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From:	General Secretariat of the Council
To:	Delegations
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Subject:	Council Conclusions on a call for action on life sciences for the Union's competitiveness - Presidency text

Delegations will find attached a Presidency text on the draft “Council conclusions on a call for action on life sciences for the Union’s competitiveness” with a view to the Research Working Party meeting on 18 September 2025.

Changes in comparison to doc. 12265/25 are marked in **bold underline** for additions and in ~~strikethrough~~ for deletions.

DRAFT COUNCIL CONCLUSIONS ON A CALL FOR ACTION ON LIFE SCIENCES
FOR THE UNION'S COMPETITIVENESS

THE COUNCIL OF THE EUROPEAN UNION,

RECALLING

- the Council Conclusions and roadmap for a strategy on life sciences and biotechnology¹ and on 'Life sciences and biotechnology - a strategy for Europe'²;

TAKING NOTE OF

- the political guidelines of the second Von der Leyen Commission announcing a broad European Life Sciences Strategy to support the green and digital transitions and develop high-value technologies. The expected European Biotech Act, aiming to help modernise entire parts of the economy, from farming and forestry to energy and health, should be part of a broader Strategy for European Life Sciences;
- the 'Competitiveness Compass for the EU' highlighting the role of life sciences as a driver of innovation in biotechnology, and holding great potential for boosting competitiveness across sectors, from pharma to agriculture, energy, food and feed.

¹ 5745/03.
² 12278/03.

TIME TO BE AMBITIOUS

1. WELCOMES the Commission's ambition of positioning the EU as the world's most attractive place for life sciences by 2030³. STRESSES that life sciences are paramount in advancing fundamental knowledge and driving innovation in strategically important areas such as healthcare, **medical technologies** and pharma, agriculture, bioeconomy, terrestrial and aquatic food systems, biotechnology, **biodiversity** and environmental sciences. **STRESSES life sciences' vital role in promoting human, animal and environmental health, in line with the One Health approach, and in strengthening preparedness and prevention of future global risks and pandemics.** Strong and innovative life sciences are essential for the Union's sustainable global competitiveness and sovereignty, **security and autonomy**, to ensure the health and wellbeing of European citizens, to tackle **societal and environmental challenges** and support the green transition. **CALLS on the Commission and Member States to pay attention to the fact that life sciences innovation contributes to the public good, with a strong focus on equity in access, affordability, and responsiveness to public health needs and the EU's environmental objectives.**
2. RECOGNISES that the Union is in fierce competition with other economies, experiencing a growing innovation gap and lagging behind global competitors in terms of translating research and innovation (R&I) into products or services. A fragmented European life sciences ecosystem and structural barriers, such as insufficient investments, **in particular private investments**, including in R&I and scale-ups, **as well as** limited technology breakthroughs and a complex regulatory framework, are challenges requiring immediate action. POINTS OUT that achieving the 2030 ambition of positioning the EU as the world's most attractive place for life sciences requires joining forces across the Union and a clear path for the future, with bold evidence-based actions and a planned and coordinated approach involving all stakeholders and existing initiatives. **EMPHASISES the importance of investment in each step of the value chain, from fundamental research to uptake.** REGRETS that the presented life sciences strategy is lacking ~~an~~ **global ambitious international** perspective.

³ 11257/25 - Communication from the Commission to the European Parliament, the Council, the European economic and social committee and the Committee of the Regions: Choose Europe for life sciences - A strategy to position the EU as the world's most attractive place for life sciences by 2030.

3. WELCOMES the inclusive and holistic approach in the Commission's strategy on life sciences. ENCOURAGES the Commission, in close collaboration with Member States, to overcome the fragmentation of legislation and strategies at Union level and to create an innovation and user-friendly environment for all R&I stakeholders. RECOGNISES that Horizon Europe, as well as the previous framework programmes for R&I, have been and continue to be important tools to support advances in life sciences. WELCOMES the reference to ongoing European partnerships, missions, projects and the information about current investments. EMPHASISES the need for a strategic forward-looking perspective building on achievements and drawing lessons from the acquired experience, without pre-empting decisions on the future of R&I in the next Multiannual Financial Framework **(MFF)**. **REQUESTS the Commission to pay specific attention to economic and research security.** ~~RECOGNISES the need to mobilise public and private funding for life sciences.~~ CALLS on the Commission to work closely with Member States to ensure continued support for life sciences across all related areas, with well-connected instruments along the value chain, and with actions to overcome administrative barriers and simplify regulations. INVITES the Commission, **without pre-empting the next MFF**, to explore the feasibility of a possible European Life Sciences Investment Fund, through the European Investment Fund, to leverage private investment.
4. EMPHASISES that the Union's urgently needs to promote research and development of advanced therapy medicinal products (ATMPs). WELCOMES the initiative to create a network of European Centres of Excellence in ATMPs, building on existing European and national networks and projects. CALLS on the Commission to ensure a transparent selection process and ~~to keep the network~~ **an** inclusive and open **network**, **while also assessing measures to improve affordability of these therapies and thus ensure access for patients.**

