

## **PAGB– Written submission (PBC0018)**

### **Over-the-counter medicines**

PAGB, the consumer healthcare association, welcomes the opportunity to provide evidence to the House of Lords Common Frameworks Scrutiny Committee.

PAGB is the UK trade association representing the manufacturers of branded over-the-counter (OTC) medicines, self care medical devices and food supplements. These products can be bought from a pharmacy or other retail outlets without a prescription and help people to stay healthy and self care for self-treatable conditions which do not require consultation with a medical professional.

PAGB's priority in respect of the Northern Ireland Protocol is ensuring that OTC medicines can continue to be supplied to people in Northern Ireland. There are a number of reasons why the Northern Ireland Protocol causes difficulties, and we outlined these in our attached briefing on OTC medicine supply in Northern Ireland.

PAGB is open to all possible solutions which would overcome these difficulties. If the existence of an active common framework provides a mechanism to address the challenges, then we would welcome it. Our briefing also suggests the following possible solutions:

- First, given the risks of medicines leaking onto the EU single market from Northern Ireland in an unregulated manner are very slim, we feel that an agreement that permits medicines licensed for use in Great Britain to be supplied to Northern Ireland only, without additional checks, would deliver on both sides' needs
- Second, a regulatory cooperation agreement (a Mutual Recognition Agreement or equivalent) for QC testing would go some way in helping resolve the problems in supply to Northern Ireland, and would be a positive step in achieving a solution
- Third, and if more time is needed to arrive at a solution, an extension to the current grace period, which expires on 31 December 2021, could be considered.

In answer to your specific questions:

**1. Do you consider it inappropriate that there is not an active common framework covering over the counter medicines in the UK?**

- 1.1 The current regulatory approach to OTC medicines in the UK seems to work well, with the exception of the Northern Ireland protocol, and this

indicates that within the existing system there is unlikely to be a need for an active common framework.

- 1.2 Aside from the requirement, under the Protocol, for Northern Ireland to comply with EU medicines regulations, we are not aware of any significant demands for divergence on OTC medicines regulation from England, Scotland or Wales which would necessitate an active common framework.
- 1.3 There is clearly a need to address the issues caused by the Northern Ireland Protocol, and we have offered our views on the potential of an active common framework to address them below.

## **2. What benefits may an active common framework bring in terms of managing divergence caused by the Protocol on Ireland/Northern Ireland, between Northern Ireland and the rest of the UK, on policy related to over-the-counter medicines?**

- 2.1 We understand that an active common framework may allow Northern Ireland to have a more clearly defined role in respect of decisions about the future of OTC medicine regulation. This may, in theory, mean that there is less divergence in the future – if the Northern Ireland administration seeks to ensure that regulations in Great Britain are similar to regulations in Northern Ireland – and this may help provide reassurance to the EU that supplying GB packs of medicines to Northern Ireland is a low-risk activity.
- 2.2 However, an active common framework is unlikely to address the challenges currently faced by our members: it is important to note that at present there is no divergence between UK and EU regulations on OTC medicines – the regulations have not been changed since the end of the EU exit transition period.
- 2.3 The current challenges stem from the fact that Northern Ireland effectively remains within the EU customs union, and therefore, from the end of the grace period, all medicines distributed from Great Britain into Northern Ireland will be considered imports and will be subject to import and regulatory checks and processes.
- 2.4 Because supply of medicines within the UK is managed as a whole, most medicines are currently supplied to Northern Ireland from or through Great Britain. Different national licensing regimes in Ireland and the UK mean it is not possible simply to supply medicines to Northern Ireland from Ireland, or another EU country, instead.
- 2.5 This is further complicated for OTC medicines because the model of supply for over-the-counter medicines is based on product being sold to retailers such as Boots and Sainsbury's for the whole of the UK, and distributed through the country, including to Northern Ireland, by the retailers themselves. It is impossible for a retailer or distributor to carry out the EU

import requirements on a product that they do not manufacture or hold the licence for.

- 2.6 We do not see how an active common framework can address these challenges, since we understand a resolution to them can only be arrived at through agreement between the UK and EU.

**24 June 2021**