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

24 March 2021

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

**COM(20) 761: Commission Communication — Pharmaceutical Strategy for Europe (41687)**

We considered your Explanatory Memorandum (EM) on the above document at our meeting of 24 March 2021.

While the Strategy is high-level, it nevertheless signals a clear intention to change the system of incentives in place, including intellectual property protection, to encourage innovation. This could represent a substantial shift for the pharmaceutical sector and, similarly, would lead to a divergent approach between the UK and the EU to the development of innovative, affordable and accessible medicines. What is your response to the Commission's fundamental hypothesis that incentives for pharmaceutical companies to innovate are not aligned with the interests of patients and thus need to be reviewed? If the EU and UK pursue divergent approaches to pharmaceutical innovation, what risks and opportunities might arise for the UK? We would welcome any of its own ideas that the Government may have to resolve the challenges identified in the document, such as: addressing unmet medical needs and ensuring accessibility and affordability of medicines; and promoting innovative, sustainable and patient-oriented pharmaceutical development.

In terms of opportunities for the UK, we note that the Commission's Strategy contains initiatives relating to research in this area. Given that the UK and EU agreed in the Trade and Cooperation Agreement that the UK could associate to the EU's research programme (Horizon Europe), what opportunities does the Government see for EU-UK research cooperation in the development of pharmaceutical products?

Turning to regulation, it is of fundamental significance that the Commission intends to present amendments to the pharmaceutical legislation and legislation on orphan and paediatric medicines. This is all key public health legislation with which Northern Ireland must remain aligned. In our view, the Commission's suggestions are possible changes with which the Government must engage as you need to be mindful not only of the direct implications for Northern Ireland, but also of the impact of regulatory divergence between Great Britain and Northern Ireland concerning medicinal products. We require from you an outline of your plans in this regard in terms of both analysis of the regulatory options and implications and intended engagement with the European Commission. If you have no such plans, we ask you to explain clearly why that is the case.

In your EM — submitted prior to provisional application of the Trade and Cooperation Agreement between the EU and UK — you questioned the value to the UK of the EU's proposals concerning regulatory cooperation, suggesting that the EU's agenda was to promote its own interests and ensure regulatory convergence. The UK then went on, however, to agree to regulatory cooperation with the EU on medicinal products, including within international fora. We therefore ask that you update your position, setting out clearly the UK's objectives for its international engagement in this area, both with the EU and others. Do you see any benefits for the UK of third countries being encouraged, whether only by the EU or by the EU in partnership with the UK and others, to strengthen their regulatory and intellectual property standards as far as medicinal products are concerned?

On the detail of international engagement on pharmaceutical regulation, we note that the UK is — alongside the EU — a member of the International Coalition of Medicines Regulatory Authorities. Unlike the EU, it is not listed as a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) nor of the International Pharmaceutical Regulators Programme (IPRP). Membership of the IPRP and ICH includes the EU but extends to many others including the US, Canada, New Zealand and Australia. We note that the TCA provides that the ICH standards are part of the baseline for the respective EU and UK approaches to pharmaceuticals regulation. Could you please explain why the relevant UK body is not listed as a member and could you also set out the international partnerships within which the UK is engaged in this area?

We look forward to a response by 14 April.

We are copying this letter to Darren Jones MP, Chair of the Business, Energy and Industrial Strategy Committee and Rebecca Davies, Clerk of the Committee;

Rt Hon. Jeremy Hunt MP, Chair of the Health and Social Care Committee and James Davies, Clerk of the Committee; Simon Hoare MP, Chair of the Northern Ireland Affairs Committee and Stephen Habberley, Clerk of the Committee; Rt Hon. Greg Clark MP, Chair of the Science and Technology Committee and Danielle Nash, Clerk of the Committee; the Earl of Kinnoull, Chair of the EU Select Committee in the House of Lords and Christopher Johnson, Clerk of the Committee; your Departmental EU Scrutiny team; and Les Saunders and Donald Harris in the Cabinet Office.

**CHAIR**