

Brussels, 14 November 2024
(OR. en)

14697/24

LIMITE

SAN 601

NOTE

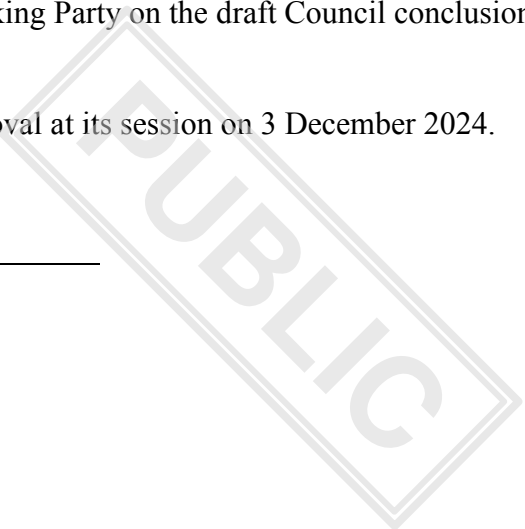
From: General Secretariat of the Council
To: Permanent Representatives Committee/Council
Subject: Draft Council conclusions on enhancing organ donation and transplantation
- *Approval*

1. On 28 August 2024, the Presidency submitted to the Working Party on Public Health a set of draft Council conclusions on enhancing organ donation and transplantation.¹
2. Several events on these topics, including the High-Level Conference on Transplantation on 11 July 2024 and the informal meeting of Ministers of Health on 24-25 July 2024 provided input for the draft Council conclusions.
3. The Working Party on Public Health examined the draft Council conclusions at its meetings on 9 September and 14 October 2024.
4. Following an informal written consultation concluded on 7 November 2024, the Working Party on Public Health reached an agreement on the Presidency compromise text for the Council conclusions as set out in the Annex to this note.

¹ 12789/24

5. The Permanent Representatives Committee is invited:

- to confirm the agreement reached in the Working Party on the draft Council conclusions as set out in the Annex to this note;
- to submit them to Council (EPSCO) for approval at its session on 3 December 2024.



Draft Council conclusions on enhancing organ donation and transplantation**Introduction**

The practice of human organ donation for transplantation has significantly advanced healthcare in the European Union, offering a solution for treating patients with end-stage organ failure, and thereby markedly improving their quality of life and health outcomes, and in the case of end-stage renal disease offering a cost-effective alternative to other treatments. In particular, the Union's collaborative efforts, particularly through the legislative framework and the Action Plan on Organ Donation and Transplantation (2009-2015)¹, have enhanced the organ donation and transplantation landscape, resulting in increased organ donations and transplant rates and improved quality and safety of organs for clinical use. Despite those achievements, the demand for organ transplantation continues to rise, driven by the ongoing burden of advanced non-communicable diseases and the ageing population. This situation underscores the critical need for sustained and enhanced efforts in organ donation and transplantation practices across the Member States. Without prejudice to the responsibilities of the Member States in terms of the definition of their health policies and the organisation and delivery of health services and medical care, the donation of organs from deceased and living donors is voluntary and unpaid, and should be founded on the principle of altruism on the part of the donor. Voluntary and unpaid donation contributes to respect for human dignity and to protecting the most vulnerable persons in society. It also contributes to high safety standards and hence to the protection of human health, increasing public trust in donation systems.

¹ Communication from the Commission - Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States {COM(2008) 818 final} {SEC(2008) 2956} {SEC(2008) 2957} (COM/2008/0819 final)

THE COUNCIL OF THE EUROPEAN UNION

RECALLS THAT

1. Pursuant to Article 168 of the Treaty on the Functioning of the European Union (TFEU), a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities, and the Union is to encourage cooperation between the Member States in the field of public health and, if necessary, lend support to their action.
2. 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 transplantation² lays down rules to ensure standards of quality and safety for human organs intended for transplantation to the human body, in order to ensure a high level of human health protection.
3. The Council of the European Union has underlined the importance of taking action on organ donation and transplantation through the approval of Council conclusions on organ donation and transplantation in 2007³ and 2012⁴.

