

Brussels, 27 August 2025
(OR. en)

12265/25

RECH 365
SAN 522
BIOTECH 8
COMPET 820

NOTE

From:	General Secretariat of the Council
To:	Delegations
No. prev. doc.:	11629/25
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 4 September 2025.

Changes in comparison to doc. 11629/25 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 ~~and medtech~~, to agriculture, energy, food **and feed** systems.

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 innovations in **strategically important** areas such as healthcare and pharma, agriculture, **bioeconomy, terrestrial and aquatic** food systems, **biotechnology** and environmental sciences, ~~as well as for the strategically important biotechnology.~~ A ~~s~~**Strong** and innovative life sciences ~~are~~ **sector is** essential for the Union's **sustainable** global competitiveness **and sovereignty**, to ensure the health and wellbeing of European citizens, to tackle environmental challenges and **support** ~~safeguard~~ the green transition.
2. RECOGNISES ~~and REGRETS~~ that the Union is ~~outpaced in the~~ fierce competition ~~on the~~ global scene with other economies, ~~with~~ **experiencing** a growing innovation gap **and lagging behind global competitors in terms of** ~~failure to translate~~ **translating research and** innovation **(R&I)** into products or services. **A fragmented European life sciences ecosystem and** ~~s~~Structural barriers, ~~across Europe's life sciences innovation lifecycle,~~ such as insufficient investments, **including in R&I and scale-ups,** ~~in research and innovation (R&I) and along the value chain, including in scale-ups,~~ limited technology breakthroughs and a complex regulatory framework, ~~remain~~ **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** ~~across the value chain~~ **all stakeholders and existing initiatives.** **REGRETS that the presented life sciences strategy is lacking a global 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. ~~VALUES~~ **WELCOMES** the inclusive and holistic approach to life sciences in the Commission's strategy **on life sciences**, ~~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, **in close collaboration with Member States**, to ensure ~~that~~ **overcome the fragmentation of legislation and strategies at Union level** ~~strategies and acts efficiently interlink and~~ **to** create an innovation and user-friendly environment for **all R&I** stakeholders. ~~ACKNOWLEDGES~~ **RECOGNISES** that Horizon Europe, ~~and 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, ~~but~~ **LACKS EMPHASISES the need for** a strategic forward-looking perspective building on these achievements **and drawing lessons from the acquired experience**, without pre-empting decisions on the future of R&I **in the next Multiannual Financial Framework** ~~partnerships.~~ **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 ~~to~~ **for** life sciences across all relevant **related** sectors ~~areas~~, with well-connected instruments along the value chain, ~~including~~ **and with** 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 **feasibility of** establishment 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 inclusive and open.**

CREATE LEADERSHIP IN CLINICAL TRIALS

45. EMPHASISES that the Union urgently needs to tackle the issue of a declining **worldwide share and reduced impact** number of clinical trials carried out **within it** the EU. Hosting clinical trials is of benefit for patients and the life sciences ~~sector~~ **and** boosts the uptake of **personalised medicine and** new technologies in the Union's health**care** 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 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 ~~In this context, establishing~~ **supporting an a common** enabling regulatory environment for the implementation of clinical trials across the ~~Union~~**EU, building on Regulation (EU)536/2014⁴ and** taking into account **best practices and** lessons learned from recent crises, **whilst safeguarding security 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, set setting** out clear steps and responsibilities for establishing ~~a strong~~ **reliable and integrated** infrastructures for **carrying out** clinical trials ~~and in~~ an effective framework that utilises existing structures and expertise, ~~in the Member States to better coordinate efforts and~~ boost multi-country **and multi-centre** clinical trials. **The plan should integrate a gender perspective and promote the active participation of patients at all stages of 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.~~

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**

~~5~~ **6.** ~~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~~ **the use of health data for R&I is** a major challenge ~~is the use of health data for R&I, and CONSIDERS that~~ **remaining** hurdles, including GDPR-related issues, need to be overcome to ensure **prevention of diseases and 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, ~~and a thorough evaluation of their results~~ **and a plan for their implementation** ~~is~~ **are** an important first steps towards finding solutions to the data-**related regulatory challenges whilst taking into account ethical concerns**. ~~AWAITS further details on the planned European Life Sciences R&I Data Assembly. RECOMMENDS~~ **CALLS on the Commission to support the Member States to** accelerating the digitalisation of health systems and ~~to ensuring~~ **to** continued support for a smooth and simple implementation of the European Health Data Space (EHDS), including the use of Artificial Intelligence (AI), ~~sandboxes~~ **to enable also secondary use of health data and simplify access for researchers and innovators.**

