September 2017

PAGB Briefing on EU exit and the Repeal Bill

Overview

As the trade association for manufacturers of over-the-counter medicines, self care medical devices and food supplements, PAGB's priority is to ensure that when the United Kingdom leaves the European Union there are no fewer over-the-counter or self care products available in the UK and those products are no less safe than they are today.

What are over-the-counter and self care products and why are they important?
Over-the-counter and self care products are medicines, medical devices and food supplements that can be bought from a pharmacy or other retail outlets without a prescription. Our members make well known and trusted products, such as Anadin, Beechams, Calpol and Gaviscon, that people in the UK use every day.

These products help people to stay healthy and self care for self-treatable conditions, which do not require consultation with a doctor, and therefore reduce pressure and costs on GPs and the NHS. This is particularly important at a time of significant financial constraint and uncertainty in the NHS. The continued availability of these products is therefore of paramount importance.

What are PAGB and its members seeking?
PAGB is seeking certainty for the consumer healthcare industry, both through the Repeal Bill and through the wider negotiation process.

Relevant mutual recognition agreements must be put in place to avoid risks of a significant extra administrative and resource burden on the consumer healthcare industry, and reductions in the availability of consumer healthcare products.

We are therefore calling for the following commitments from the Government as part of the Repeal Bill and the wider EU exit negotiations:

1. **No additional regulatory barriers will be introduced for over-the-counter medicines, medical devices and food supplements, and regulation in the future will be sensible and proportionate**
2. **Appropriate mutual recognition agreements on regulatory structures and processes will be put in place to allow over-the-counter and self care products manufactured and approved in the UK to continue to be exported to the EU and vice versa without delays**
3. **The UK will continue to participate in EU pharmacovigilance and market surveillance systems to protect public health and patient safety, including EudraVigilance and Eudamed**
4. **The EU Medical Device Regulation (2017) will be implemented and adhered to**
5. **Any necessary UK infrastructure to support the consumer healthcare industry will be put in place from day one of our exit from the EU**

As the trade body for manufacturers of consumer healthcare medicines, self care medical devices and food supplements, we face many of the same challenges as those faced by our colleagues in the prescription pharmaceutical medicines, medical devices and food sectors. PAGB is therefore working closely with colleagues in other trade associations, and is supportive of issues raised by those sectors.

Further detail on each of the commitments outlined above follows.

Access and availability

1. **No additional regulatory barriers will be introduced for over-the-counter medicines, medical devices and food supplements, and regulation in the future will be sensible and proportionate**

2. **Appropriate mutual recognition agreements on regulatory structures and processes will be in place to allow over-the-counter and self care products manufactured and approved in the UK to continue to be exported to the EU and vice versa without delays**

There are medicines on the market in the UK that have licences issued by the European Medicines Agency (EMA) via either the centralised licensing procedure or the decentralised licensing procedure. In order for these medicines to continue to be available in the UK after it leaves the EU, mutual recognition procedures will need to be in place or national licences will need to be granted by the Medicines and Healthcare Products Regulatory Agency (MHRA).

Due to the uncertainty over the nature of the final EU exit deal, and the need to be prepared in advance of ‘day one’, companies are already questioning the usefulness of Scientific Advice Meetings with the MHRA and are moving away from using the MHRA as a formal reference state in licensing applications. This means new products which are available in the EU will not be made available in the UK unless a mutual recognition agreement is put in place, or a national licensing scheme is introduced (although the latter is likely to add complexity and unnecessary additional regulatory burden).

The UK must also maintain alignment with EU guidelines and standards, such as Good Manufacturing Practice and Good Distribution Practice, to ensure supply chains remain functional and streamlined for the continued availability of medicines. Assurance should therefore be provided that new requirements that diverge from these core guidelines and standards will not be introduced.

It will be essential that products can be imported and exported without delay. To ensure over-the-counter products can easily move across the border, the UK must seek mutual recognition agreements for quality testing and batch release in the EU. A qualified person (QP) is required to release medicines as batches are produced. If mutual recognition agreements on QP and batch release are not negotiated, it may result in a duplication of efforts and delays to access. As a minimum, the UK will need to accept products QP tested and released within the EU.

As the majority of food supplements are manufactured outside the UK and imported as finished products, mutual recognition agreements and tariff free trade on food supplements between the UK and EU are also essential. Ensuring these are in place will help avoid pressure on Border Inspection Post Personnel, duplication of efforts and delays at the border.

Establishing mutual recognition agreements and formal partnerships, rather than duplicating systems, would ensure continued access to vital, every-day consumer healthcare products without delay after 'exit day'.

Patient safety

3. **The UK will continue to participate in EU pharmacovigilance and market surveillance systems to protect public health and patient safety, including EudraVigilance and Eudamed**

4. **The EU Medical Device Regulation (2017) will be implemented and adhered to**

Over the last 40 years, the UK has worked closely with the other European nations to build a system of effective medicines regulation that has ensured that over-the-counter medicines are safe and well regulated. Withdrawing from this effective system presents a number of challenges which will need to be addressed.

Data sharing across Europe is fundamental to protecting patient safety. We believe it is important for the MHRA to retain its status as an equal partner on the Pharmacovigilance Risk Assessment Committee (PRAC) of the EMA. As an absolute minimum for patient safety, MHRA must be guaranteed observer status and commit to reviewing and reflecting PRAC assessments in the UK.

EudraVigilance is the EU pharmacovigilance surveillance system, which manages and analyses information on suspected adverse reactions to medicines that have been authorised in the EEA. Access to this data is a critical patient safety issue both for the UK and the EU27. If information is not shared about adverse events in a systematic way to allow patterns and trends to be identified, potential problems with medicines risk going unidentified. The UK has invested in the updates necessary to be ready for the new EudraVigilance system, which launches in November 2017, and should at a minimum secure a partnership arrangement.

In addition, the UK should continue to participate in the Eudamed (European Databank on Medical Devices) system of market surveillance and transparency for medical devices, and continue to link into the European database of the Falsified Medicines Directive.

The **Medical Device Regulation (2017)** represents the gold standard for regulation and should be implemented in full in the UK in line with the timeline defined in the regulation. Secondary legislation will be necessary because the regulation came into force in 2017 and is due to be applied in 2020.

The current regulation in force in the UK (ie the Medical Devices Regulation 2002) implements European Directives published in the 1990s and therefore does not take account of significant developments in the medical technology industry in recent years. Significant changes would be required to ensure safety and restore public confidence in these products. Implementing the Medical Device Regulation, which the UK has helped to carefully develop over a number of years, is the most effective way to ensure appropriate regulation of these products in the UK.

UK infrastructure

5. **Any necessary UK infrastructure to support the consumer healthcare industry will be put in place from day one of our exit from the EU**

For all aspects of EU-derived legislation being repatriated into the UK, assurances should be provided that government departments are equipped with the skills, resources and expertise to take over the responsibility of enforcing it.

For PAGB members, this is most pertinent for food legislation, which has been separated across three government bodies: DEFRA, the Department of Health, and the Food Standards Agency (FSA). All three have experienced staffing cuts in recent years leaving them under-resourced and lacking the expertise required to deal with a repatriation of food regulation from the EU.

All food legislation relating to consumer safety and nutritional standards (but not agricultural and security of supply) should become the responsibility of one organisation, ideally the FSA. This needs to be sufficiently staffed and the current knowledge gaps addressed.

For further information, please contact:
Donna Castle, Director of Public Affairs, PAGB
donna.castle@pagb.co.uk or 020 7421 9315
www.pagb.co.uk