² OJ L 207, 6.8.2010, pp. 14

³ https://ec.europa.eu/health/ph_threats/human_substance/documents/organs_council15332_en.pdf

⁴ OJ C 396, 21.12.2012, p12

4. The European Commission adopted a Communication on organ donation and transplantation in 2007⁵, as well as an EU Action Plan on Organ Donation and Transplantation for the period 2009-2015⁶. In addition, since 2010 the Commission has initiated a series of joint actions and projects in the field of organ donation and transplantation⁷.
5. The European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe has been a major contributor to this field by securing fundamental rights and respect for the human body, providing a reference for legislation and professional practices, facilitating the exchange of knowledge between countries and institutions, monitoring activities for the sake of transparency and international benchmarking, and developing quality and safety standards through the periodical publication of the Guide to the Quality and Safety of Organs for Transplantation.

⁵ Communication from the Commission to the European Parliament and the Council on organ donation and transplantation: policy actions at EU level (2007): {SEC(2007) 704} {SEC(2007) 705} (COM/2007/0275 final). The Communication highlights cooperation between Member States and organ trafficking and shortages as the main priorities.

⁶ Communication from the Commission -Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened cooperation between Member States {COM(2008) 818 final} {SEC(2008) 2956} {SEC(2008) 2957} (COM/2008/0819 final)

The Action Plan sets out measures to increase organ availability and to enhance the efficiency, accessibility, quality and safety of transplantation systems.

⁷ Joint Action on Mutual Organ Donation and Transplantation Exchanges: Improving and developing deceased organ donation and transplantation programmes – MODE (2010-2012).

Joint Action on Achieving Comprehensive Coordination in Organ Donation throughout the European Union – ACCORD (2012-2015): aiming to establish a model for supranational data-sharing for organ donation and implementing practical collaboration between EU countries.

Joint Action on facilitating the exchange of organs donated in EU Member States - FOEDUS (2013-2016): creation of a platform to manage cross-border organ exchanges (cf. para 21 of the CC on transplantation).

EDITH (2017-2020) - Project focusing on different organ donation and transplantation practices;

BRAVEST (2022-2024) - a project to improve access to transplantation and the outcomes of transplant recipients.

6. The 2011 Madrid Resolution on Organ Donation and Transplantation, resulting from the third World Health Organization (WHO) Global Consultation on Organ Donation and Transplantation, proclaimed the ‘national responsibility in meeting the needs of patients, guided by the WHO principles’, and called on governments and healthcare professionals to pursue self-sufficiency in transplantation and to maximise the availability of organs for transplantation, with priority given to donation from deceased donors⁸.
7. The 2009-2015 EU Action Plan on Organ Donation and Transplantation aimed to strengthen cooperation between Member States to address the critical issue of organ shortage, and to enhance the quality and safety of organs for transplantation. The plan outlined ten priority actions under three main challenges: increasing organ availability, enhancing the efficiency and accessibility of transplantation systems and improving quality and safety. Key measures included appointing transplant donor coordinators in hospitals, promoting quality improvement programmes and fostering the exchange of best practices. The initiative also emphasised the importance of donor family communication to increase organ donation rates, and encouraged the mobility of patients and donors across Member States to ensure better organ allocation.
8. Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-2027⁹ aims to improve and foster health in the Union to reduce the burden of communicable and non-communicable diseases, by supporting health promotion and disease prevention, reducing health inequalities, fostering healthy lifestyles and promoting access to healthcare.

⁸ The Madrid Resolution on Organ Donation and Transplantation: national responsibilities in meeting the needs of patients, guided by the WHO principles. (2011) Transplantation; 91, Suppl 11, S29- S31. <https://doi.org/10.1097/01.tp.0000399131.74618.a5>.

⁹ Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-2027, and repealing Regulation (EU) No 282/2014. (OJ L 107, 26.3.2021, p. 1).

