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**Response to the DH Consultation on Amendments to the Human Medicines Regulations 2012:
'Hub and spoke' dispensing, prices of medicines on dispensing labels, labelling requirements and
pharmacists' exemption**

We welcome the opportunity to respond to this consultation and have limited our response to those proposals that, if implemented, would have a significant impact on our role as the independent regulator of pharmacy professionals and registered pharmacies.

'Hub and spoke' dispensing

The decision whether to permit a hub and spoke dispensing model to operate in circumstances where the hub and spokes are not part of the same retail pharmacy business is a matter for public policy and for Government to determine.

Our job is to protect, promote and maintain the health, safety and wellbeing of members of the public and, in particular, those members of the public who use or need the services of pharmacy professionals or services provided by a registered pharmacy. However these services are delivered, the legal principles and regulatory standards aimed at guaranteeing safe outcomes for patients and the public who use pharmacy services must still be met.

To help us do this our functions include:

- setting standards of conduct, ethics and performance, education and training, and continuing professional development (CPD); and
- setting standards for registered pharmacies and inspecting against these.

The purpose of our standards for registered pharmacies is to create and maintain the right environment, both organisational and physical for the safe and effective practice of pharmacy.

To help pharmacy owners and superintendent pharmacists to meet our standards for registered pharmacies we produced [guidance for registered pharmacies providing pharmacy services at a distance including on the internet](#). The scope of this guidance, published in April 2015, covers a pharmacy service model where any of the activities traditionally carried out in one registered

pharmacy may take place at different registered pharmacies belonging to the same retail pharmacy business or in different places but by pharmacy professionals employed by that business. A move to enable a 'hub' and related 'spokes' to be operated by different companies raises significant issues of responsibility, accountability and liability and also issues of data protection across different legal entities and interconnectivity of IT systems which will all need to be worked through.

Monitoring the accuracy of these systems across different legal entities, managing risk and the potential for system failures and building in business capacity and business continuity plans are also critical matters for providers of such models to manage and have in place and will be something that will need to be considered by providers and by commissioners of services.

A more fundamental concern which has not been addressed in the consultation is how clinical and corporate governance issues under NHS contractual arrangements can be assured within the commercial contractual arrangements as between the differing legal owners of the proposed 'hub and spoke' arrangements. These governance issues will all need to align with the professional obligations of pharmacy professionals and pharmacy owners to meet our standards.

We will need to consider the government's proposals, following consultation, as there may well be implications for the way in which we regulate particularly our standards for registered pharmacies, the guidance which sits underneath them and our inspection function.

In our FAQs that support our current registration criteria published in September 2012 we state that a 'hub' should be registered as a pharmacy. The proposals set out in the consultation are consistent with this requirement which indicate that if alternative models of hub and spoke dispensing are permitted then the hubs should continue to be registered pharmacies.

Additionally, as pointed out in our letter (available on our website) of 26 February 2016 to Will Cavendish and Keith Ridge, changes to health and care delivery and the way in which pharmacy services develop may have implications for the content of both pre and post registration pharmacy education and training and our work to develop a framework for continuing fitness to practise. These issues will need careful consideration by those with a direct role in workforce planning as well as ourselves in relation to regulation of pharmacy professionals and registered pharmacies.

We would welcome further clarification of the statement at paragraph 10 of the consultation document that 'hub' pharmacies would not require a wholesale dealing licence. Since August 2012, following the repeal of section 10(7) of the Medicines Act 1968, it has been made clear that a registered pharmacy can no longer supply medicinal products by way of wholesale dealing if the owner does not also hold a wholesale dealing licence. Therefore there may be circumstances when a 'hub' pharmacy may be required to hold a wholesale dealing licence.

Prices of medicines on dispensing labels'

In the consultation document the DH sets out a positive desire to reduce waste and improve patient adherence to medication. The consultation refers to work around behavioural insights in relation to hospital appointments as a comparable model. We agree with the points highlighted in the consultation that the potential for negative consequences needs to be properly considered. We can see a strong case for specific piloting or testing on this topic before any national roll-out is considered particularly into how patients responded. Communication between pharmacy staff and

patients will be key to mitigating these risks and is an issue we will consider as part of our own standards development work and inspection process.

Pharmacists' exemption

We find the drafting of new regulations 4A to 4C difficult to follow. We would welcome clarification on the following:

- What is included in the term 'dispensing'?
- What is the definition of 'preparation'?
- Can the assembly and dispensing of a medicinal product as provided by new 4A (1) & (2), if the assembly, dispensing, sale or sale and supply takes place in the same relevant clinical setting, be in advance of the prescription or direction being issued or in advance of the identity of the individual patient being known if under a PGD without the need for a manufacturing licence or marketing authorisation?
- Would a manufacturing licence and/or a marketing authorisation be required if the assembly and dispensing is undertaken in one relevant clinical setting and the sale or sale and supply takes place at or from a different relevant clinical setting not being part of the same business? Could this assembly and dispensing be in advance of the prescription or direction being issued or in advance of the identity of the individual patient being known if under a PGD without the need for a manufacturing licence or marketing authorisation?
- Can the preparation of a medicinal product as provided by new 4B(1) & (2) be in advance of the prescription or direction being issued or in advance of the identity of the individual patient being known if under a PGB, without the need for a manufacturing licence or marketing authorisation?
- New 4B (3) appears to provide that if a medicinal product is sold or supplied at or from a different relevant clinical setting from that in which it was dispensed and the product was prepared in advance of the prescription or direction being issued or in advance of the identity of the individual patient being known if under a PGD, then a marketing authorisation is required. Would a manufacturing licence also be required in such circumstances?
- Should there be a reference in new 4B along the lines of 4A (9) i.e. that the provisions here would not apply in the case of preparation of a medicinal product which is either prepared industrially or manufactured by a method involving an industrial process?
- Reg 8 may also need to include the definition of 'supply'. This is currently found in reg 213 for that part of the HMR but perhaps should be inserted here so as to ensure that supplies made in 'circumstances corresponding to retail sale' are also included in these new provisions.

We will continue to work with the DH, MHRA, the RPS and other relevant stakeholders to ensure that our registration criteria for pharmacies accurately reflects any changes in the law and that we take account of proposals, as far as is possible given their draft nature, in our standards for registered pharmacies and inspection function.

Yours sincerely



Duncan Rudkin
Chief Executive & Registrar

