

MHRA Informal Consultation: Review of the Regulation of Unlicensed Medicines

Response date: 30 June

The Pharmaceutical Society of Northern Ireland welcomes the MHRA's informal consultation paper on the review of the regulation of unlicensed medicines and is grateful for the opportunity to provide input at an early stage of the project.

The Society agree with the rationale given in the MHRA's concept paper for conducting a review of the regulation of unlicensed medicines: that current provisions have been in place for a considerable time and there is a case for reviewing how well the provisions are suited to today's healthcare context.

Joined-up regulation:

The Society support the ability of clinicians to exercise their professional judgement, in appropriate circumstances, to commission the supply of an unlicensed medicine in order to meet the needs of an individual patient.

However, the unlicensed use of medicines should only be considered when there is no equivalent licensed alternative available and its use can be clearly justified clinically and pharmaceutically.

It is also of great importance that clinicians commission unlicensed medicines within clearly defined parameters of responsibility and accountability.

The Society therefore recommends the forthcoming review includes within its scope an investigation of:

- the strength or otherwise of professional regulation and guidance in the area of unlicensed medicines use; and
- the extent to which professionals understand their accountability in relation to the use of unlicensed medicines.

The review should aim to ensure that the medicines regulator and the relevant professional regulators are working together to deliver robust, transparent and coherent regulation of the use of unlicensed medicines.

The concept paper states that *“a broad interpretation of the term regulation will be taken, to include alternatives to medicines regulation that may achieve the same objectives.”* For the purposes of the review then, the interpretation of the term regulation should include professional regulation. Professional regulators should be closely involved in the work of the review.

“Appropriate circumstances”

In the concept paper one of the four primary objectives of the review is:

- 1. That clinicians should have the ability in appropriate circumstances to exercise their professional judgement to commission the supply of an unlicensed medicine to meet the special needs of an individual patient.**

The Society supports this objective. Furthermore, the Society recommends the MHRA review investigate the current regulatory procedures for defining what constitutes an “appropriate circumstance” and if this well understood by professionals. The MHRA should work with professional regulators such as the GMC, RPSGB, GDC and NMC as necessary in reaching its conclusions.

In the months ahead as the review progresses, the Society would be willing to participate in any informal consultation meetings or workshops with the MHRA on the regulation of unlicensed medicines, in so far as they apply to the professional regulation of pharmacists.