



**PHARMACEUTICAL COMMITTEE**  
**8 March 2018**

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**Subject: Evaluation of the EU legislation on blood, tissues and cells**

**Agenda item 3iii**

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The Commission is currently carrying out an evaluation of the EU blood and tissues and cells legislation. This is the first formal evaluation of this legislation since the adoption of the basic Acts in 2002 (blood) and 2004 (tissues and cells). The evaluation is in line with the Commission's Better Regulation Package and aims to assess whether the legislation has achieved its original objectives and whether it is still fit for purpose. It consists of several steps, many of which have already been completed, and the final evaluation report is expected to be published early in 2019.

The process began in February 2017 with the publication of a Roadmap, outlining the purpose, content and scope of the evaluation. Stakeholders were invited to submit comments on the Roadmap and their responses were published online. The roadmap defined the evaluation questions, addressing five evaluation assessment criteria as follows:

**Relevance:**

To what extent is the legislation and its original objectives still valid and meeting current regulatory needs? In particular to what extent is the legislation:

1. Sufficiently adapted to, adaptable to, and up-to-date with scientific, technical and epidemiological developments / innovation?
2. Adapted to other changes in the sector such as commercialisation and internationalisation?
3. Are there any gaps in terms of substances of human origin or activities that are not regulated by the Directives?

**Effectiveness:**

4. To what extent has the legislation increased the quality and safety of blood and tissues and cells and achieved a high level of human health protection?
5. Has the legislation led to any unintended effects (positive or negative)?
6. What, if any, have been the barriers preventing effective implementation of the legislation?
7. Are the rules on oversight sufficient to address the increased internationalisation?
8. What, if any, are the challenges to maintaining compliance with the legislation?

9. To what extent, if any, has the legislation impacted on patient access to blood, tissues and cells.

**Efficiency:**

10. How cost-effective has the application of the quality and safety requirements in the legislation been for operators (have the benefits outweighed the costs)?
11. Are there particular administrative or other burdens for specific groups of operators, including downstream users of blood, tissues and cells as starting materials for medicinal products?
12. To what extent has the legislation resulted in cost implications for hospitals/patients using/receiving blood, tissues and cells?
13. To which extent does the oversight required by regulatory bodies pose a burden to public authorities (has the burden been proportionate to achieving the original oversight objectives of the legislation)?

**Coherence:**

14. To what extent is the legislation on blood and tissues and cells consistent and coherent within its own provisions? To what extent is the legislation coherent and consistent with other relevant Union legislation? Are the requirements of the Directives suitable when blood, tissues and cells are used as starting materials for the manufacture of medicinal products/medical devices? To what extent is the legislation coherent with other relevant international / third country approaches to the regulation of the quality and safety of blood and tissues and cells?

**EU Added Value:**

15. To what extent has the legislative framework at EU level added value to the regulation of blood and tissues and cells across the EU-28 in a manner that could not have been achieved by measures taken at national or global level?
16. To what extent do stricter national measures pose an obstacle to exchange of supplies between Member States?

An external contractor was commissioned to conduct an independent study to gather supporting evidence for the evaluation. This study has been completed by ICF Consulting Services Ltd. and their report will be published together with the Commission's final Evaluation Report.

Stakeholder consultation is one of the key sources of evidence to support this evaluation. Stakeholders are being consulted in the following ways:

- An Online Public Consultation was launched on May 29, 2017 and ran until September 14. Submissions were received from 158 organisations and 43 citizens. A summary of the outcome, together with the individual submissions (consent permitting), has been published online.
- Meetings with key stakeholders are ongoing to gather focused/specific input through direct interaction. Summary minutes are published on the DG SANTE website.
- A Stakeholder Event was held on September 20, 2017 in Brussels. The event attracted a high level of interest with over 200 stakeholders attending. A summary of the issues raised has been published.

All of the published outputs, to date, can be found on a dedicated SANTE web page at this address:

[https://ec.europa.eu/health/blood\\_tissues\\_organs/policy/evaluation\\_en](https://ec.europa.eu/health/blood_tissues_organs/policy/evaluation_en)

**Action to be taken:**

For information