9. World Health Assembly Resolution 77.4 on ‘Increasing availability, ethical access and oversight of transplantation of human cells, tissues and organs’¹⁰, adopted in May 2024, urges member states to integrate donation, transplantation and transplant follow-up activities into health care systems in such a way that deceased donation is routinely considered as an option at the end of life and transplantation is incorporated into the continuum of care of patients, develop deceased donation to its maximum therapeutic potential and to protect the living donor, to take measures to improve access to transplant therapies, to improve the oversight of practices and to promote innovation in the field. It calls on the WHO Secretariat to support member states, among others, through the development of a Global Strategy in Transplantation, scheduled for presentation at the 2026 World Health Assembly.
10. The Santander Statement ‘Towards Global Convergence in Transplantation: Sufficiency, Transparency and Oversight’¹¹ provides high-level recommendations aimed at improving patient care, making progress towards sufficiency in transplantation, ensuring transparency and oversight of practices, and strengthening the prevention of human trafficking for organ removal as well as for other substances of human origin.

¹⁰ https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_R4-en.pdf

¹¹ https://esot.org/wp-content/uploads/2023/11/SantanderStatement_FINALVERSION.pdf

CONSIDERS THAT

11. Organ transplantation significantly improves patient survival and quality of life, serving as a critical intervention for managing the public health and socioeconomic burdens of organ failure in the EU. This necessitates sustained efforts to enhance organ donation and transplantation systems across Member States while safeguarding and securing the well-functioning of existing structures and cooperations.
12. The collaborative environment established within the EU, including through the legislative framework and the 2009-2015 EU Action Plan on Organ Donation and Transplantation, has played a pivotal role in advancing transplantation services, as demonstrated by a significant increase in the number of organ donors and transplantations both during and following the Action Plan's implementation period.
13. The increases observed across various types of organ transplants during the 2009-2015 EU Action Plan, including a 16% increase in both kidney and liver transplants, a 10% increase in heart transplants, a 7% increase in pancreas transplants and a significant 41% increase in lung transplants, highlight the success of EU initiatives in improving transplantation activities, with the aim to increase patient survival¹².

¹² European Commission: Consumers, Health, Agriculture and Food Executive Agency, Schoten, S., Coppen, R., Wiegiers, T., Bouwman, R., & Friele, R. (2017). Study on the uptake and impact of the EU Action Plan on Organ Donation and Transplantation in the EU Member States - FACTOR Study. Publications Office. <https://data.europa.eu/doi/10.2818/24713>

14. Despite the achievements of the EU Action Plan, challenges persist, including the continuing difficulties of countries to cope with the increasing demand for organ transplantation, mainly as a result of the burden of non-communicable diseases (NCDs), against the backdrop of demographic changes and an escalating prevalence of risk factors, the variability in access to transplant therapies across Member States or the need to strengthen the resilience of transplant systems, as made evident during the COVID-19 pandemic¹³.
15. The success of some Member States to increase organ donation does not always result in an increase in the number of patients receiving organ transplants in those particular Member States, therefore cooperation within the EU might be instrumental to improve the situation.
16. There are several crucial areas that require further focus, including: enhancing cross-border organ donation and exchange, fostering peer-to-peer exchanges to elevate hospital performances, exchanges of the latest scientific findings, developing EU-wide agreements and initiatives for transplant excellence, and improving data collection and sharing on post-transplant outcomes, while safeguarding and securing the well-functioning of existing structures and cooperations.

¹³ Eurotransplant. (2023). Annual Report 2023.

https://www.eurotransplant.org/wp-content/uploads/2024/06/ETP_AR2023_LowRes.pdf

17. The COVID-19 pandemic underscored the varying levels of resilience and vulnerability across Member States, accompanied by a significant 17% decline in organ donation from deceased donors from 2019 to 2020¹⁴, highlighting the urgent need for strengthened health system preparedness and support for organ donation activities during global health crises.
18. The recent situation in which 50 000 persons were awaiting a transplant in the EU as of late 2023¹⁵, alongside the critical life-or-death nature of organ availability for many patients, particularly in the case of vital organs such as the liver, heart and lungs, underscores the urgent need to increase organ donation rates and improve transplantation systems to save more lives.
19. Transplantation offers life-saving therapy and improved quality of life for patients with end-stage organ failure, and can also present a cost-effective solution compared to other treatments such as long-term dialysis, thereby significantly reducing healthcare expenditure and contributing to the economic resilience of healthcare systems within the EU.
20. The environmental impact of transplantation is considerably lower than that of other treatments, particularly in the context of dialysis and kidney failure, thereby underlining the broader societal benefits of enhancing transplantation efforts.
21. The WHO advocates for self-sufficiency in transplantation as a critical component of addressing the healthcare challenges posed by NCDs, emphasising the importance of maximising the therapeutic potential of deceased donation alongside efforts to prevent NCDs and their progression.

