EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Brussels, 8 June 2020
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dated 23 January 2018

NOTICE TO STAKEHOLDERS

WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES IN THE FIELD OF SUBSTANCES OF HUMAN ORIGIN (BLOOD, TISSUES AND CELLS, ORGANS)

Since 1 February 2020, the United Kingdom has withdrawn from the European Union and has become a "third country".[1] The Withdrawal Agreement[2] provides for a transition period ending on 31 December 2020.[3] Until that date, EU law in its entirety applies to and in the United Kingdom.[4]

During the transition period, the EU and the United Kingdom will negotiate an agreement on a new partnership, providing notably for a free trade area. However, it is not certain whether such an agreement will be concluded and will enter into force at the end of the transition period. In any event, such an agreement would create a relationship which in terms of market access conditions will be very different from the United Kingdom's participation in the internal market,[5] in the EU Customs Union, and in the VAT and excise duty area.

Therefore, all interested parties, and especially economic operators, are reminded of the legal situation applicable after the end of the transition period (Part A below). This notice also explains certain relevant separation provisions of the Withdrawal Agreement (Part B below), as well as the rules applicable in Northern Ireland after the end of the transition period (Part C below).

Advice to stakeholders:

1 A third country is a country not member of the EU.

2 Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, OJ L 29, 31.1.2020, p. 7 ("Withdrawal Agreement").

3 The transition period may, before 1 July 2020, be extended once for up to 1 or 2 years (Article 132(1) of the Withdrawal Agreement). The UK government has so far ruled out such an extension.

4 Subject to certain exceptions provided for in Article 127 of the Withdrawal Agreement, none of which is relevant in the context of this notice.

5 In particular, a free trade agreement does not provide for internal market concepts (in the area of goods and services) such as mutual recognition, the "country of origin principle", and harmonisation. Nor does a free trade agreement remove customs formalities and controls, including those concerning the origin of goods and their input, as well as prohibitions and restrictions for imports and exports.

To address the consequences set out in this notice, stakeholders are in particular advised to adapt distribution channels, in order to take account of importation requirements.

Please note:

This notice does not address

- EU law on medical devices and medicinal products;
- EU law on protection of personal data.

For these aspects, other notices are in preparation or have been published.[6]

A. LEGAL SITUATION AFTER END OF THE TRANSITION PERIOD

After the end of the transition period, the EU rules in the field of substances of human origin (blood, tissues and cells, and organs) no longer apply to the United Kingdom.[7] This has in particular the following consequences:

1. BLOOD AND BLOOD COMPONENTS

According to Article 21 (second subparagraph) of Directive 2002/98/EC[8], imports of human blood and blood components have to be tested in conformity with the Union testing requirements (Annex IV to that Directive). They will also need to meet equivalent standards of quality and safety (Annex V to Directive 2004/33/EC[9]).

After the end of the transition period, these requirements apply to blood and blood components imported to the EU from the United Kingdom.

2. TISSUES AND CELLS

According to Article 9(1) of Directive 2004/23/EC,[10] imports of human tissues and cells into the EU intended for human application have to be undertaken by

6 https://ec.europa.eu/info/european-union-and-united-kingdom-forging-new-partnership/future-partnership/preparing-end-transition-period_en

7 Regarding the applicability of these rules to Northern Ireland, see Part C of this notice.

8 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.

9 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.

10 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.

authorised importing tissue establishments located in the EU, 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[11]).

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 authorised 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.

After the end of the transition period, these requirements apply to imports of tissues and cells to the EU from the United Kingdom, and exports of tissues and cells to the United Kingdom from the EU.

3. ORGANS

According to Article 20 of Directive 2010/53/EU[12], exchanges of human organs with third countries have to be supervised by an EU 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.

After the end of the transition period, this requirement applies to the exchange of organs between the EU and the United Kingdom.

