Teva UK Limited - Written evidence (FUI0003)

1. About Teva

1.1. Teva is one of the top ten largest pharmaceutical companies in the world, and the leading supplier by volume of prescription medicines to the NHS. We estimate that we supply about one in six of all prescription medicines dispensed in the UK. We employ over 1,500 people in the UK across several locations, focusing on research and development and the manufacturing, production, packaging, and marketing of medicines and devices used in the UK and across the world. These products make an important contribution to the health and wealth of the UK, with generic medicines in particular bringing an estimated £13 billion of savings for the NHS medicines bill every year.[i]

2. About Teva in Northern Ireland

2.1. Teva UK Limited is a major supplier to Northern Ireland of speciality, generic and over-the-counter (OTC) medicines. We currently supply 620 stock keeping units (SKUs) to Northern Ireland.

2.2. In 2020, approximately four million packs were sold by Teva directly to Northern Ireland, which represents less than two per cent of our total UK volume. All of our UK portfolio is currently available to patients in Northern Ireland, and Teva UK make daily deliveries into Northern Ireland via a dedicated transport provider.

3. Summary: key points

3.1. We welcome the ongoing progress made in enabling continued access to medicines for patients in Northern Ireland. As a result of this, we were able to

halt proposed discontinuation of medicines from Northern Ireland, and are unlikely to make any discontinuations during 2022.

3.2. However, in spite of the progress made on negotiations and the legislative proposals that were announced on 17 December 2021, there is one very significant issue which remains outstanding, which is the treatment of so-called CP (Centralised Procedure) product licences. This covers 48 medicines that Teva currently supplies to the Northern Irish market, as well as most new patented medicines – i.e. those that create new treatments or address unmet clinical needs; and all biologic medicines including biosimilars.

3.3. Throughout our written and oral evidence, we have been clear that any situation that leads to the need for two product licences (also known as Marketing Authorisations, or MAs) create an administrative and cost burden that will make many medicines unviable to supply to Northern Ireland. Companies will always do their best to continue supply, but they cannot do so if this threatens the company's economic viability.

3.4. We welcome the acknowledgement from Minister Cleverley in his letter to Lord Ewelme of 28 March 2022 that the EU's package is not comprehensive; and that without one, a UK-wide route may be needed to avoid companies needing to supply Northern Ireland with two separate licences.

3.5. The risk remains that we will be forced to discontinue some products in the future should this issue not be resolved. It is not commercially viable to maintain separate licenses for all medicines supplied to Northern Ireland.

3.6. We propose to the Committee that it should continue to regard the CP issue as a problem in maintaining access to medicines for patients in Northern Ireland; and respectfully submit that the Committee might wish to urge the UK and EU negotiators to address the CP issue as a matter of urgency.

4. The Centralised Procedure (CP) problem

4.1. We examined the issue of medicines that were licensed under the EU's 'Centralised Procedure' (CP) in detail in our written submission to the Committee in January 2022.

4.2. To summarise, as NI is still subject to EU rules on pharmaceuticals, it is subject to the rules on CP licensing. The practical outcome is that, for products subject to the EU's CP route, there is a national licence for GB; and a CP licence for NI. This brings us back to the scenario of having two licences and two separate packs for one product across the UK, and this is unviable in the majority of cases.

4.3. Although licences have already been officially divided due to the transition period, companies have still been able to provide the same SKUs (stock keeping units) to both GB and NI. That transition period is coming to an end, so we have had to begin the process of submitting licence variations to products under CP licenses to introduce separate SKUs and hence separate packs for GB and NI. We are approaching this on a product-by-product basis, assessing each medicine based on patient need and commercial viability and we can make no guarantees that we can provide Northern Ireland with 100% of our UK portfolio under this procedure.

4.4. This means that medicines that are not commercially viable for supply to the NI market (due to added costs and complexities) may have to be discontinued. However, patient need will continue to be a priority and we have mechanisms in place to safeguard the interests of patients who depend on products supplied only by Teva.

4.5. This issue could also impact launches of new medicines that go through the CP approval process. We will be assessing commercial viability for the NI market for all new launches.

4.6. We do not have visibility of other companies' market share in Northern Ireland and the commercial decisions they may be taking to withdraw medicines, so there could be a bigger patient impact should several companies decide to make withdrawals of the same product.

4.7. We understand that the MHRA is planning to implement a process to address potential patient shortages, and introduce a scheme whereby a company may be asked to supply NI with a GB-only SKU in exceptional circumstances, but we do not know how this will be managed in practice. While we support this as a positive interim step, we do not believe it is sustainable as a solution in the long term.

4 May 2022

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[i] BGMA (2021). 'About us'. Available: https://www.britishgenerics.co.uk/about-us/our-members.html [Accessed: April 2022]