

Summary of Proposed Changes to Dispensing Regulations

The Department of Health is signed up to the Pharmaceutical Price Regulation Scheme (PPRS) which is an agreement with the Association of the British Pharmaceutical Industry to control the price of branded drugs sold to the NHS. One of the scheme's aims is to reduce the amount spent on branded drugs by the NHS. Some price cuts have been introduced to do this but the department also wants to introduce 'generic substitution' so that fewer branded drugs are supplied by pharmacists. Branded drugs are more expensive than generic ones.

What are the reasons for the change?

- Cost - In 2008, 5% of drugs prescribed in primary care were prescribed by brand where there was a generic alternative available. Decreasing this 5% is the main reason for bringing in generic substitution.
- Flexibility - Pharmacists would have greater flexibility meaning patients could receive drugs more quickly and less stock would be held by the pharmacy.
- Certainty about treatment - Prescribing generically is said to encourage 'treatment recognition', which is said to give healthcare professionals greater certainty about the right medication to use.

What are the proposed options?

1. Do nothing.
2. Create an **exempt list** of branded drugs so that certain products **could not** be swapped for a generic equivalent. The list would need to be constantly updated to reflect new products becoming available and drugs would be likely to move on and off it. The Department of Health argues that this would entail settling a legal definition of 'generic equivalent' which could be very difficult.
3. Creating a **specific list** of drugs that **could be** swapped. The opposite of option 2. This would mean that legally defining 'generic equivalent' would be simpler because of the fewer instances where substitution is possible. Under this option, all prescriptions would be dispensed as written except those on the list. This is the Department of Health's preferred option.

'Opting in' and 'opting out'

Under options 1 and 2, doctors and other prescribers would have the discretion to 'opt in' or 'opt out' an individual prescription.

- Opting in - If the doctor prescribes by brand and the item **is suitable to be replaced** with a generic alternative, doctors would have to indicate this on the prescription.
- Opting out – If the item **is not suitable to be replaced** with a generic alternative, the doctor would have to indicate this in the same way. This is the Department of Health’s preferred option.

For opting in and out, prescription pads and electronic systems would be changed to make sure this happened. There are two suggestions for how this would work:

- A tickbox could be added to prescription pads and electronic systems. It is feared that with this option patients would incur additional prescription charges because lack of space on the forms would mean using more than one.
- An endorsement being added by the prescriber next to each item. For example, to opt in the prescriber could add ‘GS’ (Generic Substitution) to indicate generic substitution is suitable or, to opt out, ‘NGS’ (Not for Generic Substitution) to indicate when it is not suitable. This fits with existing GP systems and is the Department of Health’s preferred option.

Some Considerations:

- The alternative drug may be made with different ingredients. This could potentially have a serious impact especially for epileptic conditions, neurological conditions, or when several drugs are taken together.
- Some ingredients may be unsuitable for dietary, cultural or intolerance reasons.
- Some patients may become confused by or be resistant to a change to the colour of their medication where a lot of different drugs have to be taken together.
- Regulations would need to be set out for informing patients if / when repeat prescriptions are changed.

If you have any queries or would like to discuss this then please do not hesitate to contact

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