¹⁴ Organ donation during the COVID-19 pandemic Ahmed, Ola et al. American Journal of Transplantation, Volume 20, Issue 11, 3081 – 3088 <https://www.amjtransplant.org/article/S1600-6135%2822%2921554-8/fulltext>

¹⁵ European Directorate for the Quality of Medicine and HealthCare of the Council of Europe (EDQM). Newsletter transplant: international figures on donation and transplantation 2024. ISSN: 2171-4118 / NIPO: 691-15-002-5 <https://freepub.edqm.eu/publications/PUBSD-87/detail>

22. The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, adopted in 2008¹⁶ and updated in 2018¹⁷, provides ethical guidance for professionals and policymakers and urges them to maximise and equitably share the benefits of transplantation in conformity with objective, non-discriminatory, externally justified and transparent rules, guided by clinical criteria and ethical norms.
23. The Commission Communication (2007) highlighted the link between the scarcity of organs and the phenomenon of trafficking (paragraph 7), while the WHO Executive Board, in its resolution 154/7 (2024), stated that ‘insufficient access to transplantation therapies is one of the root causes of trafficking’. The Council of Europe Convention against trafficking in human organs¹⁸ (adopted in March 2015 and entered into force in March 2018) also addresses the interconnection between the organ shortage and the human organ trafficking. Moreover, Directive 2011/36/EU on preventing and combating trafficking in human beings and protecting its victims determines criminal penalties for trafficking of human beings for the purposes of removal of organs.
24. Innovative practices and technological advancements in organ preservation and transplantation offer promising avenues for expanding the donor pool, improving transplant outcomes and addressing the limitations of current treatment modalities, thereby underscoring the need for continued investment in research and development in this field.
25. The ongoing need for transplantation highlights the importance of fostering a supportive legal, ethical and operational framework that encourages organ donation from deceased and living donors, enhances the efficiency and accessibility of transplant systems and ensures the quality and safety of transplantation practices across the EU.

¹⁶ The Declaration of Istanbul on organ trafficking and transplant tourism. *Transplantation* 2008; 86(8):1013-8. doi: 10.1097/TP.0b013e318185ffc9.

¹⁷ The Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2018 Edition). *Transplantation* 2019;103(2): 218-219. doi: 10.1097/TP.0000000000002540.

¹⁸ <https://rm.coe.int/16806dca3a>

INVITES THE MEMBER STATES TO:

26. DEVELOP and ENHANCE institutional, legal and ethical frameworks to facilitate organ donation and transplantation, in accordance with the current Union legislation and guidelines, including by addressing financial and infrastructural barriers, implementing legislation based on the different solutions, as chosen by the Member States, and strengthening efforts to combat organ trafficking and trafficking in persons for the purpose of organ removal.
27. TAKE MEASURES TO DEVELOP organ donation from deceased donors to its maximum therapeutic potential by including appropriate initiatives involving all stakeholders, and by creating and strengthening donor coordinator networks to support the pro-active identification of possible organ donors and the appropriate realisation of the deceased donation pathway¹⁹.
28. STRENGTHEN the role of donor coordinators and other professionals in hospitals, including emergency care, intensive care and neurology with a role in identification and care of patients of possible organ donors by developing a well-structured and functioning collaboration between Intensive Care Unit (ICU) initiatives²⁰ and donor coordination organisations, in order to increase the number of potential donors identified and optimise performance in the donation process.

