Medicines and Healthcare Regulatory Agency (MHRA) "Consolidation and review of UK medicines legislation"

Section 11 concerns

On October 25 2011, the MHRA issued a consultation document on the need and options for consolidating the UK medicines legislation.[1] This exercise aims to rationalise and simplify the existing fragmented and complex medicines legislation, to improve the coherence of the regulatory framework. All interested parties are entitled to respond to this consultation, and the consultation closes on the 17 January 2012.

It is important that any new legislation is clear and is not open to misinterpretation. Having reviewed the document, there are some concerns over section 11: "Optimisation of medicines use". Sections 11.1 and 11.3 propose that a pharmacist would be able to change the name of the product or its common name, and the directions for use of the product (presumably dosage instructions), on a prescription without notifying the prescriber. While it is important that pharmacists review prescriptions and act as a safety net in case of prescriber error, this should not extend to the ability of the pharmacist to change the name of the product prescribed.

Allowing pharmacists to change the name of the prescribed medicine and its directions for use could in effect lead to generic or therapeutic substitution by pharmacists. The way the proposed legislation is currently drafted, a pharmacist would be free to dispense a generic medicine against a prescription for the brand. This was subject to a full public consultation process by the Department of Health (DH) in 2009 and was deemed not to be in the best interest of patients.[2]

DH automatic generic substitution consultation overview

In March 2009, the DH and the Association of the British Pharmaceutical Industry (ABPI) proposed the introduction of automatic generic substitution (AGS). AGS would have allowed pharmacists to switch prescriptions for branded medicines to generic medicines unless the doctor had specifically specified that substitution should not occur. Under AGS, these switches would have occurred without informing the prescriber.

Initially, there was no plan for a consultation on this issue. However, such was the concern from interested parties that the DH announced in September 2009 that there would be a full public consultation.[3]

On Thursday 14 October 2010, the DH announced that it had stopped plans to introduce AGS by pharmacists.[4] The DH consultation had resulted in written responses from 423 organisations and individuals. There were three key concerns raised by respondents:

- The threat to patient safety
- Doubts that AGS really would generate cost-savings
- Other ways for generic prescribing could continue to be encouraged, and might be more effective

An analysis of responses, undertaken by an independent company, was reviewed by the DH. It decided that the concerns over patient safety were sufficiently grounded in fact and that it was therefore not appropriate to implement AGS.[2]

Response to the MHRA consultation

The importance of optimising medicine use is clear, both for patient well-being and to ensure that the ever-stretched NHS budget provides maximum benefit for the greatest number of patients. The correct use of medicines is important for achieving this goal, and the role of pharmacists is fully acknowledged in helping to achieve this. However, it is important that the relevant legislation is worded accurately to ensure that generic substitution or even therapeutic substitution by pharmacists is not inadvertently embedded in medicines legislation. The extensive review undertaken following the DH/ABPI proposal of generic substitution has clearly shown that patient safety would be jeopardised for limited, if any, cost savings.

Anyone who has concerns should visit the MHRA website where they can review the consultation document and express any concerns or views:

http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON132054

Alternatively, go to the MHRA website, click on 'your views' and 'consultations' and you will find the consultation document and the reply form there.

Concerns to highlight to the MHRA

Responses to the consultation, pointing out that the currently proposed wording of the legislation may enable generic substitution by pharmacists – which poses dangers to patient safety as previously recognised by the DH – will be vital to avoid a serious error by the MHRA, which could have significant but unintended consequences.

Should you wish to respond in this way, the information could be communicated in section 27 of the response document: "Do you agree with the proposal to facilitate the optimisation of medicines use? Why, or why not?"

Responses could set out that:

- Sections 11.1 and 11.3 of the proposed UK medicines legislation state that a pharmacist would be able to change the name and dosage instructions of a prescription drug without notifying the prescriber
- As it currently stands, Section 11 would allow generic and therapeutic substitution by pharmacists, which we assume is not the intention of the MHRA
- The DH has already consulted on generic substitution by pharmacists and concluded that it was not appropriate for three key reasons
  - The threat to patient safety
  - Doubts that AGS really would generate cost-savings
  - Other ways for generic prescribing could continue to be encouraged, and might be more effective
- We ask that the MHRA changes the wording to ensure that the legislation does not inadvertently allow generic substitution by pharmacists
- In addition, the legislation should specify that changing the name of a drug is allowed only in circumstances where the pharmacist suspects a genuine error by the prescriber, and does not permit generic or therapeutic substitution.

Remember that the consultation deadline is 17th January 2012.

If you have any queries or would like any further information please do not hesitate to contact us.

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References

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