ROYAL PHARMACEUTICAL SOCIETY

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DH Review of the Balance of Competencies: Health Call for evidence

The Royal Pharmaceutical Society (RPS) is the new professional body for every pharmacist 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 within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.
Its functions and services include:
Leadership, representation and advocacy: promoting the status of the pharmacy profession and ensuring that pharmacy's voice is heard by governments, the media and the public.
Professional development, education and support: helping pharmacists to advance their careers through professional advancement, career advice and guidance on good practice.
Professional networking and publications: creating a series of communication channels to enable pharmacists to discuss areas of common interest.

General Comments

European legislation encourages a pan European approach to best practice and attempts to provide improved patient and public health outcomes for all citizens of the EU. This approach has addressed issues which would otherwise perhaps not been as high on the UK agenda.
Although there are long term benefits to the UK citizens, this can sometimes prove initially disrupting or potentially have financial consequences. Pharmacy systems differ considerably across the member states and there are examples where the EU directive is not a good fit for UK models or practices, raising the potential for disruption to health services and increased risks to patient safety. Examples are provided below.
The RPS has a commitment to make Great Britain one of the safest places to take medicines and will champion advances in patient safety and improved patient outcomes. However apparent lack of stakeholder consultation by the UK regulator and subsequent negotiations at an early stage in proposed EU legislation has sometimes hampered progress. In our response to the recent consultation on the MHRA corporate plan we have requested earlier stakeholder engagement and more transparency to address these issues.

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1. **MHRA Consolidation and Review of UK medicines legislation. The EC directive 2011/62/EU**

This is an example of Shared Competencies where it would have been helpful for the UK to adapt the directive to be a better fit with pharmacy practice in the UK.

Section 10 of the Medicines Act traditionally allowed pharmacists to move small amounts of stock (up to 5% of turnover) without the possession of a Wholesale Dealers Licence (WDL) This facilitated supplies to GP surgeries, ships medical rooms, sports clubs, mountain rescue teams, universities, other pharmacies, between hospital sites and other such examples, in the normal course of community pharmacy business.

The amendment of an EC directive removed this exemption, requiring a solution to be found, or for widespread disruption to be caused to healthcare supplies across the UK.

Unfortunately by the time this was addressed by UK regulatory authorities, the opportunity to work with the EU legislators to find a suitable solution that addressed the issue had passed. It is understood that the UK had a period of 18 months to adopt the legislation. Advice was sought from the Royal Pharmaceutical Society and other stakeholder organisations after 14 months had elapsed.

The amount of work required to be undertaken in a very short period of time, following the passing of European legislation, was beyond what should be expected and the only possible outcome partially ameliorated the key issue for the UK. In order to provide continuity of patient care registered pharmacies are now required to purchase WDLs at considerable cost, making many small business transactions financially prohibitive. This has resulted in restriction of movement of medicines, with some pharmacies no longer able to supply their customers and difficulties in obtaining supplies for some organisations.

In this example there was no discernible benefit to pharmacy practice or patient care in the UK to be gained from implementing this aspect of the directive as it stood, and engagement with the EU Institutions before the Directive was published, or engagement with key stakeholders 14 months earlier would have resulted in a Directive that recognises UK practice or a more pragmatic outcome.

1. Falsified medicines

This is another example of where difficulties will be experienced by pharmacists and other stakeholders, due to the perceived reticence of the UK Government to engage fully with all stakeholders.

The wording of the EC directive 2011/62/EC has resulted in differences in interpretation by member states rather than a unified approach to this issue. The adoption of the Directive in the form set out by the MHRA does not recognise current pharmacy practice in the UK. It offers no benefits to those responsible for using the system and it appears there is little potential to police the National IT system the Directive introduces. There appears to be little reason why this Directive will be implemented in this form.