¹⁹ Council of Europe. Resolution CM/Res(2015)11 on establishing harmonised national living donor registries with a view to facilitating international data sharing. <https://search.coe.int/cm?i=09000016805c2a78>

²⁰ Council of Europe. Resolution CM/Res(2015)10 on the role and training of critical care professionals in deceased donation. <https://search.coe.int/cm?i=09000016805c2b4a>

29. FACILITATE education and training of healthcare professionals and in new therapeutic protocols to optimise the efficiency and duration of the donation process and donor organ suitability.
30. ENCOURAGE, where appropriate and in accordance with national legislations, the development of programmes for Donation after the Circulatory Determination of Death (DCDD) ²¹ to offer more patients the opportunity to donate organs after death and increase the availability of organs for transplantation.
31. OPTIMISE living-donation programmes throughout the donation chain, for example by ensuring lifelong follow-up, and the protection of the living organ donor from a medical and psychosocial perspective, offering systematic information on the option of living donation in a transparent and comprehensive manner and overcoming technical barriers to living organ donation (e.g. biological incompatibility), by ensuring that such donations are carried out only within the limits of applicable laws, procedures and standards and do not result in any financial loss for the donor, and by fostering greater intention for donation through appropriate procedures for recruitment and provision of information, including respect for the principle of voluntary and unpaid donation.
32. INCREASE cross-border cooperation agreements on organ donation and transplantation within the EU while recognising and respecting existing well- functioning cooperation mechanisms/initiatives (e.g. Eurotransplant, Scandiatransplant, South Alliance for Transplant, the FOEDUS platform and bilateral agreements between Member States), including by fully unlocking the potential of organ perfusion systems to ensure longer transportation times and optimise use of the limited number of organs available, and promoting the international exchange of clinical outcome data in order to assess and improve outcomes.

²¹ Council of Europe. Recommendation CM/Rec(2022)3 of the Committee of Ministers to member States on the development and optimisation of programmes for the donation of organs after the circulatory determination of death, <https://rm.coe.int/0900001680a5a3e7>

33. ENCOURAGE comprehensive education and training programmes for healthcare professionals in organ donation and procurement, including by incorporating basic information on donation and transplantation in undergraduate curricula, supporting participation in accredited training programmes and establishing continuous training for teams involved in donor identification, reporting, management, family approach and organ retrieval.
34. ENCOURAGE public education adapted to the age and specific needs of each audience on and awareness of organ donation and transplantation through education in schools, and engagement of the media including efforts to reach isolated groups that require a different approach and transparency in living and deceased donation processes with a view to enhancing public trust.
35. IMPROVE peri- and post-operative care and patient education for living donor transplant recipients through multidisciplinary medical professional teams and patient organisations to prevent organ loss while ensuring a multidisciplinary and patient-centred approach, and to enhance recovery and ensure informed consent and understanding of treatment options for patients.
36. CONSIDER to secure funding for programmes and research relating to organ donation and transplantation, including EU technical support for infrastructure, education, training, digitalisation and research, as well as policies for cost reimbursement to hospitals for donor management, organ retrieval and data on donor follow-up.
37. FACILITATE the exchange of health professionals between member states to discuss technical and operational knowledge of different donation and transplant programmes.

38. ADDRESS inequities relating to organ donation and transplantation by developing national strategies and actions to support registration on transplant waiting lists, reviewing the waiting lists and allocation criteria, reducing longer waiting times for patients such as highly-sensitised and paediatric candidates and developing communication schemes and educational initiatives tailored to diverse communities.
39. SUPPORT cross-border organ transplantation by leveraging the existing and future digital health infrastructures to enhance the primary use of standardised electronic health records and enable seamless access to patient data in accordance with the relevant data protection legislation.
40. ENHANCE research capabilities and advance the secondary use of data supporting benchmarking and data-sharing among national authorities and appointed independent European organisations, in accordance with the relevant data protection legislation, to ensure proper registration and analysis of transplant outcomes, encourage the sharing and consolidation of anonymised data between hospitals and the utilisation of Patient-Reported Outcome Measures (PROMs) within the framework of research projects to assess the quality of life and well-being of patients and living donors both before and after transplantation.
41. COLLABORATE to improve registration of patients with end-stage organ failure on transplant waiting-list systems to provide equal access for patients in need of life-saving organ transplantation.