CREATE LEADERSHIP IN CLINICAL TRIALS

5. EMPHASISES that the Union urgently needs to tackle the **multifactorial** issues of a declining worldwide share and reduced impact of clinical trials carried out within it. Hosting clinical trials is of benefit for patients and the life sciences and boosts the uptake of personalised medicine and new technologies in the Union's healthcare systems. HIGHLIGHTS that multi-country and multi-centered clinical trials are among the best solutions to facilitate gender equal patient recruitments, provide timely and robust clinical evidence and early and equitable access to innovative therapies for patients in **all** Member States. Such trials also ease the uptake of new and existing treatments and technologies in the national health services without unnecessary delays, as they facilitate the assessment by regulatory agencies and Health Technology Assessment bodies. UNDERLINES that supporting a common enabling regulatory environment for the implementation of clinical trials across the Union, building on Regulation (EU) 536/2014⁴ and taking into account best practices and lessons learned from recent crises, whilst **ensuring** ~~safeguarding security~~ **safety** of patients and public health, is essential. WELCOMES that the Commission proposes an investment plan for clinical research, and URGES the Commission to deliver it as soon as possible, preferably before the end of 2025, with clear milestones for the coming years. The plan should be developed in close collaboration with Member States and stakeholders, setting out clear steps and responsibilities for establishing reliable and integrated infrastructures for carrying out clinical trials in an effective framework that utilises existing structures and expertise, to coordinate and boost multi-country and multi-centre clinical trials. The plan should **reflect** ~~integrate a~~ gender perspective **equality and inclusiveness** and promote the active participation of ~~patients~~ **individuals** ~~at~~ **in** all stages of clinical trials.

⁴ Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

6. RECOGNISES that the use of health data for R&I is a major challenge, and CONSIDERS that remaining hurdles, including GDPR-related issues, need to be overcome to ~~ensure~~ **strengthen disease** prevention of diseases and **provide** ~~give~~ European citizens' access to the best possible healthcare. DRAWS ATTENTION TO the fact that many European partnerships, research infrastructures, projects and other initiatives are already active on clinical trials including related data aspects. A better coordination between these, a thorough evaluation of their results and a plan for their implementation are important first steps towards finding solutions to the data-related regulatory challenges. **This should be done** ~~whilst~~ taking into account ethical concerns **and ensuring proportionate, precise and effective security measures to protect sensitive information and uphold data integrity, supported by secure digital infrastructures**. AWAITS further details on the planned European Life Sciences R&I Data Assembly. CALLS on the Commission to support the Member States to accelerate the digitalisation of health systems and to ensure continued support for a smooth and simple implementation of the European Health Data Space, including the use of Artificial Intelligence (AI), to enable also secondary use of health data and simplify access for researchers and innovators.

SEIZE NEW OPPORTUNITIES AND ENSURE SKILLS

7. STATES that opportunities offered by new developments in areas such as quantum technologies and AI need to be incorporated into life-sciences strategies immediately, to boost the Union's leadership in both life sciences and digital technologies. CALLS on the Commission and the Member States to ensure the Union has the **required** ~~right~~ future-oriented, multidisciplinary and intersectoral skills to develop and exploit new knowledge and technologies, taking into account the importance of building on excellent fundamental science and advancing gender equality. SUPPORTS the Science, Technology, Engineering and Mathematics Education Strategic Plan. CONSIDERS that a holistic approach on skills should also **cover** ~~extend to the early years of secondary~~ **all stages of** education, **in full respect of national competences**. WELCOMES the 'Choose Europe **for science**' initiative to develop, attract and retain talents, **in compliance with the criterion of scientific excellence**. REITERATES the importance of ecosystems around higher education institutions, research performing organisations and research infrastructures to foster skills, innovation and spin-offs, startups and scaleups, particularly in life sciences, where innovative technologies are increasingly relevant.

