Preparing for ‘no deal’: maintaining the supply of consumer healthcare products

Introduction

PAGB is the UK trade association which represents manufacturers of branded over-the-counter medicines, self care medical devices and food supplements. We have been working constructively with officials and ministers in the UK Government, and with our counterparts in Europe, to help inform the preparations for the UK’s exit from the EU in March 2019. Our ambitions are to ensure:

- That there are no fewer products available in the UK after withdrawal date; and
- That no products are less safe than they are today

Although we and our members have been encouraged by the progress in negotiations between the UK and EU, naturally our members must prepare for the possible scenario of a ‘no deal’ exit. To this end, we have gathered the views of our members to understand:

- What steps our members are taking now to prepare for a ‘no deal’ exit
- What actions our members hope the Government may take, both in advance of withdrawal date, and on and after withdrawal date, to help them prepare for a ‘no deal’ exit

This short paper therefore sets out:

- The risks of a ‘no deal’ exit to the consumer healthcare industry and the potential impact on the economy and wider society – including shortages of important medicines and other consumer healthcare products, operational pressures on the NHS, and loss of confidence in the Government
- Actions that our members are taking ahead of withdrawal date, and how the Government may help them prepare
- Steps the Government may consider taking on or immediately after withdrawal date to mitigate any supply issues

The views set out in this paper have been gathered through a series of semi-structured interviews with a subset of our members. The questions which guided our interviews are included in the appendix.

This paper will be shared with government officials to assist with the UK’s contingency planning, as well as with parliamentarians and other interested stakeholders to further inform their scrutiny of the Government’s actions.

To encourage candid and comprehensive feedback, views were sought on the basis that they would be anonymised in this report. If any views contained in this report are of particular interest to parties engaged in EU exit discussions, we would be happy to put them in touch with the member/s who contributed them (subject to their consent).

The risks of 'no deal'

The UK will cease to be a member of the EU in March 2019. Although negotiations are continuing on the UK's future relationship with the EU, in a worst-case scenario the UK may leave the EU without any deal in place. This would result in a customs border being established between the UK and the EU, risks of divergence arising in the regulation of healthcare products and how these regulations are enforced, and - ultimately - potentially serious disruption to the supply of the goods made by our member companies to people in the UK.

This is a situation that none of our members wish to see: the UK is an important market to the consumer healthcare industry, worth £2.47 billion a year, and accounting for an estimated £1.5 billion worth of exports. Every day, tens of thousands of people use a product made by one of our members. A 'no deal' exit may lead to serious disruption to our members' operations, as a result of:

- **Delays in supplying the market due to customs controls**. Ground transportation is the main route from the EU into the UK for consumer healthcare products made by our members – and customs checks between the UK and EU may therefore put significant pressure on the port infrastructure on both sides of the English Channel. Our members have estimated that, in the event of a no deal scenario, goods may be held up at these ports for up to 5 days in the immediate aftermath of withdrawal, and even in a best-case steady state situation after a number of months may still be experiencing around 24 hours of delay

- **Delays in importing raw materials due to customs controls.** As well as importing final products, our members also import raw materials and manufacture final products here in the UK. A 'no deal' scenario would disrupt our members' manufacturing operations

- **Extra costs for our members and for consumers.** If tariffs are applied to our products, these extra costs will either have to be absorbed by our members or passed on to consumers. One of our members estimated that the potential additional costs arising from tariffs on over-the-counter medicines may be in the region of £5-£10 million a year, for their products only

These challenges may result in:

- **Shortages of consumer healthcare products.** Our members make products which are frequently used by people to self care, and therefore any disruption caused by a 'no deal' exit may mean that people are not able to obtain the medicines they need – leading to worsening health outcomes. In the case of some products, the challenges caused by a 'no deal' may exacerbate the current, worldwide shortages in certain active substances which members have worked hard to address

- **Operational pressures on the NHS.** There is a risk that if the general public is unable to purchase products manufactured by our members – whether (for example) painkillers, cough medicines, or emergency contraceptives – they will present at NHS services,

including GP practices and A&E. This would add pressure onto NHS services at a time when they are already under unprecedented historical pressure

- **Loss of confidence amongst the general public in government.** Our members supply products to the UK which are prominent in many shops and supermarkets across the country. If shelves cannot be stocked or prices increase due to tariffs, and if people cannot therefore self care, the consequences of a no deal scenario would rapidly become very visible to the general public. Any continuing failure to overcome supply problems may lead to a loss of faith amongst the public in the Government of the day's ability to handle our withdrawal from the EU effectively

