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2025/2087(INI)

ALTERNATIVE COMPROMISE AMENDMENTS

on public health aspects of biotechnology and life sciences
(2025/2087(INI))

Committee on Public Health

tabled by

MEP Humberto, on behalf of the EPP Group

MEP González Casares, on behalf of the S&D Group

MEP Chastel, on behalf of the Renew Group

AMs covered: 2, 3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 17, 19, 21, 23, 28, 29, 30, 32, 33, 34, 35, 36, 37, 38, 40, 42, 43, 44, 46, 48, 49, 50, 51, 52, 53, 54, 55, 57, 58, 59, 60, 62, 66, 67, 68, 69, 71, 72, 73, 75, 76, 77, 78, 79, 80, 82, 83, 85, 86, 87, 89, 90, 92, 93, 95, 98, 101, 104, 105, 106, 107, 108, 110, 111, 112, 114, 115, 116, 117, 118, 119, 120, 121, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 134, 135, 136, 137, 138, 139, 140, 142, 143, 144, 145, 146, 147, 148, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 163, 164, 165, 166, 167, 168, 171, 172, 173, 174, 175, 178, 179, 180, 182, 183, 184, 185, 186, 187, 188, 190, 197, 200, 201, 203, 205, 206, 208, 210, 215, 216, 217, 220, 221, 222, 223, 226, 227, 229, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 245, 247, 249, 251, 252, 253, 254, 256, 257, 259, 260, 261, 262, 266, 267, 268, 270, 272, 273, 275, 277, 278, 280, 282, 283, 284, 285, 286, 288, 289, 290,

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The following amendments fall: 225, 228, 230, 244, 246, 248, 250, 255, 258, 263, 264, 265, 269, 271, 274, 276, 281, 287, 293, 294, 309, 311, 313, 315, 316, 317, 319, 321, 322, 336, 337, 342, 344, 345, 346, 347, 348, 351, 353, 355, 361, 364, 365, 372, 374, 375, 376, 377, 381, 382, 389, 390, 391, 395, 401, 405, 408, 419, 432, 435, 436, 439, 440, 443, 448, 449, 454, 455, 463, 464, 467, 468, 470, 472, 484, 488, 491, 492, 494, 495, 496, 497, 498, 499, 512, 520, 522, 527, 558.

COMPROMISE AMENDMENT 1

- Having regard to the Treaty on European Union, in particular Articles 6, 8 and 21 thereof,
- Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 4, 5, 6, 9, 114, 151, 153, 168, 169, 173, 179, and 191 thereof,
- Having regard to the Charter of Fundamental Rights of the European Union of 7 December 2000, as adapted on 12 December 2007 in Strasbourg, and in particular Articles 3, 8, and 35 thereof,
- Having regard to the European Convention for the Protection of Human Rights and Fundamental Freedoms,
- Having regard to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine), signed in Oviedo on 4 April 1997,
- Having regard to the Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (CETS No. 168),
- Having regard to the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (CETS No. 195),
- Having regard to the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes (CETS No. 203),
- Having regard to Directive 2011/24/EU on the patients' rights in cross-border healthcare,
- Having regard to 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,
- Having regard to Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on quality and safety standards for substances of human origin intended for human application, and repealing Directives 2002/98/EC and 2004/23/EC
- Having regard to the Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU,
- Having regard to Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space, and amending Directive 2011/24/EU and Regulation (EU) 2024/2847,
- Having regard to Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules for fair access to and use of data, and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act),

- Having regard to the Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (Text with EEA relevance),
- Having regard to the Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (Text with EEA relevance),
- Having regard to the European Parliaments motion for resolution on EU action to combat antimicrobial resistance (2023/2703(RSP)), – having regard to the Universal Declaration on the Human Genome and Human Rights, adopted by UNESCO on 11 November 1997,
- Having regard to the Commission proposal of 26 April 2023 for a Council recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach (COM(2023)0191), – having regard to Rule 55 of its Rules of Procedure,
- Having regard to the report "The Future of European Competitiveness" by Mario Draghi,
- Having regard to the report "Much More Than a Market" by Enrico Letta,
- Having regard to the report "Stronger together" on strengthening EU civil and military preparedness and readiness by Sauli Niinistö,
- Having regard to the report of the Scientific and Technological Options Assessment (STOA) panel, "Improving Access to Medicines and Promoting Pharmaceutical Innovation," November 2023 (PE 753.166),
- Having regard to the Commission communication of 28 May 2025 entitled ‘The EU strategy for start-ups and scaleups: Choosing the EU to start and grow’ COM (2025)270),
- Having regard to the 1948 Universal Declaration of Human Rights,
- Having regard to the 1997 UNESCO Universal Declaration on the Human Genome and Human Rights
- Having regard to the 2003 UNESCO International Declaration on Human Genetic Data,
- Having regard to the 2005 UNESCO Universal Declaration on Bioethics and Human Rights,
- Having regard to the report of the UN Human Rights Committee Special Rapporteur on Cultural Rights, Farida Shaheed, on the right to enjoy the benefits of scientific progress and its applications (A/HRC/20/26)
- Having regard to the report of the UN Human Rights Committee Special Rapporteur on Cultural Rights, Alexandra Xanthaki, on the right to participate in science (A/HRC/55/44),

