

Ann Ryan  
MHRA  
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151 Buckingham Palace Road  
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## NOTIFICATION OF INTENTION TO AMEND THE HUMAN USE REGULATIONS 2012:

Dear Ms Ryan,

We write on behalf of the Royal Pharmaceutical Society (RPS) to respond to the above consultation document.

The Royal Pharmaceutical Society is the professional body for every pharmacist in Great Britain. We are the only body that represents all sectors and specialisms of pharmacy in Great Britain.

The RPS leads and supports the development of the pharmacy profession to deliver excellence of care and service to patients and the public. This includes the advancement of science, practice, education and knowledge in pharmacy and the provision of professional standards and guidance to promote and deliver excellence. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

Thank you for the opportunity to respond to this informal consultation.

In principle we support the proposals to amend the Human Use Regulations 2012 to implement changes arising from the adoption of Article 11 of the Cross-Border Healthcare Directive EU Directive 2011/24 EU on the application of patients' rights in cross-border healthcare.

The additional information, along with the measures you propose in Annex A, section 2 will be helpful for pharmacists in using their professional judgment as to whether or not to dispense a prescription, however there are some aspects which could raise unforeseen challenges and which we feel warrant further discussion before a full response could be submitted.

Most patients requiring supplies of medication in another EU member state would be presenting with an NHS prescription form and the non-exhaustive list in Annex B contains some items which are not presently included on these forms. Prescription forms also vary across the devolved countries.

Electronic prescribing is at different stages across the three nations and electronic signatures are not the norm.

There is potential for confusion among patients regarding the status of prescriptions which can be written by various health professionals and charges vary across GB

In answer to your specific questions:

1. To what extent do you think these proposals will have a positive or adverse impact?

There is not enough information in the informal consultation to give an informed answer to this question. We would like to discuss this with you in further detail to help inform any profession guidance which would be necessary to minimise any disruption to patient care.

2. What can be done to manage any adverse impact?

The list of requirements and conditions along with any supporting information should be easily accessible on the MHRA website and close liaison with all healthcare professional bodies would be necessary to ensure that prescribers, pharmacists and the public are clear on the procedures to be followed.

These proposals will be very pertinent to our members and we would very much like to discuss the potential implications further with you at the earliest opportunity.

Kind regards,



Aileen Bryson  
Practice and Policy Lead, Scotland