Actions by companies ahead of withdrawal date

Our members are working hard to address the challenges set out above. Although UK authorities – including the MHRA – are aiming to reassure our members that disruption will be limited, our members cannot rely on these assurances. This is because:

- First, although UK authorities are aiming to provide reassurance, EU authorities are asking us to plan on the basis of the worst-case scenario – and in the absence of any legal certainty our members have to protect themselves against this risk

- Second, the retailers and distributors who our members work with – both in the UK and in the EU – are themselves requesting assurances that any supply problems will be identified, managed and minimised

As a result, all members who we interviewed have conducted comprehensive risk assessments and undertaken detailed contingency planning to ensure that their operations are as unaffected as possible. Larger companies in particular – who have the capacity and resource to take early action – are also already taking steps to implement these contingency plans. Steps being taken by our members include (amongst others):

- **Transferring the entities which hold the marketing authorisations for their products (ie marketing authorisation holders, or MAHs), to EU member states**. This is because it is a requirement that products supplied to the EU have a MAH in a EU country

- **Identifying 'notified bodies' to assess product conformity which are located in the EU.** A notified body is an organisation designated by a EU country to assess whether a product meets the standards for CE-marking. Because notified bodies must be in the EU, most of our members are working on the assumption that UK-based notified bodies cannot carry out conformity assessments and are taking action accordingly

- **Transferring batch release and testing arrangements to EU member states.** Because medicines on the market in the EU must be batch-released in the EU, our members who currently have batch release arrangements located in the UK are establishing arrangements in EU countries

- **Preparing for batch release in the UK.** Whether or not member companies currently have batch release arrangements in the UK, our larger members (in particular) are taking steps to establish parallel batch-release arrangements in the UK as well as the EU, to cover the possibility that the UK will have its own batch release requirements in the event of a no deal scenario

- **Redesigning artwork.** Given that it is a requirement to note the MAH on many products made by our members, packaging is being redesigned. Across all of our members, many thousands of products are affected

- **Reviewing and redesigning supply chains.** All of our members are reviewing and if necessary redesigning their supply chains: a number of our members' existing supply chains include the UK (for example, there are some which import raw materials to the UK and then export completed products, and others which use the UK as a 'land bridge' between Ireland and the rest of the EU). Many of our members are now considering ways in which supply chains can be re-routed away from the UK

- **Stockpiling medicines and raw materials.** In order to mitigate any risks of delays at the border, some of our members are planning to increase their stockholdings of medicines and raw materials to ensure that their markets can continue to be supplied. Some companies are already taking action accordingly, but it is not a simple endeavour: medicines in particular typically need to be stored in an authorised (and sophisticated) facility (as opposed to a basic warehouse), whilst retailers typically request products which have at least 75% of their original shelf life remaining, limiting the extent to which stockpiling is a viable solution for some products

All of the actions listed above are resource-intensive, and although many of our members told us that they are not acting with a view to 'future-proof' their operations against all possible EU exit scenarios in perpetuity, in practice the plans being implemented are costly and will not be reversed. In essence, therefore, although future-proofing is not the primary factor in our members' decisions, it is a by-product of their actions – and their likely irreversibility may be lastingly detrimental to the UK's life sciences infrastructure.

Our members are taking the actions listed above – and others – of their own volition, because they must act responsibly to prepare themselves for the worst-case scenario. Although their actions do not rely on any support from the UK Government, and they do not necessarily expect it, we were told that there are some steps that the UK Government could take now to help our members with their preparations, and minimise costs:

- **Be clear about the unilateral actions the UK Government will take in the event of no deal.** Although our members appreciate the difficulties of the UK Government in setting out what it will do in the event of a no deal situation (given that it may suggest that its negotiations with the EU are taking place in bad faith), they feel that increasingly there is a need for more clarity over the steps the UK will take, however unlikely the situation is to arise. To this end, our members would like the UK Government as soon as possible to commit in writing to, in the event of a no deal scenario:

  - Confirming that batch release anywhere in the EU would be deemed acceptable in the UK. This will allow companies to avoid the cost of establishing parallel batch release arrangements in the UK. Members made clear that this confirmation would need to be provided by September 2018 at the latest to be of benefit

  - Guaranteeing the rights of EU citizens in the UK for a defined period of time. In the event of a 'no deal' scenario, the status of EU citizens working with our members will be uncertain. For some of our members, EU citizens comprise a significant proportion of their workforce, and without such guarantees their colleagues may decide that they need to leave the UK