- Having regard to the WHO guidelines on addressing key gender inequalities in the prevention, diagnosis and treatment of drug-resistant infections,
 - Having regard to the analysis by the Joint Research Centre (JRC) of 20 March 2024 on the global biotechnology innovation landscape, providing preliminary insights based on a patent analysis, as set out in the report entitled "Exploring the global landscape of biotech innovation: preliminary insights from patent analysis",
 - Having regard to the 2025 concluding observations on the European Union by the United Nations Committee on the Rights of Persons with Disabilities,
 - Having regard to the Commission communication of 25 July 2023 on the European Citizens' Initiative (ECI) 'Save cruelty-free cosmetics – Commit to a Europe without animal testing', C(2023) 5041 final,
- A. whereas the OECD defines biotechnology as “the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services”, aimed at improving human health;
 - B. whereas Advanced Therapy Medicinal Products (ATMPs) represent a strategic frontier in biotechnology, with the potential to address high unmet medical needs and redefine the treatment of severe and rare diseases, markedly enhance patient outcomes, and alleviate burdens on healthcare systems;
 - C. whereas the EU’s leadership in research is not yet adequately matched by its capacity to translate scientific breakthroughs into therapies, due to structural barriers in early-stage development and short support for technology transfer and manufacturing scale-up;
 - D. whereas the sequencing of human genome, along with the manipulation of stem cells and the emergence of gene editing mechanisms, among other innovations, have transformed the capabilities for understanding human biology and accelerated the development of new fields of innovation to improve health;
 - E. whereas recent scientific breakthroughs, such as the development of mRNA vaccines, have demonstrated the immense potential of biotechnology to respond rapidly and effectively to global health emergencies, as shown during the COVID-19 pandemic; whereas these biotech-driven innovations not only exemplify the swift translation of advanced research into life-saving solutions with high societal impact, but are also essential to advancing a prevention-focused healthcare model, centred on early intervention, screening, preparedness, and broad immunisation strategies;
 - F. whereas biotechnology contributes significantly to better preparedness and response, following the One Health approach all hazards, by providing integrated and flexible tools and knowledge to monitor, prevent and treat diseases in the fields of human, animal and environmental health, including in the fight against antimicrobial resistance and unexpected emergencies;
 - G. whereas biotechnology should aid to cover the full spectrum of natural risks and threats, promoting coordination, efficiency and fostering capacity building, coordination and cooperation between Member States;

- H. whereas biotechnology has been identified as a critical technology area for the EU; whereas investment in this field represents a strategic opportunity to reduce dependencies on other regions, strengthen Europe’s health sovereignty and build resilience in essential sectors; whereas the Union can build on its scientific excellence, world-class research institutions and dynamic innovation ecosystem to develop a competitive biotechnology sector that supports high quality job creation, contributes to strategic autonomy, and reinforces the EU’s clinical, scientific and manufacturing leadership in a context of growing global technological competition;
- I. whereas resilient supply chains are critical for a strong biotechnology sector; whereas barriers to trade should be addressed to ensure a level playing field that supports innovation;
- J. whereas an analysis by the Joint Research Centre (JRC) of 20 March 2024 shows that biotechnology patents accounted for approximately 5% of all patent applications filed between 2001 and 2020; whereas the United States held a leading position in biotechnology patent development in 2020, accounting for 39% of the total, followed by the European Union with an 18% share, while China is rapidly gaining ground with a 10% share; whereas these figures highlight the importance of strengthening the European Union’s competitive position in the biotechnology sector; whereas the overwhelming majority of these patents, over 96%, are linked to industrial and medical applications¹;
- K. whereas biotechnology is a key tool within a comprehensive approach to health policies, due to its ability to enhance and integrate key innovations in the healthcare system as a public service, as well as the opportunity to incorporate innovative therapies and improve the quality of healthcare, all contributing to the improvement of health for the citizens of the Union; whereas innovations in biotechnology can be game changers for all patients, particularly those living with rare diseases and certain disabilities; whereas four out of five individuals with an autoimmune disease are women, and women with cardiovascular conditions are often underdiagnosed and undertreated; whereas the holistic development of knowledge within the life sciences must systematically take into account the gender dimension and other relevant vulnerability factors, in order to achieve a better understanding of underlying causes and mechanisms;
- L. whereas integrating human, animal and environmental health under One Health approach into research and development strategies can enable the underlying causes of diseases to be identified and addressed more effectively by biotechnology-based treatments;
- M. whereas scientific knowledge from which biotechnological applications arise stems from basic and preclinical research, which is mostly carried out by universities and research centres;
- N. whereas clinical research and innovation in biotechnology enhances disease prevention, diagnosis, and treatment, and offers significant advances in the management of chronic, rare, autoimmune, and metabolic diseases, thereby contributing to more resilient and sustainable healthcare systems across Europe;

