Written evidence submitted by Teva Pharmaceutical Industries Ltd (BBP0012)

About Teva

Teva is one of the top ten largest pharmaceutical companies in the world, and we estimate that we are the largest supplier by volume of prescription medicines to the NHS. With 1 in every 8 packs of medicines used in the UK being a Teva medicine, we estimate that, on average, every second of every day, over 350 tablets or capsules supplied by us are taken by patients all around the UK.

We employ over 1,500 people in the UK across several locations focusing on R&D and the manufacturing, production, packaging, and marketing of medicines and devices. Our portfolio focuses on innovative specialty medicines and generic treatments, which make an important contribution to the health and wealth of the UK. Generic medicines in particular bring an estimated £13 billion of savings for the NHS medicines bill every year compared to the cost if their branded equivalents had been dispensed. Teva contributes more than £3 billion to these savings, playing a crucial role in driving NHS sustainability. Further information on our UK activities can be found here: https://www.tevauk.com

Introduction

Teva welcomes this opportunity to respond to the Business, Energy and Industrial Strategy Committee's inquiry into Business and Brexit preparedness. A number of significant outstanding issues and an ongoing lack of clarity from the UK-EU negotiation process have seriously affected our ability to prepare adequately for Brexit across the entirety of our business, and we have serious concerns about our ability to supply medicines to patients especially in Northern Ireland after the end of the Transition Period.

Our primary concerns relate to certain regulatory issues and the implementation of the Northern Ireland Protocol. We have escalated these both via our trade body, the British Generic Manufacturers' Association (BGMA), and also directly with the Department of Health and Social Care. With just one month left of 2020, there are still some significant unknowns and there is a real danger that patient welfare will be compromised.

Concerning specific challenges to business preparedness for the medicine and medical devices industry, the threats are twofold: potential delays at the borders (either on the EU or UK side); and additional regulatory burdens and misalignment. Examples of the latter include:

- Each import into the UK requires a manufacturer's import authorisation (MIA), and the MHRA has indicated that a wholesale distribution licence is sufficient. However, there is a risk of stoppages at the border and/or filing incorrect declarations
- With regards to the appointment of a Qualified Person (QP) and implementation of the process for testing and release, packaging and supply of medicines, the current EU arrangement is only acceptable for a two year standstill period. After this period, establishing this system for the UK only will cause significant burden and cost to the industry. Furthermore, it takes a long time to create and establish a QP functionality: industry needs as much certainty as possible, soon
- Safety monitoring of medicines will be a challenge as a UK-only database will not be sufficient to generate early signals for medicines safety. The UK system must work with EU/USA/global systems to be meaningful

To summarise, our key concerns relate to:

1) Northern Ireland Protocol and ability to supply medicines from January 2021
2) Supply chain resilience
3) Mutual recognition of quality activities
4) Personal data

Northern Ireland Protocol (NIP)

We appreciate that this is a highly complex and sensitive issue, but an ongoing lack of clarity on exactly how the regulatory framework will function from January 2021. Consequently, we feel there is a real danger that there will not be enough time for us to satisfy all the necessary changes to be able to operate in accordance with any new legislation.

Immediately following the transition period, the regulatory arrangement for medicines in Northern Ireland (NI) will be distinct from that for the rest of the UK, resulting in additional regulatory work and cost for a relatively small market. In particular the likelihood as it stands now is that to continue trading in Northern Ireland, a UK medicines supplier will need to have one Marketing Authorisation (MA) for Great Britain, and a separate one for Northern Ireland, This creates a cost, regulatory and logistical burden that could well result in some pharmaceutical suppliers deeming the supply of medicines in this way to be too onerous to continue.

To develop this point: MHRA-published guidance indicates that post-Brexit, the MHRA will be in a position to grant UK wide (Great Britain [GB] & NI) Marketing Authorisations (MAs) and that these MAs can have a UK market authorisation holder (MAH) and Qualified Person Responsible for Pharmacovigilance (QPPV). However, during the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) meeting held on 11 November, the concept of UK-wide MAs was discussed, with the EU view being that it is not possible to have UK wide MAs, and that NI would need to comply with the Acquis Communautaire to remain on the market. This includes having an EU MAH and EU QPPV. If this is the case, and separate MAs are needed for GB and NI, then the regulatory burden and expense associated with securing separate MAs is significant and presents a significant challenge for business wishing to operate in NI post-Brexit. We have some 600-plus MAs that would require transferring to a new system, taking significant time and resource. It is therefore extremely important that further clarity be given on this issue urgently in order to ensure continuity of supply to NI.