4. TRACEABILITY

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

B. RELEVANT SEPARATION PROVISIONS OF THE WITHDRAWAL AGREEMENT

Article 41(1) of the Withdrawal Agreement provides that an existing and individually identifiable good lawfully placed on the market in the EU or the United Kingdom before the end of the transition period may be further made available on the market of the EU or of the United Kingdom and circulate between these two markets until it reaches its end-user.

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11 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.

12 Directive 2010/53/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.

The economic operator relying on that provision bears the burden of proof of demonstrating on the basis of any relevant document that the good was placed on the market in the EU or the United Kingdom before the end of the transition period.[13]

For the purposes of that provision, "placing on the market" means the first supply of a good for distribution, consumption or use on the market in the course of a commercial activity, whether in return for payment or free of charge.[14] "Supply of a good for distribution, consumption or use" means that "an existing and individually identifiable good, after the stage of manufacturing has taken place, is the subject matter of a written or verbal agreement between two or more legal or natural persons for the transfer of ownership, any other property right, or possession concerning the good in question, or is the subject matter of an offer to a legal or natural person or persons to conclude such an agreement."[15]

C. Applicable rules in Northern Ireland after the end of the transition period

After the end of the transition period, the Protocol on Ireland/Northern Ireland ("IE/NI Protocol") applies.[16] The IE/NI Protocol is subject to periodic consent of the Northern Ireland Legislative Assembly, the initial period of application extending to 4 years after the end of the transition period.[17]

The IE/NI Protocol makes certain provisions of EU law applicable also to and in the United Kingdom in respect of Northern Ireland. In the IE/NI Protocol, the EU and the United Kingdom have furthermore agreed that insofar as EU rules apply to and in the United Kingdom in respect of Northern Ireland, Northern Ireland is treated as if it were a Member State.[18]

The IE/NI Protocol provides that EU legislation on blood, tissues and cells, and organs applies to and in the United Kingdom in respect of Northern Ireland.[19]

This means that references to the EU in Parts A and B of this notice have to be understood as including Northern Ireland, whereas references to the United Kingdom have to be understood as referring only to Great Britain.

More specifically, this means *inter alia* the following:

- blood, tissues and cells, and organs in Northern Ireland have to comply with EU legislation on blood, tissues and cells, and organs;

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13 Article 42 of the Withdrawal Agreement.

14 Article 40(a) and (b) of the Withdrawal Agreement.

15 Article 40(c) of the Withdrawal Agreement.

16 Article 185 of the Withdrawal Agreement.

17 Article 18 of the IE/NI Protocol.

18 Article 7(1) of the Withdrawal Agreement in conjunction with Article 13(1) of the IE/NI Protocol.

19 Article 5(4) of the IE/NI Protocol and section 22 of annex 2 to that Protocol.

- blood, tissues and cells, and organs shipped from Northern Ireland to the EU are not an import for the purpose of EU legislation (see above, section A);

- blood, tissues and cells, and organs shipped from Great Britain or any third country to Northern Ireland are an import for the purpose of EU legislation (see above, section A);

- an establishment in Northern Ireland fulfils the requirement for being established in the EU;

- designations, authorisations, accreditations or licences granted to blood establishments in Northern Ireland to distribute blood and blood components, and to tissue establishments in Northern Ireland to distribute tissues and cells, are recognised in the EU.[20]

However, the IE/NI Protocol excludes the possibility for the United Kingdom in respect of Northern Ireland to participate in the decision-making and decision-shaping of the Union.[21]

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

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[20] The IE/NI Protocol excludes the recognition, in the EU, of authorisations by the United Kingdom in respect of Northern Ireland (first subparagraph of Article 7(3) of the IE/NI Protocol). However, in the present case, the second subparagraph of Article 7(3) of the IE/NI Protocol applies.

[21] Where an information exchange or mutual consultation is necessary, this will take place in the joint consultative working group established by Article 15 of the IE/NI Protocol.