¹ European Commission, Joint Research Centre, Exploring the global landscape of biotech Innovation: preliminary insights from patent analysis, 2024

- O. whereas it is the responsibility of public authorities both to promote research activities and to encourage the development of applications that contribute to advancing solutions for the benefit of human health; whereas adequate protection of the conditions under which research is conducted is crucial for the development of biotechnological research, covering labor and professional conditions, access to and continuation of academic and educational progression, as well as scholarships, internships, and the incorporation of a gender perspective in access to and promotion within academic careers, especially in STEM fields;
- P. whereas biotechnology must be developed in accordance with the highest standards for the protection of fundamental rights, and taking into account that its development involves extensive use of highly sensitive data, both through the large-scale use of health data and medical records for developments such as those based on artificial intelligence, and due to the sensitivity of data used in many bioengineering applications—therefore, the architecture for the design, collection, processing, and sharing of data must be guided by the fundamental rights recognized in the Charter of Fundamental Rights of the European Union, the European Convention on Human Rights, and the common constitutional traditions of the Member States, in their objective dimension;
- Q. whereas the principle of equal treatment and non-discrimination in the medical field requires particular vigilance when automated decision-making, diagnostic, or evaluation mechanisms are incorporated, whether in administrative or medical decisions, and therefore, the use of AI and automated decision-making must be implemented in a manner that prevents both direct and indirect discriminatory outcomes, through explicit legal protection of individuals against multiple and interconnected forms of discrimination in all areas of life, including sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation ;
- R. whereas accessibility to innovative treatments must be universal, biotechnology should be made available to all citizens of the Union, regardless of their place of residence, socioeconomic status, or any other factors that may affect their access to healthcare services. This should entail the development of a fast, simplified, and effective cross-border healthcare system for innovative therapies that, due to their nature, the potential number of patients benefiting, cost, and/or access conditions, cannot be made available in all Member States;
- S. whereas biotechnological applications have increasing uses in the field of health and in the production of healthcare products for human health, including recombinant proteins—used, for example, in the in vitro production of insulin as well as monoclonal antibodies, interferons, and interleukins, among others;
- T. whereas biotechnology holds significant potential for development in the field of personalized medicine, such as tailoring treatments and preventing adverse effects, and that this potential should be harnessed to strengthen the preventive approach of our healthcare systems, in the interest of both promoting health and enhancing the efficiency of the healthcare systems of the Member States;
- U. whereas biotechnology applied to diagnostics, through integrated AI, biosensors, or nanotechnology, has the potential to offer even greater precision and to enhance medical decision-making for the benefit of patients' health;

