. If

our additional suggestion were to be incorporated then the criteria would also need to consider products that are available in multiple dosage forms.

#### **Question 6**

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

Yes, there are no branded amoxicillin suspensions available as Amoxil was discontinued last year, nor are there any branded doxazosin tablets available as Cardura 4mg were discontinued when the XL formulation was launched. There are also no branded fluoxetine 60mg capsules so the inclusion of these drugs in the list is illogical. Indeed, for the fluoxetine, there is a significant saving to be made by prescribing 3X20mg instead of the 60mg capsules. We believe that the proposed policy requires further thought and discussion.

In addition, finasteride 1mg tablets are not allowed to be prescribed on the NHS so their inclusion in the list is pointless.

Some of the medicines listed do not currently have a generic equivalent manufactured so to include in the list is not rational.

#### **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 do not understand why dispensing doctors have been excluded from this consultation as this will lead to a variable service across the NHS. Also, we believe that all doctors should be treated equally in terms of prescribing for their patients. If the proposed option is carried forward it sets a precedent for a two-tier prescribing system, with preferential treatment for patients of dispensing doctors.

It is not clear whether the proposed 5% gain in generic prescribing is solely based on prescriptions that are dispensed by community pharmacists. If the figures include those prescriptions dispensed by dispensing doctors then there is unlikely to be a 5% gain as frequently the branded prescriptions are actually initiated by the dispensing doctors due to the different reimbursement deals they have available to them with drug manufacturers.

#### **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 do not believe that these estimates are accurate. The implications on pharmacy workload have not been considered and the potential costs of additional non-adherence and poorer patient outcomes have also not been considered.

It should also be noted that stock of medicines held in the pharmacy are not paid for by the NHS, pharmacists are only reimbursed once a medicine is dispensed, so we are unsure how claims of reduced stockholding can bring savings to the NHS (6a page 7).

### **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?**

Yes, potentially as certain minority ethnic groups require their medication to be Kosher. It may well be that the branded product is the only product where the manufacturer has obtained Kosher status. If a prescriber forgot to 'opt out' on the prescription, then the patient may receive a non-Kosher product. More work is required in this area to provide a readily available list of which medicines are / are not Kosher.

Where substitution occurs and the patient and dispenser do not have a common language, there may be reduced confidence by the patient in the medicine dispensed and this may lead to reduced adherence and wastage of medicines

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

No, all three options would require more work to promote equality as in the example given above.

### **Further comments**

#### **Question 10**

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

This consultation only applies to human medicines. It should be clarified that this does not apply to veterinary medicines where generic substitution is unlikely to be lawful as it applies to medicines supplied under the 'cascade' system. The veterinary surgeon would need to be contacted if any changes are made to a veterinary prescription.

As stated earlier, if the scheme were to also include substitution between different formulations that are considered to be bio-equivalent then pharmacists will be able to improve uptake of medicines by patients and reduce costs due to wastage and non-adherence. The suggested list includes ramipril capsules and tablets as there is a saving to be made when supplying these in preference to the brand. Taking this a step further, there is a saving to be made by supplying the capsule instead of the tablet.

We do not believe that there has been sufficient patient input into this suggested scheme; what are patient's views on generic substitution in relation to acceptance of a generic, especially if they are paying for their medicines.

The National press articles suggest that generic substitution, as outlined in this consultation, is not acceptable to the public and patients

The scheme does also not make clear, obviously depending on the choice and opt in / out method chosen, whether the pharmacist will have any discretion in choosing to substitute with a generic or not. The pharmacist may well be aware of a reason why the patient should not be substituted that the prescriber may not be aware of, and whilst this can be addressed by the pharmacist communicating with the prescriber, that is not always feasible, will add to the pharmacist's workload and be could be detrimental to patient care, especially those patients presenting outside of normal hours.

We would ask the question - does generic substitution apply to the location of the prescriber or the location of the dispenser? The consultation does not appear to take into account cross border issues. We would encourage the DH to make these proposals UK wide by working in conjunction with the relevant departments in Wales and Scotland simultaneously.



**Conclusion:**

We believe that the current proposals could harm both pharmacy / patient and pharmacy / GP relationships and that patient care could suffer and that pharmacists could face financial loss.

Yours sincerely

A handwritten signature in black ink, appearing to be 'L. Gilpin', written over a horizontal line.

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