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Representing the UK Animal Health Industry

NOAH statement re NIP and continuation of current arrangements

30/01/23

Regarding European Commission Notice about the Northern Ireland Protocol (NIP) and veterinary medicines, December 2022

NOAH (National Office of Animal Health) represents the UK animal health industry. We promote the benefits of licensed medicines and solutions for all animals. The association's membership represents around 97% of the UK animal medicines market worth more than £738 million per annum (Q2 2022).

The Northern Ireland Protocol (NIP), were it to be applied in full to the veterinary medicines sector, requires regulatory, logistical and supply chain changes that are simply not feasible for the UK animal health industry to make. There are concerns that up to 50% of veterinary medicinal products would be at risk of discontinuation for the Northern Ireland (NI) market, which would lead to a lack of products and consequential animal health and welfare problems. Similar concerns existed over human medicines and adaptations to the NIP were agreed between the EU and UK government to address them. A similar approach is needed for veterinary medicines.

NOAH welcomes the announcement by the European Commission in December 2022 that the current transition arrangements that were previously agreed between the UK government and European Commission can continue until the end of 2025 to help ensure continuity of supplies of veterinary medicinal products to NI.

However, animal health industry concerns remain; there is no change in the current divergent positions of the European Commission and the UK with regards to the requirements for regulation of products and supply into NI. Consequently, there is an absence of consistent direction for industry to follow, which is an extremely challenging situation for our highly regulated sector and there remains a real risk to the future availability of veterinary medicinal products in NI.

The solutions that are sought are as follows:

- Allowing regulatory functions to remain in the UK if they are currently located there. In particular, there is a need for the MA holder location for nationally authorised products on the NI market to be permitted to be located in either the UK or EU.
- For medicines moving from Great Britain (GB) to NI, batch testing and release should not need to be repeated if it has already been carried out in GB or the EU.
- No manufacturing authorisation or import licences should be required for medicines supplied from GB to NI.
- Authorisation by the UK regulator can allow companies located in GB to use a single pack and leaflet when supplying markets in both GB and NI, with no need for separate packaging for the NI market.

The problems that the animal health industry continues to face cannot be solved by additional time alone, as the main driver of these issues remains the cost of making the significant changes specifically for NI, which is a small marketplace. The additional costs of either establishing repeat batch testing and release in NI or moving these activities to the EEA, as well as any changes that require NI specific packaging, can render these products economically non-viable. The viability of products in NI are largely dependent on remaining part of the UK-wide market with GB, including sharing packaging with GB. As these challenges will not be solved by simply giving more time for companies to make changes, only a change in the approach by the negotiating parties will finally resolve this situation.

NOAH calls on the UK government and European Commission to continue their positive discussions and to urgently resume specific talks to address the long term needs of the veterinary medicines sector in NI. A negotiated and mutually agreed regulatory outcome, with an appropriate implementation period if necessary, will help to ensure the long-term supply of a wide range of veterinary medicines to NI, with the associated animal health and welfare benefits that this would bring.