- V. whereas reproductive and prenatal biotechnology warrants special attention within diagnostic and therapeutic possibilities, particularly in relation to therapeutic models that are not yet available but hold great potential for improving treatment options for a wide range of currently complex diseases, such as in utero gene therapy;
- W. whereas innovation in biotechnology is often driven by progress in life sciences, with breakthroughs in one area, such as healthcare, enabling cross-sectoral applications in fields including agriculture, environmental technologies and beyond; whereas biotechnology strengthens the development of biological manufacturing processes that produce sustainable alternatives to synthetic chemicals, reducing environmental pollution and its negative impact on human and animal health. The role of biotechnology, following the One Health approach, is multifaceted and multisectoral, covering various challenges and improving the Union's capacity to protect the health of all living beings and the environment;
- X. whereas the European Commission, through the Health Emergency Preparedness and Response Authority (HERA), with financial support from the European Investment Bank (EIB), can provide an incentive to startups and scale-ups to bring innovations to the market and manage health crisis more quickly and efficiently;
- Y. whereas rare diseases in the European Union are defined as conditions affecting no more than 1 in 2,000 people; whereas it is estimated that there are between 6,000 and 8,000 different rare diseases affecting approximately 36 million people in the EU; whereas rare diseases are recognized across the EU and worldwide as an urgent public health challenge; whereas around 80% of these conditions have a genetic origin, and the limited number of patients per disease results in a lack of investment in research and development; whereas in 2018, 25 EU Member States had established national action plans for rare diseases, 19 of which were time-limited; whereas many of these plans have since become outdated, with end dates dating back to 2020, 2018, or even 2013;
- Z. whereas universities and research centres in the Union, most of which are publicly owned, possess strong research capabilities in the field of biotechnology, leading in scientific publications yet faces persistent challenges in translating research breakthroughs into innovative medical products and commercially viable solutions, due in part to obstacles in early stage development, limited access to scientific and regulatory guidance, fragmentation of clinical trial processes and insufficient support for manufacturing scale-up;
- AA. whereas the freedom of scientific research, as enshrined in Article 13 of the Charter of Fundamental Rights of the European Union, is a fundamental principle of the Union; whereas respect for academic freedom is essential for independent, ethical, and responsible research in the fields of biotechnology and the life sciences, with particular attention to public health;
- BB. whereas the EU has led for the last two decades on the development of the scientific and regulatory principles, R&D and manufacturing evolution for biosimilar medicines, contributing to the availability, accessibility and affordability of key biologic therapies for millions of patients while contributing to healthcare systems economic sustainability;
- CC. whereas supporting biotech innovation requires early engaging with regulators, and using scientific evidence in a responsible way, all within a stable and predictable

environment;

- DD. whereas the industrial dependency of European research on certain inputs that are not produced in Europe, which may hinder its development such as DNA sequencers.
- EE. whereas the need to ensure that current and future legislative initiatives are aligned with the whole legislation in the areas of biotechnology, pharmaceuticals, and health in general, and therefore establish mutually synergistic links including the Pharmaceutical Package, the Medical Devices Regulation (MDR), the In Vitro Diagnostic Medical Devices Regulation (IVDR), the Clinical Trials Regulation, the Orphan Medicinal Products Regulation and the Critical Medicines Regulation, and the AI Act, among others; whereas the rapid pace of innovation in biotechnology has created challenges for existing regulatory systems, making the development of clear, coherent regulatory pathways essential to support innovation and ensure patient safety;
- FF. whereas an effective regulatory framework for conducting clinical trials is essential to the competitiveness of the most innovation-intensive aspects of the EU's pharmaceuticals and biotechnology sector; whereas the divergence in standards applied by National Competent Authorities and Ethics Committees across Member States slows down the assessment of applications for multi-country trial approvals, making the process more costly and burdensome;
- GG. whereas small and medium-sized enterprises (SMEs) constitute a significant part of the industrial fabric dedicated to biotechnology, and recognizing the importance of supporting growth environments and business-university programs that enable companies in this sector to gather knowledge of basic research and to achieve both financial independence and sufficient economies of scale to be competitive in the international market, as they play a key role particularly in driving early-stage innovation, advancing emerging technologies, and contributing to medicines discovery and development;
- HH. whereas close cooperation between the pharmaceutical sector, patient associations, and public health bodies plays a crucial role in advancing and applying biotechnological and life science innovations that meet patient needs and contribute to better health outcomes; highlights the need to strengthen public-private partnerships that support scientific research and facilitate fair and timely access to novel therapies;
- II. whereas effective global supply chains are essential for resilience, especially for products like critical medicines; whereas trade barriers should be tackled to ensure fair conditions for innovation, and tariffs on inputs and equipment should be avoided, as they increase overall supply chain costs and reduce competitiveness;
- JJ. whereas one of STEP's target investment areas is biotechnology; whereas, according to the EU Competitiveness Compass, the European life science strategy and the EU Biotech Act that will be presented by the European Commission ; whereas the European Commission only commissioned its preparatory study on the Biotech act in early 2025;
- KK. whereas the recent trends of international trade and the impact on European research projects and universities of the budget cuts and policy shifts in the United States regarding research, higher education, and academic management, must be addressed;