AN ATTRACTIVE INNOVATION AND MANUFACTURING ENVIRONMENT

8. STRESSES the importance of a well-functioning European, national and regional R&I ecosystems for life sciences, advancing ~~the innovation principle and~~ the use of regulatory sandboxes, and supporting innovative Small and Medium-sized Enterprises. RECALLS the need to urgently implement and deliver on the EU Startup and Scaleup Strategy to support key European sectors, like life sciences. UNDERLINES that sustainable local production and an innovation- and business-friendly regulatory framework is essential for safeguarding the Union's supply security and maintaining sustainable manufacturing within Europe. CALLS on the Commission to assess the regulatory challenges that **the use of research results and innovative life sciences companies encounter on their way to market, and to propose appropriate measures** ~~a clear action plan~~ to overcome these in the forthcoming **European Innovation Act**, as part of the wider initiative to reduce regulatory burden. WELCOMES the Commission's proposal for legislative intervention to address challenges identified regarding medical and in vitro diagnostic devices. ADVOCATES for a more **widespread and** proactive use of public innovation procurement in the life sciences sector to boost innovative markets.
9. AWAITS the announced European Biotech Act and URGES the Commission to unlock the broad opportunities offered by this key technology. RECALLS the importance to support R&I, as well as the application of biotechnology across all relevant areas ~~in which biotechnology~~ **where this technology** can drive innovation. Synergies between the different areas should be fostered, for mutual benefits. INVITES the Commission to set out actions horizontally across Union's policies to further streamline the relevant Union's legislation and its implementation, to reduce fragmentation, enhance simplification, increase transparency and shorten the time for research-intensive biotech innovations to reach the market, **while maintaining environmental standards.** This should be done through an evidence-based approach and in close coordination with Member States and stakeholders. STRESSES that the upcoming Biotech Act offers a timely and unique opportunity to establish structured exchanges.

10. WELCOMES the announced strategic R&I agenda on food systems. RECOGNISES the importance of a competitive, sustainable and resilient agriculture and food systems, capable of guaranteeing food security and access to healthy and nutritious food for all, while at the same time combating climate change, biodiversity loss and environmental pollution, and developing resilience to climate change. ~~STRESSES life sciences' vital role in promoting human, animal and environmental health, in line with the One Health approach, and in strengthening preparedness and prevention of future global risks and pandemics.~~ CALLS on the Commission to present the R&I agenda on food systems before mid-2026 and to ensure that it will be developed closely with Member States and all relevant stakeholders, take a systemic value chain approach, align with relevant Union's policies and initiatives, ~~and look at~~ **address** outstanding regulatory challenges **and consider regional specificities**. AWAITS also the forthcoming Bioeconomy Strategy and HIGHLIGHTS the importance of a **sustainable and** circular bioeconomy and optimisation of the use of **available biomass** ~~sustainable biogenic resources~~, and therefore the need to interlink the strategic R&I agenda on food systems with the Bioeconomy Strategy, **considering also the specific requirements of industrial sectors that rely on bio-based feedstocks.**

A COORDINATED GOVERNANCE AND CALL FOR ACTION

11. INVITES Member States and the Commission to enter into a strategic dialogue and coordination with regards to establishing, maintaining, optimising and interlinking research and technology infrastructures, innovation hubs, science parks and centres of excellence relevant for life sciences, to strengthen common efforts and guarantee the Union's R&I autonomy and technological leadership. ENCOURAGES the Commission and Member States to consult the European Strategy Forum for Research Infrastructures in this context. RECOGNISES the importance of a strong European capacity for testing, experimentation and validation of services and products **and STRESSES the role of cutting-edge databases and infrastructures in this regard.** LOOKS FORWARD to the upcoming strategy on research and technology infrastructures and RECALLS the need to ensure that infrastructures and processes enable FAIR data (Findable, Accessible, Interoperable, and Reusable) and can deploy new AI based tools in alignment with the forthcoming AI in Science Strategy.

12. RECOMMENDS the Commission internal ‘Life Sciences Coordination Group’ to be bold and ambitious in its task to ensure innovation-friendly coherent policies, funding and activities within and across the life sciences sector. The Commission should regularly report to and engage with Member States and a wider stakeholder forum to discuss progress and required actions towards the 2030 ambition.
13. HIGHLIGHTS the importance of fostering citizens’ trust in science and technology and promoting accurate information, through a dialogue among the life sciences’ stakeholders, the policy makers and the public at large. WELCOMES the Commission’s proposal of setting up a repository of tools and best practices so that science communication can be improved, and public outreach measured. **STRESSES the importance of developing EU-level science for policy initiatives for evidence-based policies.**
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