Outcome of consultation MLX 384

PROPOSALS FOR AMENDMENTS TO MEDICINES LEGISLATION TO SIMPLIFY THE INFORMATION REQUIRED TO BE INCLUDED IN SOME ADVERTISEMENTS TO PRESCRIBERS AND SUPPLIERS OF MEDICINES

The MHRA published the MLX 384 consultation in February 2014 and wrote to bodies representing doctors, pharmacists and other healthcare professionals and the pharmaceutical industry to invite their comments. The proposals also received coverage in the main pharmacy journals. The consultation closed on 22 April 2014.

Sixteen responses were received, including seven from healthcare professional and NHS bodies, four from trade associations and industry self-regulatory bodies, four from pharmaceutical companies and one from a regulatory consultant.

All respondents who commented agreed that the short form of advertisement was suitable for GSL products and that the full SPC could be provided instead of a summary for medicines being promoted for over-the-counter (OTC) sale. The proposal to use short form advertisements for P medicines was supported by industry but views were more mixed among healthcare professionals. The main pharmacy body, two NHS pharmacy responses and one medical body were supportive but two bodies, representing pharmacists and GPs, had concerns about access to information for staff in training and pharmacy staff in general.

These concerns are addressed by non-legislative safeguards. The MHRA will use the marketing authorisation and self-regulation to require that the short form of advertisement is not used for innovative medicines for the first two years after launch. This will ensure pharmacy staff have the opportunity to gain familiarity with the product. The MHRA has also gained agreement from PAGB to include a requirement that their Code of Practice will require that training materials always carry the full prescribing information.

The legislative changes are included in the Human Medicines (Amendment No. 2) Regulations 2014 (SI 2014/1878) and come into force on 1 October 2014. Regulation 24 enables advertisements for medicines available without a prescription to contain a website address where information on adverse reactions, precautions, contra-indications and methods of use can be found as an alternative to providing that information on the face of the advertisement. Regulation 29 enables advertisements to include relevant entries from the medicine's summary of product characteristics as an alternative to a summary of those entries.

MHRA
30 September 2014