LL. whereas ensuring a stable and autonomous supply of critical raw materials and feedstock is essential for the EU's strategic sovereignty, economic resilience, and leadership in biotechnology;

MM. whereas security policy in the European Union should address and fund health security issues and investment in healthcare as part of the security strategy, as highlighted by the Niinistö report;

NN. whereas the biotechnology regulation must take into account crisis preparedness and the Union's strategic autonomy, both from the perspective of security, public health, and the ability to respond to health threats such as those addressed by Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health, repealing Decision No. 1082/2013/EU, or the Regulation on Compulsory Licensing for Crisis Management agreed upon by the co-legislators on 21 May 2025;

OO. whereas, in light of rising antimicrobial resistance, the EU Biotech Act should acknowledge the significance of innovative biological therapies such as bacteriophages in advancing the Union's One Health goals, enhancing health system resilience, and fostering sustainable and targeted biocontrol strategies, whereas in July 2022, the Commission, together with the Member States, identified antimicrobial resistance (AMR) as one of the top three priority health threats in the EU;

PP. whereas biotechnology is one of the EU's fastest growing and most innovative sectors, contributing significantly to economic growth and job creation; whereas in 2018 alone, the sector directly generated €31 billion in GDP and provided over 210,000 direct jobs across healthcare and other sectors, while supporting more than 625,000 additional jobs indirectly.

QQ. whereas regulatory and health technology assessment (HTA) sandboxes represent effective tools to future-proof healthcare systems by providing controlled environments for testing and refining innovative solutions, ensuring the safe and effective integration of new technologies and methodologies into healthcare;

RR. whereas biotechnologies offer an important opportunity for the EU to enhance its scientific leadership and competitiveness; whereas it raises ethical and security considerations that must be addressed through clear, science-based and transparent governance frameworks;

Exploring the Potential of Biotechnologies in Healthcare

1. Highlights that biotechnology therapies, such as CAR-T, mRNA, CRISPR and other ATMPs, are transforming care and prevention targeting previously untreatable diseases;

2. Stresses that during the COVID-19 pandemic, biotechnology played a key role in the swift development of innovative vaccines, including mRNA vaccines and advanced molecular diagnostic tools; proves the need for long-term strategic investment in biotechnological research;

3. Stresses that Europe's competitiveness in life sciences must encompass a strong patient perspective, ensuring that research and innovation translate into timely access to effective treatments and medicines across the EU;

4. Emphasises that biotechnology preventive medicine and therapies have a growing impact on treating and preventing diseases such as cancer, cardiovascular conditions, rare, neurodegenerative, psychiatric, autoimmune, infectious diseases, and metabolic disorders;
5. Underlines the role of off-patent biologic medicine will play in enhancing the sustainability of healthcare systems and ensuring equitable and timely access to treatment for patients;
6. Emphasizes the role of biotechnological innovation can play a major role in reducing and replacing animal testing, such as laboratory-grown tissues or the use of stem cells, in promoting regenerative medicine, disease modelling, and drug testing through procedures like the "organ-on-a-chip" for therapies, clinical trials and testing, and also the importance of continuous innovation in biomanufacturing processes throughout the technology life-span, including from off-patent medicines actors;
7. Stresses the importance of blue biotechnology (marine biotechnology) for the development of health applications, for example in the discovery and development of new medicines with antimicrobial properties, treatments modulating the immune and anti-inflammatory response, new materials for tissue regeneration, cosmetic and dermatological applications, or identification of enzymes and biosensors for use in medical diagnostic systems;
8. Recalls that molecular diagnostics using genomic and proteomic biomarkers are essential for the early detection and personalized treatment of serious diseases, and, where appropriate, enable the implementation of public policies for population-wide disease screening, whether selective or general depending on the case;
9. Underlines the need to scale up genomic sequencing capacity to support early diagnosis and screening; calls for adequate funding and improved coordination of national genetic testing programmes, including the adoption of EU guidelines to harmonise newborn screening;
10. Emphasizes the importance of genetic surveillance of pathogens and the rapid design of vaccines in epidemiological control and public health;
11. Underlines that biotechnology innovations influence biosecurity of human population in the era of new viral and microbial hazardous agents responsible for high mortality rate and therefore being significant biohazardous factors;
12. Stresses that new applications of biotechnology, such as phagic therapies, can provide solutions for microbial resistance, which is directly responsible for the deaths of more than 1 million people globally each year and for increased costs for health systems and society; Highlights that bacteriophage therapy is a leading example of innovative biotechnology with the potential to tackle the growing challenge of antimicrobial resistance (AMR); stresses that this targeted approach offers a promising alternative or complement to traditional antibiotics; notes with concern that, despite its potential, the field receives little commercial interest and limited funding; therefore calls for increased public investment in research and development of phage therapy and similar biotechnological solutions to AMR;
13. Stresses the importance of biotechnology research and development in addressing unmet medical needs, such as treatments for rare and paediatric diseases; calls for public funding to be directed towards these priorities;

