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NOAH
Supporting the future of animal health

Representing the UK Animal Health Industry

Regarding Northern Ireland Protocol (NIP), Veterinary Medicinal Product (VMP) availability and the impact on animal health and welfare in Northern Ireland

NOAH (National Office of Animal Health) represents the UK animal health industry. We promote the benefits of safe, effective, quality products and services for the health and welfare of all animals. The association's membership represents around 97% of the UK animal medicines market worth in excess of £735 million per annum (2020).

Veterinary Medicinal Products (VMPs) and the NI Protocol

- Veterinary medicinal products (VMPs) are essential to animal health and welfare and make a major contribution to the UK's food security and public health.
- The majority of animal health companies have operated historically in both Great Britain (GB) and Northern Ireland (NI) with the NI business being managed and supplied from GB.
- NOAH member companies are growing increasingly concerned about the implications of the Northern Ireland Protocol (NIP) for their ability to fulfil regulatory requirements to maintain product authorisations, the impact on supply chains and disruption to product supply.
- NI is a small market for products meaning that the introduction of any NI specific requirements, either from a regulatory or supply chain point of view, poses serious challenges to product supply.
- The NIP in its current form will lead to NI specific requirements putting many products at risk of being discontinued for the NI market.
- An 'all island of Ireland' Marketing Authorisation (product licence) approach is not the solution. Products authorised in the Republic of Ireland are not automatically legally authorised in NI. The UK regulatory agency for veterinary medicines, the Veterinary Medicines Directorate (VMD), remains the regulator for NI.
- Industry estimates that between 40%-50% of product portfolios are at risk of being removed from the NI market, resulting in a negative impact on disease status and animal health and welfare.

Solutions

Agreement has already been achieved to adapt the NIP for human medicines which addresses many industry concerns. The adapatations for human medicines include:

- Allowing regulatory functions to remain in the UK if they are currently located there.
- For medicines moving from GB to NI, batch testing does not need to be repeated if it has already been carried out in GB or the EU.
- No manufacturing authorisation or import licenses needed 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 animal health industry is seeking similar solutions to those granted for human medicines. To date, the European Commission has not agreed that this is necessary and simply states that "more time (until the end of 2022) is being granted to industry." More time is not the answer and will not resolve the concerns of the animal health industry, vets, farmers or pet owners.

Another possible solution may be to remove veterinary medicines from the scope of the NIP; a possibility suggested in the UK Government's Command Paper, July 2021.