Written evidence submitted by the Bristol Myers Squibb (BMS) (FRE0141)

About Bristol Myers Squibb (BMS)

BMS is a leading global biopharma company focused on discovering, developing and delivering innovative medicines for patients with serious diseases in areas including oncology, hematology, immunology, cardiovascular and neuroscience. Our employees work every day to transform patients' lives through science.

In the UK, BMS employs approximately 1,000 people. Over half a million NHS patients rely on our medicines to manage their disease, stay well and live their life to the full. We supply over 30,000 packs of medicines to Northern Ireland each month to treat patients, including those with life-threatening conditions.

BMS welcomes the opportunity to submit to the Committee on the Future Relationship with the European Union inquiry into the progress of the negotiations on the UK's Future Relationship with the EU. BMS are also members of the Association of British Pharmaceutical Industry (ABPI), and in addition to this inquiry response support both the oral and written evidence (FRE0102) provided by the Association.

This inquiry presents an important opportunity to highlight the impact negotiations between the UK and EU could have on the supply of medicines to Northern Ireland following the end of the transition period, in particular relating to the Northern Ireland Protocol.

There are a number of measures that the UK Government could undertake in agreement with the EU to mitigate any risk to medicines supply, which are outlined below. These are now urgently required. BMS has, to date, worked closely with the UK Government to address the risk to medicines supply associated with the UK's departure from the European Union (EU) and stands ready to support in whatever way we can on this issue in the future.

Access to medicines in Northern Ireland following the end of the transition period as a priority for UK and EU negotiations

We believe that ensuring unfettered access to medicines in Northern Ireland must be a priority area in UK and EU negotiations. Currently we are concerned that UK packs of medicines supplied to Northern Ireland may not be compliant with EU regulations after the end of the transition period, meaning companies are at risk of not being able to lawfully dispense them in Northern Ireland.

Part of this concern relates mainly to the Falsified Medicines Directive (FMD) unique identifier and revocation of UK FMD 'safety features legislation'. The FMD is a set of rules created to protect people from counterfeit medicines in the EU, including anti-tampering security on packaging, and tracking medicines using a unique identifier and database.[1]

Following the end of the transition period, the Directive will cease to apply in the UK, except in Northern Ireland where it will continue to apply under the terms of the Protocol. This may lead to a situation where packs of medicines for the UK market cannot be dispensed in Northern Ireland, as they will be considered to have been exported from the EU (into Great Britain), and will no longer be covered by the anti-counterfeit system and [1] NHS Digital. Falsified Medicines Directive. Available at: https://digital.nhs.uk/services/falsified-medicines-directive-fmd [Accessed: July 2020] not be compliant with EU regulations.

The European Commission (EC) and European Medicines Agency (EMA) confirmed within 'Notice to Stakeholders – Withdrawal of the United Kingdom and EU roles for medicinal products for human use and veterinary medicinal products' that medicinal products marketed in NI will have to comply with EU regulations after the end of the transition period.[2]

While guidance has been received from the EC and the EMA, BMS is still seeking clarity from the UK Government on the issues raised within this inquiry response. Critical questions remain including whether packs of medicines may be moved from Great Britain to Northern Ireland and dispensed lawfully, if there will be access in Northern Ireland to the relevant FMD databases to track and release medicines, and how medicines for the Northern Ireland market should be packaged.

Because of the lack of clarity and as a contingency, BMS has so far worked to stockpile our medicines in Northern Ireland to cover a six month period in order to mitigate potential issues with the supply of medicines following the end of the transition period. However, this is only a short term measure and may not be possible with all medicines. Longer term measures such as alternative supply routes will take many months to complete and have knock-on implications for packaging and regulatory requirements; guidance is therefore required from the UK Government now.

There is also little clarity on how the Internal Market Bill might impact medicine supply in Northern Ireland, with clause 42 of the Bill empowering Ministers to adopt regulations that override provisions of the Protocol and domestic legislation, this could include the FMD application in Northern Ireland, as contained within the Protocol. The Bill does not include any provisions on customs in relation to the movement of goods from Great Britain to Northern Ireland, furthering the lack of clarity on the impact the Bill may have on access to medicines.

In addition, the Medicines and Healthcare products Regulatory Agency (MHRA) has provided guidance[3] on what is regarded as 'placed on the market' under Article 41. This guidance means that medicines certified before 11pm on 31 December 2020 have been 'placed on the market', meaning these batches will remain available for sale or supply between Great Britain, Northern Ireland and the EU after 1 January 2021, without additional regulatory checks.

However, such product will be viewed as an "import" and Article 41 of the Withdrawal Agreement is without prejudice to controls that may apply to imports. Consequently, further clarity is required from the Commission whether regulatory controls that are triggered on import will apply.

We also note that in accordance with the Protocol, there is a risk that tariffs would potentially apply on the import of the product into NI, unless the product is deemed "not at risk" of subsequently entering the EU. However, in accordance with the Protocol, it is the UK-EU Joint Committee that decides which products are not at risk. We therefore also require clarity on tariffs and whether a medicinal product clearly labelled for the UK internal market should be considered not at risk of subsequently entering the EU.

---

[2] The European Commission. Notice to stakeholders – Withdrawal of the United Kingdom and EU rules for medicinal products for human use and veterinary medicinal products. Available at: https://ec.europa.eu/info/sites/info/files/notice_to_stakeholders_medicinal_products.pdf [Accessed: July 2020]

[3] UK Government. Supplying medicines to Northern Ireland from 1 January 2021. Available at: https://www.gov.uk/guidance/supplying-medicines-to-northern-ireland-from-1-january-2021 [Accessed October 2020]

Potential ways in which the Government could ensure the continued supply of medicines following the transition period ending could be:

- The UK and the EU to agree an extensive Mutual Recognition Agreement for medicines between the UK and EU to allow continuation of current supply logistics to Northern Ireland.
- The EU to grant the UK access to FMD and pharmacovigilance databases under authority of Art. 13(5) of the NI Protocol, on the basis that "full or partial access" is "strictly necessary" to enable the UK to comply with its obligations under the NI Protocol and to minimise supply disruption of medicines to Northern Ireland.

There is also the possibility that the UK Government requests a derogation of FMD and importation regulations. Whatever the approach, BMS urgently request that the UK Government prioritise the issue of medicine regulation and supply and provides urgent clarity on how medicinal products will be provided to patients in NI, in a compliant manner, following the end of the transition period, which is soon approaching.

October 2020