European Scrutiny Committee
House of Commons, London, SW1A 0AA
Tel (020) 7219 3292 Email escom@parliament.uk Website www.parliament.uk/escom

From: Sir William Cash MP

9 March 2022

Edward Argar MP
Minister of State for Health Parliamentary Under Secretary of State
Department of Health & Social Care
39 Victoria Street
London SW1H 0EU

COM(2021) 997: Proposal for a Directive amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland, as well as in Cyprus, Ireland and Malta (41987)

COM(2021) 998: Proposal for a Regulation amending Regulation (EU) No 536/2014 as regards a derogation from certain obligations concerning investigational medicinal products made available in the United Kingdom with respect to Northern Ireland as well as in Cyprus, Ireland and Malta (41988)

C(2021) 9700: Commission Delegated Regulation (EU) …/… of 17.12.2021 amending Delegated Regulation (EU) 2016/161 as regards the derogation from the obligation of wholesalers to decommission the unique identifier of medicinal products exported to the United Kingdom (42010)

C(2021) 9668: Commission Communication: Approval of the content of a draft Commission Notice on the application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland (42011)

We considered your Explanatory Memorandum (EM) on the Northern Ireland (NI) medicines package at our meeting of 9 March 2022.

We note the Commission's proposals to ensure the continued long-term supply of medicines from Great Britain (GB) to Northern Ireland (NI) and would welcome your views on two specific elements.

The first is the provision that, if the EU does not grant an authorisation for a novel medicine after six months, the medicine could no longer be used in NI even if still authorised for use in GB. It seems to us that there remains a risk that the same medicines are not available in both GB and NI in the event that EU and GB regulators take different views. Is this an accurate interpretation?

Second, the whole package appears to be based on the level of public health protection afforded by GB laws in this area remaining "essentially equivalent" to that provided by the EU's laws. While we consider it unlikely that GB law in the area of medicines will be amended to reduce the level of public health protection that is currently guaranteed, the Commission indicated in its Work Programme for 2022 that it will propose revisions later this year to the EU's body of legislation in this area. At the very least, it seems to us, the UK will need to be mindful of EU law when exercising regulatory autonomy in this area and will need to recognise that it may need to adapt policy to maintain equivalence. Do you accept that this element of the proposal places constraints on the UK's regulatory autonomy? Would you anticipate working with the Commission to develop a clear understanding of what constitutes "essentially equivalent"?

Your EM used the term "substantively equivalent" rather than "essentially equivalent". Could you explain this apparent discrepancy?

You noted in your EM that you were still analysing the proposals. We ask that, in your reply, you set out the results of that further analysis.

We look forward to a reply to this letter by 30 March 2022.

We are copying this letter to Simon Hoare MP, Chair of the Northern Ireland Affairs Committee and Stephen Habberley, Clerk of the Committee; Rt Hon. Jeremy Hunt MP, Chair of the Health and Social Affairs Committee and Joanna Dodd, Clerk of the Committee; the Earl of Kinnoull, Chair of the European Affairs Committee in the House of Lords and Nick Boorer, Clerk of the Committee; your Departmental EU Scrutiny team; and Les Saunders and Donald Harris in the Cabinet Office.

CHAIR