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Ms Judith Thompson
Policy Division
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Dear Ms Thompson

Post-Implementation review of the Human Medicines Regulations 2012 Ref: MLX 391

The Royal Pharmaceutical Society (RPS) is the professional body for pharmacists in Great Britain. We are the only body that represents all sectors of pharmacy in Great Britain. The RPS leads and supports the development of the pharmacy profession including the advancement of science, practice, education and knowledge in pharmacy. In addition, we promote the profession's policies and views to a range of external stakeholders in a number of different forums. The RPS welcomes the opportunity to respond to this consultation.

Pharmacovigilance

The RPS understands the implementation of the Pharmacovigilance Directive (Directive 2010/84/EU (amending Directive 2001/83/EC) ensured alignment of the UK and the wider European Union. This is important as most pharmaceutical companies need to comply with international regulations as well as those in the UK, and therefore international harmonisation is important for the efficient operation of these important procedures. At the time of implementation, the UK was already recognised as one of the leading member states with pharmacovigilance systems in place. The RPS in collaboration with the Association of the British Pharmaceutical Industry (APBI) have published a series of guides to raise awareness of pharmacovigilance through pharmacy. These include:

Safe and effective use of medicines: Risk minimisation activities
https://www.rpharms.com/resources/quick-reference-guides/pharmacovigilance-advice-for-pharmacists
Black triangle: additional monitoring of medicines
https://www.rpharms.com/resources/quick-reference-guides/black-triangle-additional-monitoring-of-medicine
Pharmacovigilance: risk minimisation activities
https://www.rpharms.com/resources/quick-reference-guides/pharmacovigilance-risk-minimisation-activities

Cross-border prescriptions

In 2012 the RPS supported proposals to amend legislation to adopt a non-exhaustive list of prescription requirements for both incoming and outgoing cross-border prescriptions. Generally, this has resulted in improved certainty and has enabled pharmacists to support patients travelling from the European Economic Area (EEA). We have published guidance to raise awareness and we respond to queries from pharmacists about this topic.

European economic area (EEA) prescriptions
https://www.rpharms.com/resources/quick-reference-guides/european-economic-area-eea-prescriptions

Whilst there are benefits in continuity of care for patients travelling to the UK, and UK patients travelling to the EEA with prescriptions which can be used during travels, we are sadly aware of death from the misuse of drugs associated with an EEA prescription issued remotely in the Czech Republic for a patient based in the UK. Further details are available in the coroner's report.
https://www.judiciary.gov.uk/wp-content/uploads/2016/11/Breatnach-2016-0330.pdf

Repeal of section 10(7)

Section 10(7) of the Medicines Act 1968 provided an exemption which permitted registered pharmacies to trade in small quantities of medicines without a wholesale dealer's licence (WDL). We understand that this was repealed in 2012 as it was not compatible with EU law. A regulatory note was subsequently published by MHRA enabling small quantities of medicines to be supplied on an occasional, not-for-profit basis and not for further wholesale distribution to healthcare professionals, other pharmacies, or others for the provision of healthcare services. It would be useful to have more clarity and reassurance that movement of medicines within the NHS such as the use of stock orders (GP10a used in Scotland) ) and the requirement to supply across hospital entities, which are routine parts of the NHS supply chain , are exempt from requiring a WDL.

The regulatory note is published on the MHRA website and reproduced within the annual RPS Medicines, Ethics and Practice guide and in Dale and Appelbe's Pharmacy and Medicines Law text book
This note remains important in underpinning the confidence of pharmacists in the provision of healthcare supplies.

Other comments

Informal up-to-date version of the HMR 2012 regulations
At the time of the 2012 consolidation, one key benefit was the proposal to have an informal up-to-date version of the consolidation regulations showing all amendments. This would still be very helpful if it becomes available.

Emergency supply
The HMR 2012 regulations allow emergency supplies of medicines to be made at the request of a prescriber or by a patient. Currently the pharmacist must interview the patient and it is not possible for a pharmacy to supply a medicine at the request of a patient's representative (e.g. a parent, spouse, or carer) even though it may be in the patient's best interests. This is a barrier to care and pharmacists should be empowered to use professional judgement in these situations to make an emergency supply and act in the patient's best interests if needed and appropriate.

'Appropriate date' regulation 217(7)
The RPS believes there is an inconsistency between the Human Medicines Regulations 2012 as amended and the Misuse of Drugs Regulations 2001 as amended in the definition of 'appropriate date' for health prescriptions, and prescriptions which are not health prescriptions. The HMR 2012 differentiates between the two, whilst the Misuse of Drug Regulations 2001 does not. We believe this is an anomaly.

Hopefully this response is helpful. Please do not hesitate to get in touch if you require any further information.

Yours sincerely

Wing Tang
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Royal Pharmaceutical Society