EU Exit next steps: recommendations from the consumer healthcare sector

Introduction

This briefing is intended to help inform policymakers of PAGB's current views on the EU Exit process, as the UK and EU approach the deadline for extending the transition period at the end of June, and as we look towards further negotiations on the future UK-EU trading relationship over the coming months.

As the trade body for manufacturers of over-the-counter medicines, self care medical devices and food supplements, PAGB has an important role in representing our members' views to policymakers. Our members supply products which support people self care, and they therefore make a critical contribution to alleviating pressures on the NHS and the care sector, both at normal times and particularly during the pandemic.

This briefing:

- Sets out our high level ambitions for the future trading relationship, in line with our overall aim of ensuring that there are no fewer products to help people self care on the UK market after the end of this year, and that they are no less safe
- Makes a series of recommendations for the UK Government to consider in the near future, to ensure the UK consumer healthcare sector is as prepared as possible for the full range of potential outcomes from the negotiations between the UK and EU

Our ambitions

We want to ensure that, now and in the future, there are no fewer self care products on the UK market and that they are no less safe, and that the UK remains a favourable environment for over-the-counter medicines to be developed and sold. To this end, and recognising that the Government's policy is to leave the single market and the customs union, our ambitions are for a future UK-EU trade deal in which:

- The UK and EU agree appropriate Mutual Recognition Agreements for medicines, medical devices and food supplements standards, including the recognition of good manufacturing practice (GMP)
- The UK and EU aim for zero tariffs and free-flowing goods on all consumer healthcare products, ingredients and components

Our recommendations for the near future

The transition period comes to an end in December 2020, assuming an extension is not agreed by the end of June. Unless or until a new trading relationship between the UK and EU is agreed, therefore, there will be uncertainty about the environment in which the consumer healthcare sector will operate next year. There is specific uncertainty with respect to (amongst other areas):

- **Licensing:** how products are approved for sale in the UK market in future
- **Importing and exporting:** what tariffs and customs controls might apply to goods being moved between the UK and EU
- **Batch testing and release:** how products destined for the UK and originating from the EU will be certified as safe for the UK market, and vice versa – and how any existing mutual recognition agreements between the EU and other countries will operate with respect to the UK

- **The Northern Ireland protocol**: how products moving between Great Britain and Northern Ireland, and the Republic of Ireland and Northern Ireland, will be regulated and how these regulations will be implemented

This uncertainty is impacting on our member companies' abilities to prepare for the end of the transition period – which is itself a second order priority for the sector, given that the first priority has been and remains ensuring that healthcare systems are adequately supplied during the continuing pandemic. In order to minimise this uncertainty, and give our members time to prepare, we make the following five recommendations to the Government:

- **Recommendation 1**: maintain a process of collaborative and constructive engagement with the consumer healthcare sector. We have been encouraged by the willingness of the UK Government to discuss the issues facing the sector in recent months, and hope this this approach will continue

- **Recommendation 2:** clarify as a matter of urgency what will be required for companies to comply with customs and border requirements after the end of the transition period, and what will be required by way of batch release and testing in the UK (including Northern Ireland). PAGB member companies need to understand whether commitments made in no-deal contingency planning last year will be applied at the end of the transition period in the event an extension is not agreed

- **Recommendation 3:** discuss with companies what likely levels of demand for products will be over the period spanning the end of 2020 and 2021, so that companies can support the Government in building resilient supply chains. As part of this, the Government should reactivate its multi-layered approach to contingency planning, including the government-secured ferry capacity programme. Given the immense pressure supply chains are already under as a consequence of the pandemic, it is important that the Government gives companies the flexibility to manage the continuity of supply of their products and does not mandate that companies stockpile products

- **Recommendation 4:** maintain a pragmatic approach to regulation, including seeking alignment in the regulation of medicines and medical devices and ensuring the UK maintains high regulatory standards and does not seek to diverge from international regulatory norms. The medicines and medical devices regulator – the MHRA – has been a world leader in the approach it has taken during the pandemic, and we hope this will continue. In particular, we hope to work with the MHRA on a grace period to any change in regulation, continuation of regulatory flexibilities initiated during the pandemic, and the grandfathering of products in the event no extension to the transition period is agreed

- **Recommendation 5**: make clear what will be required of companies moving goods between Great Britain and Northern Ireland under the Northern Ireland protocol. The Government should avoid requirements which would mean additional burdens for products coming from Great Britain to Northern Ireland (such as quality control and batch release testing), which could impede the supply of medicines to Northern Ireland. The EU-UK Joint Committee must prioritise discussing this issue

We understand that similar recommendations are being made by other companies and trade bodies across the pharmaceuticals and medical devices sectors.

Further information

We hope this note is helpful. For any further information, please contact Donna Castle, PAGB's Senior Director of Public Affairs and Communications, at donna.castle@pagb.co.uk.

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