INVITES THE EUROPEAN COMMISSION TO:

42. UPDATE the EU action plan on organ donation and transplantation by building upon the already reached achievements and insights gained from the implementation of the existing action plan, taking into consideration the legal, ethical and organisational differences, preconditions and differences in available resources between the Member States, and taking into account the importance of action in the field of health promotion and prevention of NCDs in attenuating the demand for organ transplantation. The action plan should aim to:
- a) emphasise a bottom-up approach in order to set clear, impactful objectives involving professionals, administrators, politicians and the general public;
 - b) strengthen mutual learning and knowledge exchange and support countries facing similar challenges through joint meetings of competent authorities and broader stakeholder engagement to share best practices and innovations in organ donation and transplantation, specifically including innovations that improve the collection, preservation and allocation procedures, thereby decreasing the deferral and rejection of donors and donor organs;
 - c) enhance cross-sectoral collaboration by identifying opportunities for learning from adjacent fields such as tissues and cells, to enrich the knowledge base and practices of the organ donation and transplantation sector;
 - d) support the development of donation systems by highlighting and addressing the needs of countries with less developed systems in order to ensure equitable progress across the EU;
 - e) focus on implementation and sustainability, ensuring a long-term impact through sustained investment in IT infrastructure and the sustained commitment of all parties involved;

- f) explore new areas for inclusion in the action plan, such as expanding DCDD for those countries which decide to follow that approach, enhancing living donation frameworks and supporting Member States in improving communication strategies to raise public awareness and education in relation to organ donation;
- g) promote professional education and training, to improve the quality of training programmes across the EU, leveraging the potential of the European approach to micro-credentials²² and fostering collaboration and sharing of best practices among healthcare professionals in organ donation and transplantation;
- h) support higher education and VET²³ institutions in their role as lifelong learning providers, including through micro-credentials and the transfer of research outcomes in education and training;
- i) address equality, diversity and inclusion, including by sharing experiences relating to care through tailored information campaigns to inform minority and vulnerable groups, and new donors, and through ensuring that transplantation services cater effectively for all segments of society;
- j) improve quality and clinical outcomes through the development of common guidelines for evaluating, auditing and benchmarking hospital performance, and the use of bio-vigilance to enhance safety and quality in organ transplantation;
- k) enhance the integration of organ donation into end-of-life care, while respecting the primary health restoration goals and prioritising palliative end-of-life care, while considering the potential for organ donation;

²² Council Recommendation of 16 June 2022 on a European approach to micro-credentials for lifelong learning and employability 2022/C 243/02 (OJ C 243, 27.6.2022, p. 10).

²³ Vocational education and training

- l) optimise transplantation efficiency and financing, by sharing knowledge on optimising the donation chain, addressing financial disparities and demonstrating the cost-efficiency of transplantation programmes to support national investment in transplantation systems;
 - m) expand research opportunities in areas such as post-transplant outcomes, donor optimisation, organ preservation and novel therapeutic technologies, to continuously improve the field of organ donation and transplantation.
43. SUPPORT the development of recommendations and guidelines by the European Directorate for the Quality of Medicines & HealthCare (EDQM) which assist Member States in refining their institutional and policy frameworks for organ donation and transplantation. The creation of those guidelines should encourage the involvement of a diverse group of stakeholders, aiming to establish supportive and effective environments for organ donation and transplantation practices.

INVITES THE MEMBER STATES AND THE EUROPEAN COMMISSION TO:

44. ENCOURAGE and SUPPORT cross-border cooperation between Member States in organ donation and transplantation activities. This includes, as necessary, the establishment of a voluntary platform for cooperation or the enhancement of exchange among national competent authorities, facilitating collaboration, establishment and growth of organ transplant services, of organ exchange programmes and mismatch programmes and the exchange of best practices to increase the efficiency and impact of transplantation services.
45. FURTHER DEVELOP national focal points and central reporting systems to gather and disseminate essential information for legal and policy responses, while respecting the human rights and fundamental freedoms of individuals in the context of the General Data Protection Regulation. Efforts should aim to enhance transparency in organ donation and transplantation, particularly for activities that extend across national borders, having particular regard for human organ trafficking in the light of the Council of Europe Convention on human organs trafficking²⁴, by enhancing and improving existing reporting mechanisms in accordance with the relevant data protection legislation, and in collaboration with the EDQM, as appropriate.
46. SUPPORT the development and implementation, within the current legislative framework, of international health data collection and sharing systems that would enable Member States to fulfil relevant public interest tasks in public health, such as ensuring the adoption of harmonised, equitable and transparent high standards of quality and safety in organ donation and transplantation.

²⁴ <https://rm.coe.int/16806dca3a>