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NOTE

From:	General Secretariat of the Council
To:	Delegations
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 24 July 2025.

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 and medtech, to agriculture, energy, food systems.

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 2030. Life sciences are paramount in driving innovations in areas such as healthcare and pharma, agriculture, food systems and environmental sciences, as well as for the strategically important biotechnology. A strong and innovative life sciences sector is essential for the Union's global competitiveness to ensure the health and wellbeing of European citizens to tackle environmental challenges and safeguard the green transition.

¹ 5745/03.
² 12278/03.

2. RECOGNISES and REGRETS that the Union is outpaced in the fierce competition on the global scene with other economies, with a growing innovation gap and failure to translate innovation into products or services. Structural barriers across Europe's life sciences innovation lifecycle such as insufficient investments in research and innovation (R&I) and along the value chain, including in scale-ups, limited technology breakthroughs and a complex regulatory framework remain 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 across the value chain.
3. VALUES the inclusive and holistic approach to life sciences in the Commission's strategy and the clear recognition of challenges faced by the sector, including the fact that the sector is covered by many different EU strategies and acts. ENCOURAGES the Commission to ensure that the strategies and acts efficiently interlink and create an innovation and user-friendly environment for stakeholders. ACKNOWLEDGES that Horizon Europe, and the previous framework programmes for R&I, have been important tools to support advances in life sciences. WELCOMES the reference to ongoing partnerships, missions, projects and the information about current investments, but LACKS a strategic forward-looking perspective building on these achievements, without pre-empting decisions on the future of R&I partnerships. CALLS on the Commission to ensure continued support to life sciences across all relevant sectors, with well-connected instruments along the value chain, including actions to overcome administrative barriers and simplify regulations. RECOGNISES the need to mobilise more public and private funding for Life Sciences for all stages of the innovation cycle. INVITES the Commission to explore the establishment of a European Life Sciences Investment Fund through the European Investment Fund.

CREATE LEADERSHIP IN CLINICAL TRIALS

4. EMPHASISES that the Union urgently needs to tackle the issue of a declining number of clinical trials carried out in the EU. Hosting clinical trials is of benefit for patients and the life science sector and boosts the uptake of new technologies in the Union's health systems. In this context, establishing an enabling regulatory environment for the implementation of clinical trials across the EU, taking into account lessons learned from recent crises, 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 set out clear steps and responsibilities for establishing a strong infrastructure for clinical trials and an effective framework that utilises existing structures and expertise in the Member States, to better coordinate efforts and boost multi-country clinical trials. HIGHLIGHTS that multi-country clinical trials are among the best solutions to provide timely robust evidence and access to innovative therapies for patients and facilitate the uptake of new treatments and technologies in the national health services.
5. CALLS on Member States to work closely with the Commission to facilitate multi-country clinical trials and foresee the necessary readiness at national level to adapt regulations and programmes. RECOGNISES that a major challenge is the use of health data for R&I and CONSIDERS that hurdles, including GDPR-related issues, need to be overcome to ensure European citizens' access to the best possible healthcare. DRAWS ATTENTION TO the fact that many partnerships, projects and other initiatives are already active on clinical trials. A better coordination between these and a thorough evaluation of their results is an important first step towards finding solutions to the data challenge. AWAITS further details on the planned European Life Sciences R&I Data Assembly. RECOMMENDS accelerating the digitalisation of health systems and ensuring continued support for a smooth and simple implementation of the European Health Data Space (EHDS), including the use of Artificial Intelligence (AI) sandboxes.

SEIZE NEW OPPORTUNITIES AND ENSURE SKILLS

6. STATES that opportunities offered by new developments in quantum technologies need to be incorporated into strategies immediately, to support the preservation of the Union's leadership in this emerging area. RECOGNISES that the EU must ensure it has the right skills and gender balance to develop and exploit new technologies and at the same time to maintain strong knowledge in fundamental sciences. SUPPORTS the Science, Technology, Engineering and Mathematics (STEM) Education Plan and the 'Choose Europe' initiative to attract and maintain talents. REMINDS of the importance of ecosystems around research performing organisations and infrastructures to foster skills as well as spin-offs, startups and scaleups. RECALLS the need to urgently implement the EU's strategy for startups and scaleups for the support of key European sectors, like life sciences.

