Teva UK Limited - written evidence, dated 18 January 2022

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.[1]

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. Our equivalent portfolio in the Republic of Ireland is 313 SKUs and, due mainly to licensing differences, the direct overlap between the two countries is only 70 SKUs.

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 available to patients in Northern Ireland, and Teva UK make daily deliveries into Northern Ireland via a dedicated transport provider.

2.3. At present, we supply Northern Ireland and the Republic of Ireland separately. Product for Northern Ireland is held at our distribution centre in Castleford, West Yorkshire, and sold to wholesalers in Northern Ireland; direct to retailer customers in Northern Ireland; or to a wholesaler in GB who sells onwards to Northern Ireland. We supply the Republic of Ireland via a pre-wholesale facility in Dublin, who ship product on our behalf to wholesalers or customers in Ireland.

2.4. Due to current licensing differences, the amount of product flowing between Ireland and Northern Ireland is negligible.

3. Summary: key points

3.1. Since the oral session of the Committee attended by Teva and others, there has been significant progress in enabling continued access to medicines for patients in Northern Ireland. Teva welcomes that progress and recognises the constructive dialogue between UK and EU negotiators to move forwards.

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

3.2. There is one outstanding and very significant issue, which is the treatment of so-called CP (Centralised Procedure) product licences.

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. As things stand, and to our knowledge, the two-licences-for-one-country problem has been addressed in all areas except for CP licences. This means that products that are licensed in the EU under the CP route are under threat, so far as supply to Northern Ireland is concerned. This covers most new patented medicines, i.e. those that create new treatments or address unmet clinical needs; and all biologic medicines including biosimilars.

3.5. We propose to the Committee that it should 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. Current status of supply to Northern Irish patients

4.1. As at the current date, in general – and with exceptions noted below – the agreements reached between the UK and EU at the end of last year, and the steps taken by the UK government and Northern Ireland Executive, mean that medicines supply from GB to NI remains in place and free from significant disruption.

5. The Centralised Procedure (CP) problem

5.1. The exception mentioned at 4.1 relates to the use of medicines that were licensed under the EU's 'Centralised Procedure' (CP).

5.2. The Centralised Procedure is a single licence application made to the European Medicines Agency (EMA) which, once granted, is valid in all EU member states. There can be no national variations in the licence, as there are no national licences. The pack and patient leaflet can be translated of course, but there can be no substantive differences in the product nor in information such as patient warnings.

5.3. The EMA website makes the following statement on the scope of CP licences issued by the European Commission in the EU:

> "The centralised procedure is compulsory for:
> - human medicines containing a new active substance to treat:
> - human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS);
> - cancer;
> - diabetes;
> - neurodegenerative diseases;
> - auto-immune and other immune dysfunctions;
> - viral diseases.

- medicines derived from biotechnology processes, such as genetic engineering;
- advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines;
- orphan medicines (medicines for rare diseases);
- veterinary medicines for use as growth or yield enhancers.

It is optional for other medicines containing new active substances for indications other than those stated above that are a significant therapeutic, scientific or technical innovation whose authorisation would be in the interest of public or animal health at EU level. Today, the great majority of new, innovative medicines pass through the centralised authorisation procedure in order to be marketed in the EU."

5.4. The significance of this is that if NI is still subject to EU rules on pharmaceuticals, it will be subject to the rules on CP licensing. The pragmatic outcome is that, for products subject to the EU's CP route, there will be a national licence for GB; and a CP licence for NI. This brings us back to the scenario of having two licences for one product across the UK, and this is unviable in the majority of cases.

5.5. The agreement between the EU and UK allows for a product that being assessed for a EU CP licence, and that has a GB national licence, to be supplied under the GB licence to NI pending the CO process. But once the European CP licence is issued, then NI must be supplied under that CP licence and so we are back to having a separate licence for Northern Ireland. **We advocate that if it is permitted to supply NI during the CP licensing process, then it is simple to continue to supply NI from that UK national licence once the C licence is granted; so long as that licence is aligned with the EU CP licence.**

5.6. A counter-argument to this is that a separate licence can be avoided if that CP product is supplied to NI from the Republic of Ireland. In regulatory terms, this is acceptable. However there are three practical obstacles:

- In this instance, if product is supplied from Ireland, the healthcare system of Ireland effectively loses control of its supply chain integrity. In other words product would flow from Ireland to Northern Ireland in an uncontrolled way, and the HSE in Ireland would find product that simply 'disappears' from its view as it is exported to Northern Ireland. One key principle is that regulators and authorities should have oversight and ultimate control over the supply chain in their country, so that shortages can be addressed effectively and supply goes to where it is needed. Product moving across the border in an uncontrolled way would present a risk to the ability to monitor and ensure adequate supply.

- There are, typically, significant price differences between selling prices in Ireland and the UK. We explained at the oral evidence session that the UK enjoys some of the lowest prices in Europe overall for medicines: this is in great part due to the regulatory regime and the freedom of the market to compete on a level playing field. Prices in general are higher in Ireland than in Northern Ireland: so product

going from Ireland to NI rather than GB to NI would be likely to do so at a significantly higher price, thus increasing the cost burden on the NHS.

- The CP process in Europe can be expected to run on a different timescale compared to the UK. Therefore it is hard to see how a single licence with a single patient pack for GB and NI can be achieved, as when the first of the two licences is granted we don't know if the other licence will have exactly the same conditions and the same agreed patient information. An issue that is already exacerbating this problem is that EMA will not share any of its submissions/assessment outcomes with MHRA, even though MHRA is the licensing authority for NI. This is placing a burden on industry to make duplicate submissions to both EMA and MHRA for NI.

5.7. We are currently experiencing significant problems with existing CP products, and the lack of resolution means that we will need to give serious consideration, as new products are launched, on whether providing new products in Northern Ireland is viable. We have one existing product in particular, a branded (patented) respiratory medicine used to treat asthma, which is giving us particular concern and whose continued supply to Northern Ireland cannot be assured for the long term unless the CP issue is addressed. We also anticipate issues with new CP products as and when we bring them to market.

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