Written evidence from British Generic Manufacturers Association BGMA

BGMA generic industry survey findings for Health and Social Care Committee, in support of inquiry on the impact of a no-deal Brexit on health and social care

Overview

The British Generic Manufacturers Association (BGMA) previously responded to the Health and Social Care Committee's inquiry on *Brexit: medicines, medical devices and substances of human origin* in which we set out our broader views and positions. We therefore welcome the Committee's further work in holding an inquiry on the impact of a no-deal Brexit on health and social care, and believe the Committee is right to consider the consequences of a 'no-deal' scenario as it is vital that the UK has sufficient contingency plans in place.

As an Association, we conducted an industry survey earlier this month to assess our members' preparedness for Brexit and future trade interests. A majority of our member companies eagerly responded, and our key results are shared for the Committee's benefit below. Additionally, the Committee should be aware that the BGMA has been working closely with the Government and our members to minimise the risk of any negative impact on patients.

We hope this information serves as an update to the Committee on the preparedness of the generic medicines industry and our concerns about a 'no-deal' outcome.

We continue to believe that continued regulatory alignment, along with free and frictionless trade, will be the best way of ensuring that UK patients can continue to access a secure supply of generic and biosimilar medicines.

Impact of a no-deal Brexit and disruption to the supply of medicines

- Based on the BGMA's recent survey data, we estimate that the BGMA's total membership account for over 600 million packs of medicines sold in the UK each year, with the wider industry selling many more in addition.

The medicines industry has been built up on the system of regulatory alignment within the EU. As we have previously said, any divergence from current arrangements or additional costs of bringing medicines to market are likely to result in delays and disruptions in the NHS and UK patients accessing generic and biosimilar medicines.

But the issue is also physical.

- In terms of crossing borders, we estimate (based on our survey data) that our members import over 12 million packs of finished product per month from the EU27, and additionally over 16 million packs of finished product per month from the outside of the EU27.
- Going the other way, we estimate that our members alone export over 5 million packs of finished product per month to the EU27 and over 2.5 million packs per month to countries outside of the EU27.

Maintaining the free flows of these products, as well as the intermediary products and active ingredients needed for UK-manufactured medicines, is obviously the only way to ensure that the supply of medicines is not disrupted. The global nature of the generic industry supply chain means the free flow of goods is essential to the efficient and timely operation of the supply chain and medicines market.

Industry planning for Brexit

<u>Company planning and business impacts</u>

The industry takes the risk of supply disruptions seriously and is doing a huge amount to prepare for Brexit.

- Most (over three quarters) of our members report having a Brexit risk mitigation plan in place, with some still working on theirs or waiting for greater clarity from Government on what will happen and when.
    - Of those who do have a plan in place, the majority have started to implement it.

However, this has come at a cost. Businesses have already borne significant costs from developing and implementing their Brexit plans.

- From our member survey, we see that the costs incurred (to date) range from the tens of thousands to £2 to £3m per company, depending on size, location and complexity of their business.

Furthermore, companies expect more costs to come and the spending to escalate the longer uncertainty continues.

- Companies estimate the total costs of their Brexit planning to range from the low hundreds of thousands to several million pounds (£2-5 million was a frequent response to the BGMA's recent survey).

Depending on the company, some have already taken physical steps to prepare for Brexit which may be irreversible, for instance moving people, business practices, or product licences.

- A third of BGMA member companies have relocated or employed additional Qualified Persons or pharmacovigilance roles, or are actively considering doing so depending on negotiation outcomes.
- Additionally, approximately a third of member companies have moved or duplicated Quality Control laboratory testing for products (of BGMA members alone, we estimate that testing for approximately 200 products has been moved).

Increasing stockholdings

Generic medicines companies hold varying levels of stock depending on the size of company, the nature of their products and how their supply chain is organised. However, a strong majority of the BGMA's members are planning to increase UK stock holding from beyond these typical levels in advance of March 2019.

- Where companies are planning to increase stockholding ahead of March 2019, they are typically accounting for an extra for 4-8 weeks of stock.

Depending on the source of supply and the type of product, lead times from placing an order to having stock available to supply vary. Most manufacturers report lead times in the region of 12-24 weeks.

However, the ability to increase stockholding is dependent on companies' inventory and manufacturing capacity, and so most companies are prioritising certain molecules/products.

Government planning for Brexit

Support for additional medicines stocks

Clearly, the complex nature of the manufacture and supply of medicines in Europe means that medicines and their constituent parts often cross many borders before reaching patients. A deal between the UK and the EU27 to maintain these free flows is obviously the only way to ensure that the supply of medicines is not disrupted.

However, BGMA and the BBA have been discussing with the Government for some time how to ensure that the medicines supply chain continues to operate effectively in the event of a no-deal Brexit. The Government has shown a welcome determination to act pragmatically on the regulation of medicines to ensure their continued supply to British patients. This is something to which they and we, as the generic and biosimilar medicines industries, are committed. But the UK Government alone cannot ensure that there are no delays at the UK's external borders in the event of a no-deal Brexit. So it is wise for the Government to plan for appropriate stockpiling of medicines to deal with possible delays.

We welcomed the fact that the Government has been putting in place planning to enable additional stocks of medicines held by manufacturers in the UK to be matched with available warehousing space. Warehousing approved for pharmaceutical use is a limited resource, and medicines manufacturers operating independently cannot be expected to ensure that it is shared out and matched to demand. Only the Government can do this, and we welcome the fact that planning is well underway.

The recent survey of our own members shows that the vast majority have been actively planning and implementing measures to ensure that the impact of a disorderly Brexit is minimised wherever possible. No-one wants to see delays at the UK's borders risking the supply of medicines to patients and we still need further clarity from Government on its intentions.

Of course, this is making the best of a bad job. No-one wants to see delays at the UK's borders risking the supply of medicines to patients that the Secretary of State's proposals are designed to cope with. As we have consistently said, what is needed to ensure the supply of medicines to British patients is an agreement between the UK and the EU27 to allow the free flow of medicines and their components.

We again call on the UK's and the EU's negotiators to recognise the unique position of medicines, which are not just another good on the market, but needed lifesaving treatments, and urgently to agree measures to ensure their continued free flow to patients on both sides of the Channel.