  - Committing to no divergence on standards underpinning devices, and in particular alignment with the new medical devices and in-vitro diagnostic devices regulations

- **Publish and consult on their own contingency plans for a 'no deal' situation**. If the UK leaves the EU without any deal, the Government may feel that it needs to take action for itself to maintain the supply of medicines and healthcare products (explored in more detail in the following section). Our members are willing to work with the Government to help inform and collaborate on these plans, but need to be made aware of them in good time so that they can plan accordingly

- **Confirm how the UK will treat countries with which the EU has mutual recognition agreements (eg Canada, Japan etc)**

More broadly, our members expressed concern about the impact both of the current uncertainty, and of the possibility of a 'no deal' scenario, on the sustainability of the MHRA. Although our members noted that the MHRA's operations are a matter for itself and the UK Government, they nonetheless expressed concern that the MHRA may not be able to:

- Accommodate the large number of variation applications concerning changes in MAHs which it will need to process in the months leading up to withdrawal

- Absorb the possible loss of income arising after withdrawal, if it loses its work on behalf of the EMA

Members also felt it would be reassuring to confirm at an early stage the arrangements through which the MHRA would share pharmacovigilance data with EMA. Although member companies have their own, robust and well-tested arrangements in place, it was noted that the portal for companies to use in notifying European regulators at present is run by the EMA, and it is not clear how the MHRA's own arrangements would interact with this after withdrawal.

Action on or after withdrawal date

In the worst-case scenario, the UK may leave the EU in March 2019 without a deal on its future relationship. In this situation, and although our members will have taken the steps

noted above to prepare as far as possible, it is highly likely that there will be disruption to our members' operations and in the supply of their products to both EU and UK markets.

We understand that the Government is now developing its own plans to help ease any supply problems in this event, particularly with respect to minimising disruption at the border. Our members would be happy to work with the Government in developing its plans, and to help the Government identify where opportunities for collaboration with industry exist. To take an example, the Government may be considering establishing its own supply routes, which it may invite companies to take advantage of. However, this plan would need to take account of the fact that (i) much haulage undertaken by our members is outsourced to logistics companies which have their own supply routes, and (ii) lorries may contain multiple products, which would make it challenging to separate priority goods from non-priority goods

In the event of a no deal scenario, and in addition to the above recommended steps, our members felt the Government could help by:

- **Taking all action possible to facilitate the flow of goods through the border** – including by simplifying border checks wherever possible, investing in additional customs capacity, and locating the point of customs inspections inland

- **Minimising any visa requirements for those involved in transporting goods**. As one member pointed out, there is little benefit in taking action to ensure goods on lorries can move smoothly through a border if the drivers of the lorries can not

- **Ensuring that tariffs on healthcare-related products are reduced to the minimum levels possible consistent with World Trade Organization (WTO) rules**

- **Prioritising healthcare-related products at the border.** Members noted that if there is limited capacity to check goods flowing through the border, an 'order of priority' should be established which protects human health first

Further information

We hope this short note is helpful. If you require any further information, please get in touch with Donna Castle: donna.castle@pagb.co.uk.

PAGB (Proprietary Association of Great Britain)
New Penderel House, 283-288 High Holborn, London, WC1V 7HP
www.pagb.co.uk
May 2018

PAGB Representing the Consumer Healthcare Industry since 1919

Appendix: semi-structured interviews

The questions below guided the interviews.

- Does your company have a contingency plan to keep goods on the UK market in the event of a 'no deal' exit?

- If you were to assume that we left the single market from March 2019, what contingency actions would you take? Are you taking any of these actions already?

- How many products on the UK market will be impacted? How many products exported from the UK to the EU would be impacted?

- What priority actions will your company take to keep your products on the market in both the UK and the EU? (eg stockpiling or moving stocks, acquiring additional warehouse space, recruiting staff to support the process)

- What is the estimated volume and scale of the process? How much does your company anticipate it will cost as a one-off cost? How many products would you need to move?

- How would a 'no deal' situation impact on other aspects of your consumer healthcare business, eg your access to pharmacovigilance data? Do you have contingency plans arranged for this?

- Would you expect the Government to advise if a 'no deal' scenario (ie leaving the single market and customs union) was likely from March 2019? If so, by when?

- What infrastructure or resources would the Government need to put in place to minimise delays or physical blockages to implementing your contingency plans?

- What other support, if any, would you expect from the Government in the event of a 'no deal' situation?