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Marie Austin
Clerk, Windsor Framework Democratic Scrutiny Committee
Room 382, Parliament Buildings
Stormont
Belfast, BT4 3XX

14 August 2024

Dear Marie,

Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

I write further to the letter from the Minister of the Cabinet Office to the Chair of the Committee, dated 7 August 2024 regarding the above mentioned Regulation. The Committee sought further engagement with the UK Government on the matters concerned by the Regulation.

Please find a letter dated 13 August 2024 sent from the Parliamentary Under-Secretary of State for Public Health and Prevention in the Department of Health & Social Care to the Minister of Health in Northern Ireland, which also covers the above mentioned Regulation attached. It contains further details of planned next steps by officials in DHSC, including a review starting this month of existing legislation in the rest of the UK with the aim of supporting public health and continued movements of Substances of Human Origin across the UK. We believe this will be of use to the Committee's work.

I trust that this information will assist the Committee to carry out its functions, and would be grateful if you could please circulate it onwards to the Chair and members of the Committee.

Kind regards,

PAUL FLYNN
DEPUTY DIRECTOR

Department of Health & Social Care

From Andrew Gwynne MP
Parliamentary Under-Secretary of State
for Public Health and Prevention

39 Victoria Street
London
SW1H 0EU

Mike Nesbitt MLA
Minister of Health
Northern Ireland Assembly
Castle Buildings
Stormont Estate
Belfast
BT4 3SJ

13 August 2024

Dear Mike,

I would like to thank your officials for continuing to engage on the Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (SoHO Regulation).

The EU SoHO Regulation

The new EU SoHO Regulation aims to continue to provide high safety and quality standards, support continuity of supply and extend protections for patients. As per the previous Blood and Tissues and Cells (BTC) Directives, the SoHO Regulation will continue to apply to blood, blood components, tissues and cells (including haematopoietic stem cells from peripheral blood, from umbilical-cord blood or from bone marrow, reproductive cells and tissues, embryos, foetal tissues and cells and adult and embryonic stem cells).

The SoHO Regulation will also bring into scope all SoHO intended for human application and used to manufacture products regulated by other specific Union legislation, with the exception of solid organs intended for transplantation (as their donation and transplantation are significantly different, determined, inter alia, by the effect of ischemia in the organs, and so remain regulated separately under Directive 2010/53/EU) and human breast milk (HBM) used exclusively for feeding one's own child. The purpose of which is to provide harmonised preparation and consistent treatment for substances intended for human application, and improve the safety, effectiveness, and accessibility of SoHO.

Compared with the previous BTC Directives, this therefore brings into scope of the Regulation of SoHO substances such as intestinal microbiota (IM), HBM (in non-exempt cases) and blood preparations that are not used for transfusion (e.g. serum eye drops, fibrin glue, platelet rich plasma). The Regulation will also apply to any future substances not yet used for human application that may be developed following scientific advances or other developments, where it comes within the definition of SoHO.

An Explanatory Memorandum (EM) was submitted to the NI Democratic Scrutiny Committee and the relevant UK Parliamentary Committees to outline the changes introduced and the potential impacts.

Next steps

The current legislation for blood, blood components, tissues and cells, IM, HBM and blood preparations that are not used for transfusion was introduced over 20 years ago. Therefore, it is important to ensure that legislation in this area continues to reflect scientific, technical, and medical advancements as well as future proofs for new technologies and emerging risks. We welcome your continued engagement as this work progresses.

My officials will be in touch to work closely with Devolved Government officials on a SoHO Regulation Review Programme that we will be commencing this month. This review will look at the SoHO Regulation and stakeholder proposals for legislation in this area. This will take into account a number of factors that may be affected by the proposals, including: patient safety; intra-UK and UK-EU supply of SoHO; innovation within the sector; and health inequalities. One of the key principles of the review is to maintain a compatible minimum set of high standards of safety and quality for HBM, IM, blood preparations that are not used for transfusion, blood, blood components and tissues and cells in order to protect public health and support the movement of SoHO across the UK.

I would like to thank the Devolved Governments and their officials involved, for their continued support and work to date in relation to the SoHO Regulations.

Your sincerely,

ANDREW GWYNNE MP