

English Pharmacy Board 4 March 2009

PUBLIC BUSINESS

Electronic Prescription Service - Substitution

Purpose

To discuss issues with the Electronic Prescription Service (EPS r2) and the implications on pharmacy practice with specific reference to substitution of another product where a particular generic or parallel imported (PI) product is not available.

Strategic objective domain

- The public recognise and use pharmacists as the professionals with expertise in medicines, with a duty of care to supply the correct medicine to the patient.

Recommendations

Having considered and discussed the relevant issues the EPB members are asked to endorse the following recommendations concerning the EPS and issues concerning the substitution of prescribed products:

- i. Guidance should be issued to pharmacists, advising them to work closely with local GP practices in implementing EPS, so that agreed local prescribing lists are used in GP and pharmacy systems, based largely on VMP product codes, and formal agreement is reached on known areas where substitution will be necessary, and where specific products must be used for clinical reasons. It is envisaged that this guidance would be part of a broader RPSGB document concerning good dispensing practice using the EPS.
- ii. System suppliers should be made aware of the issue and advised that systems should be configured to pick, store and transmit VMP product codes, except in cases where it is appropriate to use the AMP product code, for clinical or other reasons.

1. Background

When the EPS is implemented, it is likely that more products will be prescribed by both product name and supplier, and therefore community pharmacists will regularly face instances where a product substitution will be required, because a particular generic or PI product is not available.

The Professional standards and guidance for the sale and supply of medicines, which supplements and supports the Society's Code of Ethics, currently states that "*except in an emergency, a specifically named product is not substituted with any other product, without the approval of the patient or carer, and the prescriber, a hospital drug and therapeutics committee, or other similarly agreed local protocol.*"

In the future, with the Electronic Prescription Service (EPS r2), prescriptions will be issued electronically for products, using the product codes within the NHS Dictionary of Medicines & Devices (DM&D). These will be either for the Virtual Medicinal Product (VMP) code (eg: Aspirin Tablets 75mg) or for the Actual Medicinal Product (AMP) code (eg. Angettes 75mg Tablets (Bristol Myers Squibb)).

If the AMP is selected, the prescription will therefore include details of the specific formulation and supplier. Consequently, as the DM&D is implemented in pharmacy systems, it is likely that there will be an increase in prescriptions with an AMP, where the actual supplier is specified. As well as AMP product codes for generics (eg Amoxicillin Capsules 500mg Capsules (21) (Kent Pharmaceuticals)), the DM&D also lists Parallel Imported (PI) products in AMP form, with their supplier details. Also, the

DM&D lists separately products that are the same formulation, with the same Marketing Authorisation (MA) number, but sold by different companies.

However, it is not always possible for a pharmacist to supply a specific generic product or PI product against a prescription, due to stock availability and other considerations.

2. Legal Position

The Medicines Act 1968, S64, states that “*no person shall, to the prejudice of the purchaser, sell any medicinal product which is not of the nature or quality demanded by the purchaser*”.

The Society’s interpretation of the law is that substitution covers not only the formulation of the product, but also its origin. Consequently, if a prescription is for Amoxicillin 500mg Capsules (21)(Kent Pharmaceuticals) and an equivalent product from Ranbaxy is supplied, this is considered to be substitution, and therefore a contravention of the Medicines Act.

3. Questions to Consider

Members of the EPB may wish to consider the following questions:

- Should system suppliers be encouraged to configure systems for routine VMP prescribing (with AMPs used only when clinically indicated)?
- Should pharmacists be encouraged to resolve substitution issues by local agreements with GPs? (an “*agreed local protocol*”), and by encouraging local GPs to prescribe at the VMP level? (this will facilitate good local relationships between pharmacists and GPs).
- Should both of the above approaches be taken?
- What role might PCTs have in facilitating the resolution of this issue by appropriate local implementation of EPS?

Members may wish to consider the scale of this issue going forward. Initially, this issue could be assessed in the EPS r2 pilot sites, and lessons learnt fed back to Connecting for Health prior to roll-out.

4. Risk Implications

If action is not taken, pharmacists’ workload will increase due to the need to resolve substitution issues generated by the EPS software. Also, it is important for the Society to be seen to be upholding the current interpretation of the law on this issue.

5. Resource Implications

The only resource implications will be related to the production of guidance for pharmacists and system suppliers.

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- ii. System suppliers should be made aware of the issue and advised that systems should be configured to pick, store and transmit VMP product codes, except in cases where it is appropriate to use the AMP product code, for clinical or other reasons.

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