AN ATTRACTIVE INNOVATION AND MANUFACTURING ENVIRONMENT

7. HIGHLIGHTS the importance of a well-functioning European innovation ecosystem for life sciences to support innovative Small and Medium-sized Enterprises and increase the attractiveness of Europe for non-European researchers and innovators and SUPPORTS the commitment to advancing the Innovation Principles. UNDERLINES that stimulating sustainable local production and creating an innovation-friendly regulatory framework is essential for safeguarding the EU's supply security and maintain sustainable manufacturing within Europe. CALLS on the Commission to assess the regulatory challenges innovative companies in the life sciences sector encounter on their way to market, and to propose a clear action plan to overcome these. WELCOMES the Commission's proposal for legislative intervention to address some challenges identified regarding medical devices and in vitro diagnostic devices.

8. LOOKS FORWARD to the announced European Biotech Act and REMINDS of the broad opportunities offered by this key technology and the importance to support R&I as well as its application across a wide spectrum – red (medical), white (industrial), green (agriculture), blue (marine), grey (environmental) and yellow (food) – in line with it being a technology included in the Strategic Technologies for Europe Platform. Moreover, synergies between these areas should be fostered, for mutual benefits. INVITES the Commission to set out actions horizontally across EU policies and industrial sectors to further streamline the relevant EU legislation and its implementation to reduce fragmentation, enhance simplification, and shorten the time for research-intensive biotech innovations to reach the market. This should be done by building on an evidence-based approach and in consultation with Member States and stakeholders,
9. WELCOMES the announced strategic R&I agenda on food systems. RECOGNISES the importance of a sustainable and resilient agriculture and food systems capable of guaranteeing access to healthy and nutritious food for all while at the same time combating climate change, biodiversity loss and developing resilience to climate change. CALLS on the Commission to present the agenda before mid-2026 and to ensure that it will be developed closely with all relevant stakeholders, take a systemic value chain approach, align with relevant EU policies and look at outstanding regulatory challenges. HIGHLIGHTS the importance of a circular bioeconomy and optimisation of the use of available biomass and therefore the need to interlink the strategic R&I agenda on food systems with the forthcoming Bioeconomy Strategy.

A COORDINATED GOVERNANCE AND CALL FOR ACTION

10. INVITES Member States and the Commission to enter into a strategic dialogue and coordination with regards to establishing, maintaining and interlinking research and technology infrastructures, innovation hubs and excellence centres dedicated to life sciences to strengthen common efforts and guarantee Union's R&I autonomy and technological sovereignty. In this respect, LOOKS FORWARD to the announced strategy on research and technology infrastructures. ENCOURAGES the Commission and Member States to consult the European Strategy Forum for Research Infrastructures in this coordination effort. RECALLS the need to ensure that infrastructures enable FAIR data (Findable, Accessible, Interoperable, and Reusable) and can deploy new AI based tools in alignment with the forthcoming AI in Science Strategy.
11. INVITES the Commission to present a mandate and terms of reference for the 'Life Science Coordination Group' and ensure it will strive for seamless coordination between EU-level programmes and policies and their evaluation. CALLS FOR the involvement of selected experts representing both private and public stakeholders from the entire life sciences ecosystem in the Group to ensure a holistic view of life sciences and related value chains. SUGGESTS a selection process taking example from the European Innovation Council Board. RECOMMENDS the 'Life Sciences Coordination Group' to be bold and ambitious in its task to ensure sustainable innovation-friendly coherent policies, funding and activities within and across the life sciences sector. The Coordination Group should further establish a monitoring system towards the 2030 ambition and carry out regular dialogues with Member States and a wider stakeholder forum to discuss progress and required actions.