SEIZE NEW OPPORTUNITIES AND ENSURE SKILLS

~~6-7.~~ 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 support boost the preservation of the Union's leadership in both life sciences and digital technologies. ~~this emerging areas.~~ RECOGNISES CALLS on the Commission and the Member States to that the EU must ensure it the Union has the right future-oriented, multidisciplinary and intersectoral skills ~~and gender balance~~ to develop and exploit new knowledge and technologies, taking into account the importance of building on at the same time to maintain strong knowledge in of excellent fundamental sciences and advancing gender equality. SUPPORTS the Science, Technology, Engineering and Mathematics (STEM) Education Strategic Plan, and the 'Choose Europe' initiative to attract and maintain talents. CONSIDERS that a holistic approach on skills should also extend to the early years of secondary education. WELCOMES the 'Choose Europe' initiative to develop, attract and retain talents. ~~REMINDS of~~ REITERATES the importance of ecosystems around higher education institutions, research performing organisations and research infrastructures to foster skills, innovation ~~as well as~~ and spin-offs, startups and scaleups, particularly in life sciences, where innovative technologies are increasingly relevant. ~~RECALLS the need to urgently implement the EU's strategy for startups and scaleups for the support of key European sectors, like life sciences.~~

~~7.8.~~ ~~HIGHLIGHTS~~ ~~STRESSES~~ the importance of a well-functioning European, **national and regional R&I** innovation ecosystems for life sciences, **advancing the innovation principle and the use of regulatory sandboxes, and supporting** ~~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. **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 stimulating sustainable local production and creating an innovation- **and business-**friendly regulatory framework is essential for safeguarding the EU **nion**'s supply security and maintaining **ing** sustainable manufacturing within Europe. CALLS on the Commission to assess the regulatory challenges **that** innovative **life sciences** companies ~~in the life sciences sector~~ encounter on their way to market, and to propose a clear action plan to overcome these **in the forthcoming Innovation Act, as part of the wider initiative to reduce regulatory burden.** WELCOMES the Commission's proposal for legislative intervention to address ~~some~~ challenges identified regarding medical ~~devices~~ and in vitro diagnostic devices. **ADVOCATES for a more proactive use of public innovation procurement in the life sciences sector to boost innovative markets.**

- 8-9. ~~LOOKS FORWARD~~**AWAITS** to the announced European Biotech Act and ~~REMINDS~~
URGES the Commission to unlock of the broad opportunities offered by this key
technology. **RECALLS** the importance to support R&I, as well, as ~~its~~ **the application of**
biotechnology across all relevant areas in which biotechnology can drive innovation.
~~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,~~ ~~s~~**Synergies between these different**
areas should be fostered, for mutual benefits. INVITES the Commission to set out actions
horizontally across EU**nion's** policies ~~and industrial sectors~~, to further streamline the relevant
EU**nion'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. This should be done ~~by building on~~ **through** an evidence-based approach
and in ~~consultation~~ **close coordination** with Member States and stakeholders. **STRESSES**
that the upcoming Biotech Act offers a timely and unique opportunity to establish
structured exchanges.
- 9 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 EU**nion's policies and initiatives**
and look at outstanding regulatory challenges. **AWAITS also the forthcoming Bioeconomy**
Strategy and HIGHLIGHTS the importance of a circular bioeconomy and optimisation of the
use of **sustainable** ~~available biomass~~ **biogenetic resources,** 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~~**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 ~~excellence centres~~ of excellence dedicated-relevant to for life sciences, to strengthen common efforts and guarantee ~~the~~ Union's R&I autonomy and technological leadership. ~~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 context ~~coordination effort.~~ **RECOGNISES the importance of a strong European capacity for testing, experimentation and validation of services and products. 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.

~~11~~**12.** 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 Commission internal '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 Commission Coordination Group should further establish a monitoring system towards the 2030 ambition and carry out regular dialogues **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.**
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