EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Brussels, 13th of December 2017

NOTICE TO ORGANISATIONS SUBJECT TO THE UNION LEGISLATION ON SUBSTANCES OF HUMAN ORIGIN (BLOOD, TISSUES AND CELLS, AND ORGANS) CONCERNING THE UNITED KINGDOM'S WITHDRAWAL FROM THE EUROPEAN UNION

The United Kingdom submitted on 29 March 2017 the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. This means that unless a ratified withdrawal agreement[1] establishes another date or the period is extended by the European Council in accordance with Article 50(3) of the Treaty on European Union, all Union primary and secondary law will cease to apply to the United Kingdom from 30 March 2019, 00:00h (CET) ('the withdrawal date'). The United Kingdom will then become a 'third country'.[2]

Preparing for the withdrawal is not just a matter for EU and national authorities but also for private parties.

In view of the considerable uncertainties, in particular concerning the content of a possible withdrawal agreement, organisations subject to the Union legislation on substances of human origin (blood, tissues and cells, and organs) are reminded of legal repercussions, which need to considered when the United Kingdom becomes a third country.

Subject to any transitional arrangement that may be contained in a possible withdrawal agreement, as of the withdrawal date, the EU rules in the field of substances of human origin (blood, tissues and cells, and organs) no longer apply to the United Kingdom. From that date, under the Union legislation on substances of human origin, any exchange of blood and blood components, tissues and cells, or organs between the EU-27 and the United Kingdom will be considered as import/export from/to a third country. This has in particular the following consequences which need to be considered and anticipated:

- **Blood and blood components**: According to Article 21 (second subparagraph) of Directive 2002/98/EC[3] imports of blood and blood components from the United Kingdom will need to be tested in conformity with the Union testing requirements

[1] Negotiations are ongoing with the United Kingdom with a view to reaching a withdrawal agreement.

[2] A third country is a country not member of the EU.

[3] Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, OJ L 33, 8.2.2003, p. 30.

(Annex IV to that Directive). They will also need to meet equivalent standards of quality and safety (Annex V to Directive 2004/33/EC[4]).

- **Tissues and cells:** Imports of tissues and cells from the United Kingdom will have to be undertaken by authorised importing tissue establishments located in the EU-27 (Article 9(1) of Directive 2004/23/EC[5]) and meet standards of quality and safety equivalent to those laid down in the Union legislation (Article 9(1) of Directive 2004/23/EC and Directive (EU) 2015/566[6]). Directive 2004/23/EC also establishes, in Article 9(2), rules for export of tissues or cells to third countries. In particular, those Member States that export tissues or cells to third countries must ensure that the exports comply with the requirements of this Directive. Moreover, according to Article 9(3) of Directive 2004/23/EC, in some cases (where certain specific tissues and cells are distributed directly for immediate transplantation to the recipient or in case of emergency) the import or export of tissues and cells may be authorized directly by the competent authority, as long as such imports and exports meet quality and safety standards equivalent to those laid down in Directive 2004/23/EC and implementing legislation.

- **Organs**: According to Article 20 of Directive 2010/53/EU[7], exchange of organs with the United Kingdom will need to be supervised by a EU-27 competent authority or European organ exchange organisations (where the Member State delegates the supervision to them) and meet quality and safety requirements equivalent to those laid down in the Union legislation.

- In accordance with the aforementioned legislation, in all cases, blood, tissues and cells, and organs will need to be **traceable from donor to recipient and *vice versa***.

The website of the Commission on blood, tissues and organs (https://ec.europa.eu/health/blood_tissues_organs/policy_en) provide for general information. These pages will be updated with further information, where necessary.

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4 Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components, OJ L 91, 30.3.2004, p. 25.

5 Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, OJ L 102, 7.4.2004, p. 48.

6 Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells Text with EEA relevance, OJ L 93, 9.4.2015, p. 56.

7 Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation, OJ L 207, 6.8.2010, p. 14.