We did welcome the Government's recent announcement regarding flexibilities in the application of the NIP to medicines specifically, but the details around the implementation of these flexibilities continue to be subject to ongoing discussions between the UK and the EU. The one-year time-limited approach to the implementation of FMD "safety features" and regulatory importation requirements should provide some time to unpick an already complex regulatory system. However, there is a lack of clarity around how this "phased process" will work in reality and how it will impact our business and, therefore, the patients who depend on our medicines.

We have called for clarity from Government and the regulator (the MHRA) on these issues to avoid medicine shortage, delay in treatment and interruption in continuity of care for many chronic and emergency conditions.

Supply chain resilience

While we welcome the work that is already under way to ensure that supply chains are resilient post-Brexit, such as the Medicines Manufacturing Industry Partnership (MMIP), which has been working with the Office for Life Sciences (OLS) to develop proposals to improve resilience in UK medicines supply, we still have substantial concerns that more should be done in this space to ensure the continuing resilience of UK supply chains for medicines and medical devices.

The NAO's report: The UK border: preparedness for the end of the transition period outlines that "disruption at the border may be harder to manage if it also happens alongside further COVID-19 outbreaks and a background of economic uncertainty." Given the scale of the global pandemic, and the unprecedented increase in demand for some medical goods to support the effective response, this has had a knock-on effect on the medical industry's ability to prepare for the end of the transition period, through the adequate stockpiling of medicines and medical supplies. The contingency planning by the Government, such as securing additional freight capacity outside of the short Channel crossings, is welcome. However, other considerations should include strengthening the resilience of the entire supply chain, which would support

diversity of manufacturers and production sites, (not based on lowest-cost alone) and apply uptake measures to ensure effective market infiltration.

The government has commented on its longer term supply chain resilience including the potential for government owned or mandated production capacity to be expanded in the UK. Our strong view is that a government-owned facility will not address the fundamental issues of supply chain security, while creating a cost burden for the UK on a facility that would not be fit for purpose.

Pharmaceutical manufacturing facilities operate to two inter-related truths: 1) they are highly specialised and complex, and tremendously difficult to create from scratch; and 2) therefore, creation of such a facility is only worthwhile if it has enough capacity to fulfil orders from many countries. The creation of a factory to provide medicines just for the UK fails these tests on both counts.

We believe that supply chain resilience for the UK rests not on a 'silver bullet' but on a number of sensible regulatory and market measures:

- Reduce over-dependence on Far East manufacture: they have their place, but the COVID outbreak has shown the dangers of a lack of manufacturing resilience
- Reduce regulatory, tax and logistical hurdles to smooth trade
- Reduce complexity, for example by requiring slightly different formulations in different markets that have no impact on the patient but increase complexity and reduce resilience
- Encourage manufacturing closer to the UK by incentive or agreement
- Recognise that if you chase prices to the bottom, products will be made in the cheapest possible location without regard to resilience consequences

Mutual recognition of quality activities
To help businesses prepare for Brexit effectively, we would like to see the expansion of mutual recognition of quality activities (test/release) – if not negotiated, it will increase lead times of products to patients by up to two months. In addition, we would like to see the elimination/reduction of customs duties to facilitate ease of cross border sourcing of products used in manufacturing facilities.

Personal data
Personal data is another area where we would value more clarity. Without a deal, there is no guarantee that personal data will be able to flow freely from the EU to the UK. The Government gave some certainty that data could flow from the UK to EU for up to two years during what they deemed to be a transition period post-Brexit, but the EU gave no equivalent reassurance.

To ensure personal data can flow freely, and data sharing to support patient safety can continue between the EU and the UK without the need for additional interventions, an adequacy decision or equivalent statement in respect of the other is required. This would ensure that businesses within both the EU and the UK could continue to operate in an efficient and manageable way in respect of personal data they hold, store, or process and which they transfer to the other. In addition, because the UK is governed by the General Data Protection Regulation (a European Regulation) and is required to comply with standards and legal requirements equal to those in Europe, an adequacy decision, confirming that the UK offers an adequate level of data protection, would benefit both EU and UK businesses. In addition, such a system would avoid resulting in a detrimental impact to data subjects to whom the personal data relates.

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