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Directive 2011/62/EU Falsified Medicines

Dear Ms MacDonald,

Thank you for the opportunity to respond to your letter seeking views on the listing of prescription medicines that shall not bear the safety feature and the non prescription medicines that shall bear the safety feature as stipulated in the Falsified Medicines Directive (FMD)

For reference I have attached the Royal Pharmaceutical Society (RPS) policy on this directive which was developed across the three national pharmacy boards with an expert working group representing both primary and secondary care. Our policy has tried to address the practical implications of the Directive and focuses on solutions which will minimise disruption to patient care and pharmacy practice across the UK when the Directive is implemented. We support the FMD as a means of further improving patient safety but recognise that it presents challenges and would be happy to work with the MHRA as work progresses towards implementation.

The proposals for black and white lists raise several questions for pharmacy practice across all sectors which merit further discussion and we would like to meet with you to discuss these more fully. We have consulted with our expert working group and I have outlined their general issues and some specific concerns below.

- For prescription only medicines the criteria are generally sound. However, specifying those medicines that are exempt increases the potential for counterfeiters to target those items. We therefore believe that the simplest approach to prescription items would be to have no exceptions and all items to be routinely scanned. i.e. there would be no requirement for a white list.

- The situation for over the counter (OTC) products is more complex and raises some questions on the practical aspects of implementation.

- Who would monitor the black list for amendments?

- If one brand of a product was found as counterfeit, would all brands containing that active ingredient need to be scanned?

- The lists would be available for counterfeiters to see, helping them target new items on an ongoing basis.

- There is a wide variation in the legislation across the member states with regards to sale and supply. Our understanding is that only one black and white list will operate across the EU and member states will not be able to adapt this in order for the database to function efficiently Is this correct and if so how will the list take into account variation across the member states ?

- The price criterion seems arbitrary and adds another layer of bureaucracy into the system. In addition there is potential for manufacturers to drive costs up to ensure their products are above the two Euro mark and therefore protected by the safety features

- Not all pharmacies or other retail outlets currently use end point of sale scanning systems. Would a black list mean the installation of new scanners and software for OTC sales?

- Can we be assured that pharmacies will not have to refer to lists before dispensing and that software would incorporate this check?

- Have pharmacy medication record (PMR) suppliers been consulted on software and system requirements, and are they aware of the potential statutory changes?

- How would requests for imports of unlicensed items be dealt with? e.g. patient named medicines. Is there a potential gap for manufacture of unlicensed medicines?

We hope you agree that further discussion on the above issues would be useful, and therefore request a meeting with you to explore these issues in more detail. A meeting at your earliest convenience would help us support you as much as possible in taking this work forward.

Kind regards,

Aileen Bryson
Policy and Practice Lead
Royal Pharmaceutical Society

The Royal Pharmaceutical Society (RPS) is the professional body for pharmacists in Great Britain. We represent all sectors of pharmacy in Great Britain and we lead and support 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.