Directive 2011/62/EU has the potential to improve patient safety and reduce the incidence of falsified medicines in the legitimate medicine supply chain – if the spirit of the Directive is followed and it is implemented as fully as other member states. However, if implemented in the form currently proposed by MHRA stakeholders have given views to the UK Government that there is no incentive or rationale for pharmacists to use the new system.

To date, the UK regulator appears to be unwilling to engage. The result is a reduced period of time to introduce the required systems, which will incur additional cost and resources. It is anticipated that software providers will be required to use additional resource to meet shortened deadlines rather than merge the creation of new software with existing work streams.

The directive will conflict with several current practices in pharmacy, which are interwoven into other pieces of UK legislation and will present pharmacists with conflicting legal frameworks. Currently prescriptions in the UK are not always for original pack quantities and pharmacists frequently split packs to accommodate this. In other member states original pack dispensing is the norm and the EC Directive reflects this.

RPS is fully supportive of the need to recall medicines where there is a risk to patient safety however there are areas where the proposed requirement to recall individual supplies could cause significant disruption to patient care including:

- Hospital pharmacies where medicines are still frequently distributed to individual patients from pharmacy stock, rather than using patient's own supplies.
- People whose medicines are supplied in multi-compartment compliance aids to support medicines adherence .This will include many of the growing care home and frail elderly population.

There is the potential to create a national IT system that is a benefit to those who will use it, in addition to the patients who this legislation seeks to protect.
Engagement with the EU Institutions before the Directive was published, or engagement with key stakeholders earlier would have resulted in a Directive that recognises UK practice or a more pragmatic outcome.

2. Free Movement of Persons. The Directive 2005/36/EC of the European Parliament and Council; The Professional Qualifications directive.

The directive has enabled the free movement of pharmacists between EU member states despite professional activities being quite different across the EU. For instance, in the UK, pharmacists deliver additional activities above the limited list of authorised activities described in the Directive. Thus, the current role of the pharmacist in the UK is much wider than that described in the directive and .therefore compared to other healthcare professions such as medicine and dentistry, the impact of free movement has been limited for pharmacy.
An analysis of the General Pharmaceutical Council's (GPhC) register of pharmacists indicated that of the 46,310 pharmacists (in England, Scotland and Wales), 5,460 qualified overseas (11.8%) and of these, about half (49.5%) entered via the European route.
The impact of the free movement of pharmacists between EU member states can also be assessed from the GPhC register of pharmacists in 2011. In 2011, there were 3,526 new entrants to the register, 791 of these (22.4%) qualified overseas and 517 of the new registrants (65.4%) came from Europe.
RPS responded to the consultation on this directive to highlight the omission of the need for language testing in some instances when employing health professionals from the EU. This can have serious patient safety measures. There appears to be an anomaly between qualified professionals with English as a first language from outside the EU who must negotiate many steps before practicing in the UK and EU nationals whose English can present safety issues but who in theory have no barrier to practicing.

3. Pharmacovigilance Transposition of Pharmacovigilance Directive 2010/84/EU

The Pharmacovigilance Directive is an example of where EU directives have been very effective in streamlining practice across the EU, minimising the bureaucratic burden and improving patient safety overall.
The new black symbol proposals build on the established UK black triangle reporting principles but extend these European wide to streamline and widen the breadth of the response, giving speedier access to patient safety information. It also extends the scope by introducing risk management plans for individual medicines, for reporting to include

adverse reactions caused by errors and to highlight important safety warnings on high risk drugs.

4. **EU Proposal for a clinical trial regulation**

These proposals aim at reducing administrative burden and streamlining the application process for clinical trial regulatory and ethical approval by introducing a single process European wide. This would enable faster recruitment of patients EU wide and could speed up clinical trial results with resulting improved patient outcomes and earlier detection of adverse events. Presently a similar process must be carried out in each member state where the trials are taking place resulting in an unnecessary bureaucratic load with no additional patient benefits. These proposals should be supported to encourage more UK participation in European wide clinical trials.

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