Teva UK Limited – Written evidence (NIP0017)

Teva UK Limited additional written submission to the House of Lords European Affairs Sub-Committee on the Protocol on Ireland/Northern Ireland, November 2022

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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 one in seven 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 medicines. We currently supply 630 stock keeping units (SKUs) to NI.

2.2. In 2021, approximately four million packs were sold by Teva directly to NI, which represents less than two per cent of our total UK volume. All of our UK portfolio is currently available to patients in NI, and Teva UK makes daily deliveries into NI via a dedicated transport provider.

3. How would you summarise the impact (both positive and negative) of the Protocol as it currently operates on Northern Ireland?

3.1. We welcomed measures taken by both the EU and UK to overcome some of the most onerous regulatory burdens arising from the Protocol. These mitigations included the legislative changes brought forward by the European Commission in its Medicines Non-Paper in 2021, which enabled us to continue supplying our medicines to NI without additional complexities.

3.2. However, despite progress in other areas, there is one very significant current issue and one potential issue which remain outstanding:

i. The current problematic issue is the treatment of so-called CP (Centralised Procedure) product licences. This covers 48 medicines that Teva currently supplies to the NI 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).

ii. In order to continue to supply products approved via the CP route in NI, the EU authorisation is required, so a company needs to have two different product licences and stock keeping units (SKUs). 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) creates an administrative and cost burden that will make many medicines unviable to supply to NI. Companies will always do their best to continue supply, but they cannot do so if this threatens the company's economic viability.

iii. We believe the full impact of the CP issue is yet to be seen. As a company, we are making decisions based on current market share and

historical sales. However, as the November 2023 deadline approaches, suppliers may start to begin withdrawing SKUs from NI, meaning the landscape and market share will look very different.

iv. The future potential issue is the possibility of a dual regulatory regime for Northern Ireland. This is examined at paragraph 5 below.

4. What is your overall assessment of the UK Government's approach to the Protocol, including bringing forward the Northern Ireland Protocol Bill? To what extent will it alleviate the issues with the Protocol that it seeks to address?

4.1. It is difficult to give an accurate assessment, as we will not know the full impacts of the Bill for some time. So far, however, the sensitivities surrounding the operation of the Protocol and the ongoing negotiations between the UK and the EU have created a degree of uncertainty for our business which has made planning and decision-making difficult. It remains unclear how the Bill will alleviate the ongoing issues it seeks to address, but we welcome the progress made to-date, and the opportunity for further constructive talks.

4.2. Teva has already made changes in order to adapt to current requirements and guidance for operating in NI. If further amendments are made to the Protocol, or parts of it are scrapped altogether, this may mean that we have to make additional changes. These will likely bring disruption to medicines supply, increased costs, and may even reduce the viability of some medicines to the NI market.

5. What will be the practical and legal impact of the UK Government's proposals for a dual regulatory regime for goods (clauses 7-11 of the Bill)?

5.1. Throughout our written and oral evidence, we have been clear that any situation that leads to the need for two product licences and two SKUs creates 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.

5.2. In theory, we could be supportive of a dual regulatory regime for goods as this should allow us to have a UK-wide licence. However for a dual regime to be attainable, there could be no divergence between UK and EU regulations. As soon as there is any divergence (e.g. an additive is legal under one regime, but not the other) then this becomes extremely problematic.

5.3. Furthermore, the MHRA has expressed a desire to have closer collaboration with other markets, such as the USA. However, it is impossible to see how this can be achieved, while also maintaining regulatory alignment with the EU.

5.4. Therefore in summary, the UK is positioned between a dual regime, which only works so long as UK and EU standards are fully aligned; or a separate GB-NI approach which is back to the 'two SKUs' approach that the industry has already highlighted as unviable.

6. What is your overall assessment of the EU's approach in relation to the Protocol? Is the EU going far enough in addressing the problems that have arisen under the Protocol?

6.1. There have been some positive developments from the EU side with regards to the Protocol; however, at the moment all NI-related issues have been rolled

into one. This means that the EU is not considering things individually, which affects a number of other issues, and makes agreement more difficult.

6.2. As mentioned previously, the changes brought about by the EU have not solved the issue surrounding CP. We would like to see specific negotiations take place on this issue to find a practical solution in a similar way to how other concerns have been addressed. We urge both UK and EU to look at this as a technical, rather than political issue.

7. What, in your view, is the best way forward to resolve the current impasse?

7.1. With regards to medicines, there needs to be more discussion and negotiation on specific technical issues, rather than conflating them into one broader Protocol issue. This will mean that individual problems can be sorted out much quicker, and more bespoke solutions can be identified that bring better outcomes for both the UK and EU. One of the main problems Teva faces is the uncertainty that the unresolved problems and protracted negotiations are causing, as this creates all sorts of knock-on effects for our business and potentially patients.

8. Do you see, and how would you describe, a potential landing zone for compromise and agreement between the two sides?

8.1. There is potential for agreement on issues relating to medicines if both sides agree to look at individual issues from a practical perspective. We believe that one of the main concerns for the EU is that goods could move from GB to NI, and then from NI to Ireland and the rest of the EU without sufficient checks, standards or ability to track products. However, with medicines, these are all licenced products and have details such as licence numbers in the packs. This means that it shouldn't be possible to legally sell UK SKUs anywhere but the UK. Therefore, there should be scope for the UK and EU to come together and negotiate through these issues.

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