Department of Health & Social Care

Edward Argar MP
Minister of State for Health

39 Victoria Street
London
SW1H 0EU

020 7210 4850

Lord Jay of Ewelme
House of Lords
London
SW1A 0AA

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Dear Michael,

I am writing to update you on the latest developments on the supply of medicines to Northern Ireland.

You may have seen that last Friday the EU published a proposal to resolve the ongoing regulatory issues for medicines moving from Great Britain into Northern Ireland. My officials will be scrutinising the detail of the legal text, but our initial reading is that it resolves some of the key problems.

The package is made up of an extension to the current grace period from 1 January alongside new legislative proposals to come into effect in 2022.

The extension to the grace period means that existing flexibilities for medicines supplied to Northern Ireland will remain in place until the long-term solutions can be legislated for. This means that companies can continue to supply medicines to Northern Ireland as they are able to now, which should provide legal certainty from 1 January beyond the "standstill" announcement.

The long-term proposals aim to remove the main regulatory barriers for the movement of medicines from Great Britain to Northern Ireland. It proposes that companies can use a UK wide authorisation route for generic medicines. This will remove unnecessary duplication for suppliers. The role of the European Medicines Agency (EMA) in authorising novel medicines for Northern Ireland is maintained. Here, companies will be able to make use of a new bridging mechanism to ensure their product is licensed for the whole of the UK if the MHRA issues a licence for a product before the EMA.

The UK Government has been cautious about welcoming this proposal because we have not had sufficient time to review and scrutinise the legal text. We will begin this process now and will continue to work with the European Commission in January. In the meantime, we will engage closely with industry to hear their feedback and to understand how effective it is in addressing the issues.

Thank you for your Sub-Committee's work to date on medicines supply for Northern Ireland.

EDWARD ARGAR MP