HOUSE OF LORDS
European Union Committee

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Edward Argar MP
Minister for Health
Department for Health and Social Care
39 Victoria Street
London, SW1H 0EU

Dear Edward,

Supply of pharmaceuticals to Northern Ireland

As you will be aware, the vast majority of the medicines used in Northern Ireland are imported either from or via Great Britain, often originating in the EU. As you may also be aware, pharmaceutical companies do not feel they have the information they need about how the Protocol on Ireland/Northern Ireland will operate in relation to that transport of medicines. As a result, we have serious concerns about the risk to the supply of prescription medicines in NI from 1 January next year.

Particular difficulties arise in light of the Falsified Medicines Directive. From 1 January the unique identifiers applied to packages of medicines originating in the EU as required by the Directive will be decommissioned when medicine packages enter GB; but the packages will need an active identifier to be dispensed in NI. It is unclear what steps companies will have to take in order to supply those medicines in NI.

In light of this challenge, what steps is the Government taking to ensure the consistent, affordable supply of a full range of genuine prescription medicines in NI in the medium-term, after any immediate adjustment period at the end of transition? We are particularly interested in whether you have explored the possibility of bonded warehouses, which may allow medicines to be transported from the EU to NI via GB without being decommissioned.

In addition, and in light of the industry's immediate and pressing concerns, we would be grateful if you could respond to the following questions:

1) Are medicines stockpiled as per the letter sent to the pharmaceutical industry in August[1] considered to have been 'placed on the market' as per the guidance issued

[1] https://www.gov.uk/government/publications/letter-to-medicines-and-medical-products-suppliers-3-august-2020/letter-to-medicine-suppliers-3-august-2020

on 1 October;[2] and if not, can medicines stockpiled now be sold legally in NI from 1 January with no changes to their package, label or inserts?

2) What assessment has the Government made of the warehouse capacity for medicine stockpiles in NI ahead of 1 January?
3) Will medicines placed on the market from 1 January have to be re-labelled or otherwise adjust their packaging if they originate in the EU but pass through GB on their way to NI?
4) Will medicines placed on the market from 1 January have to be re-tested if they originate in the EU but pass through GB on their way to NI? And if so, what steps is the Government taking to increase the testing capacity in NI?
5) Given the time it will take pharmaceutical companies to adjust their packaging and / or supply routes as required, has the Government had discussions with the EU about a potential derogation period from the FMD to ensure there is no interruption to the supply of medicines to NI?
6) Has the Government made progress on seeking a mutual recognition agreement with the EU to cover the inspection and batch testing of medicines?
7) Is the Government taking any other steps to ensure the consistent, affordable supply of a full range of prescription medicines in NI from 1 January 2021?

Given the urgency of these matters, please respond by 11 November.

Yours sincerely,

Lord Teverson
Chair of the European Union Environment Sub-Committee

[2] https://www.gov.uk/guidance/supplying-medicines-to-northern-ireland-from-1-january-2021