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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY

of the

Evaluation of the Union legislation on blood, tissues and cells

{SWD(2019) 375 final}

Executive Summary

1 Context

All surgery, as well as treatments of serious conditions such as blood cancers or burn wounds, rely on the availability of blood, tissues or cells. Three percent of EU babies are born following *in vitro* fertilisation. For the past 15 years, EU rules have ensured the safety of millions of patients undergoing blood transfusion, transplantation and in vitro fertilisation. The availability of these therapies depends on public trust and the public willingness to donate.

In the EU, 1400 blood establishments handle 20 million blood donations every year, enabling around 25 million transfusions to patients. Over 4000 tissue establishments collect and supply around one million tissue and cell donations, including corneas, heart valves and bone marrow, every year. EU Member States also exchange these substances. Blood, tissues and cells are also starting materials for the manufacture of medicinal products.

During the 1980s and 1990s, 'tainted blood' scandals saw thousands of patients in the EU infected with HIV and hepatitis by blood and plasma-derived medicinal products. Virus transmissions by tissues and cells were also detected. In the wake of these events, the EU Treaty, since 1999, has provided the possibility for the EU to set high standards of safety and quality for these substances. In response, the EU adopted two acts, in 2002 and 2004, to protect patients receiving blood, tissues and cells.

The acts aimed to set out minimum **requirements on quality and safety** for all steps from donation to human application. EU Member States had to establish an **oversight** system as well as EU-wide alert systems, supported by the Commission services. In this way, the acts aimed to establish a degree of **harmonisation** in regulatory approaches across Member States, **legal certainty** in relation to other EU legal frameworks, and strengthened assurance of **sufficiency** and access to these therapies for EU citizens, through voluntary and unpaid donation.

2 Evaluation

This evaluation has assessed whether the blood, tissues and cells directives have achieved their objectives and whether they remain fit for purpose after more than 15 years. In addition, it assessed whether the requirements were cost-effective and offered EU added value. The evaluation also addressed the coherence of the legislation on blood, tissues and cells with the legislation governing organs, medicinal products (including advanced therapy medicinal products), medical devices and other relevant Union legislation.

The findings are based on an extensive set of inputs from various sources, including an online public consultation, with more than 150 responding organisations, a study by an external contractor, meetings with key stakeholders, exchanges with EU and international authorities, published scientific literature and Commission reports.

3 Key findings

The evaluation found that the EU legislation has **effectively helped increase safety and quality** of blood, tissue and cell therapies. Legally binding safety and quality requirements for tissue and blood establishments have been adopted in all Member States. Prior to the adoption of the legislation

there were shortcomings and differences in the existing national rules and in particular limited or absent oversight functions for blood, tissue and cells in many Member States. National authorities now oversee activities through inspections, authorisations and vigilance. No major secondary spread of disease through transfusion or transplantation has occurred since the adoption of the legislation, despite a number of new emerging infectious risks during this time, and the number of serious adverse reactions are at a very low level.

However, the evaluation found that many of the current **safety and quality requirements are outdated** and it has been challenging to keep detailed technical provisions in pace with this rapidly changing sector. Changes include scientific and technological developments (e.g., better donor tests, new processing methods including pathogen inactivation), availability of digital tools (for monitoring), increased commercialisation and more frequent epidemiological outbreaks (e.g., West Nile Virus) associated with global warming and increased global mobility. Clinical application of novel substances of human origin, such as faecal microbiota, fall outside the scope of the current blood, tissues and cells legislation but imply risks equivalent to donated tissues and cells. While expert bodies such as the European Centre for Disease Prevention and Control or the Council of Europe adapt their guidance in this field regularly, frequent and timely updating of technical requirements in EU law has proven resource intensive and in some instances too slow.

The evaluation also suggests that requirements for **national oversight are not specific or adequately robust**, leading to divergent approaches to oversight, reduced mutual trust and consequent barriers for exchange of, and access to, these therapies. The shortcomings concern the lack of requirements for oversight independence and for verification of effective implementation of oversight functions. The missing legal framework for joint inspections or inspection system auditing, unclear rules and criteria for vigilance and activity data reporting and limited requirements to demonstrate clinical effectiveness for new processing methods are also highlighted. In these cases, the legislation addresses the topics only in a limited and generic manner. While tools, such as audits of inspection systems or joint inspections, have been developed in EU-funded projects, the use of inputs from those projects remains voluntary.

The evaluation highlights some concerns in terms of comprehensive **protection of EU citizens**. There are insufficient provisions to protect **donors**, who make it possible in the first place to offer these therapies to EU patients, and whose trust and effort are critical to ensuring the availability of these substances. This becomes increasingly important in areas of strongly growing demand and significant commercialisation, such as plasma and egg donation. Some gaps were also identified in protecting the offspring born from donated sperm, eggs or embryos.

It was also found in the evaluation that the current EU legal framework **does not keep up with the high level of innovation** in a sector where innovation can facilitate patient access to treatments in an affordable manner. Regarding coherence with other legal frameworks, while most blood, tissue and cell substances and products based on them, fall clearly within either the legislation for blood, tissues and cells, or medicinal products or medical devices, some stakeholders have referred to instances of uncertainty as regards classification and regulation of some borderline cases. Tissue and cell establishments need timely and consistent advice on which requirements will apply for the authorisation of innovative therapies. There is also consensus that some novel blood, tissue and cell therapies require close monitoring and assessment of clinical effectiveness, which is not foreseen in the current legal provisions on blood, tissues and cells.

Finally, while the legal frameworks encourage **sufficiency**, in particular through voluntary unpaid donation, the current provisions are insufficient to support an adequate and sustainable supply for

blood, tissue and cells in the context of significantly increasing demand, particularly for plasma as the starting material for medicinal product manufacture. The result is an EU dependence on import of large quantities of substances such as plasma from the United States. This evaluation also identified the lack of provisions and actions to ensure continuity of supply, of both human substances and critical devices needed to prepare these substances for use in emergency situations.

In conclusion, the EU directives have substantially improved safety and quality of blood, tissues and cells in the EU. While public confidence in the sectors remains high, there are some gaps and shortcomings to address. It will be important to ensure that donors continue to make their crucial contribution and that patients continue to have access to safe blood, tissues and cells of high quality across the EU, while benefitting from the huge potential they bring for innovative treatments.