14. Highlights the potential for integrating these techniques into the healthcare systems of the Member States to enhance the efficiency of primary and hospital care, contributing to more effective service delivery and the deployment of new opportunities in preventive medicine;

Shaping the Future EU Biotech Act

15. Calls for the EU Biotech Act to review, simplify, and optimise the regulatory framework of biotechnology in healthcare to foster innovation, including off-patent-led developments, while maintaining high standards of safety, quality, efficacy, and ethical compliance, as well as public health and environmental protection; underlines that such a framework must remain science-based, coherent with evolving Union legislation and international best practices, and take due account of the specific characteristics of different categories of biotechnology, including orphan medicinal products (OMPs) and advanced therapy medicinal products (ATMPs); stresses, furthermore, the need to streamline procedures, building on evidence and practical experience, in order to improve patient access to treatments and ensure a clearer, more effective and globally competitive regulatory environment; Urges regulators, healthcare providers, researchers, and industry to collaborate on ATMPs throughout their lifecycle, including future off-patent versions, in order to improve oversight through reporting systems, anticipate availability and affordability, and ensure timely patient access; Stresses the need to simplify and rationalise the interplay between intersecting legislative frameworks, such as SoHO (Substances of Human Origin) and ATMP regulations, and to enhance regulatory coherence and clarity so as to avoid additional burdens;

16. Calls for a harmonised, streamlined, and science-based clinical trials framework to increase efficiency, transparency, and cross-border collaboration, including reducing approval timelines to 30 days through risk-based assessments; Emphasises that the approval of biotechnology products, such as monoclonal antibodies, gene therapies, and mRNA-based treatments, should be based on thorough, independent, assessments of health risks; calls for a precautionary approach that focuses on preventing harm rather than reacting to it after it occurs; Stresses the need for better scientific coordination between regulatory authorities and unified processes for biotechnologies involving IVDs, MDs, and drug–device combination products, as well as improvements to the Clinical Trials Information System (CTIS); welcomes the ACT EU initiative and the Commission’s plan to explore a targeted revision of the Clinical Trials Regulation; Underlines that the EU Biotech Act must align with the revision of the Pharmaceutical Legislation and the proposed Critical Medicines Act to ensure policy coherence, avoid fragmentation, and strengthen Europe’s strategic autonomy; Notes that greater use of multi-country clinical trials is key to unlocking the value of the Single Market and positioning the EU as a global leader in clinical research; Calls for adapted regulatory pathways and fee structures for public sector innovators such as university hospitals, recognising their societal value;

17. Calls on the Commission to explore the establishment of a centralised coordination mechanism for clinical research governance, aimed at providing developers of medicines, medical devices and combination products with a more predictable and efficient interface for scientific advice, assessments and authorisations; Suggests that the European Medicines Agency could play a coordinating role in this structure, in close cooperation with notified bodies and national competent authorities;; Stresses that adequate resources, staffing, and training for national regulatory authorities are essential to ensure timely and effective assessments of innovations;

18. Highlights the need to streamline and make more predictable the work of national ethics committees in approving clinical trials, including cross-border clinical trials; Stresses that this could be achieved via clear and unified European Commission guidelines, more centralised review processes supported by standardised EU templates, the harmonisation and the standardisation of responsibilities and ways of working;

19. Highlights the importance of further developing and rolling out multi-country platform trials embedded in clinical practice to ensure the efficient and streamlined testing of novel interventions and their effective implementation in EU public healthcare systems;

20. Underlines that EU clinical trials should be fully representative of Europe's population, including women, which would be a competitive advantage for the EU life sciences ecosystem as a whole and which would help deliver effective medical products for all EU citizens;

21. Stresses the need to simplify, align, and better coordinate clinical approval processes across the EU, which are currently fragmented due to multiple, disconnected regulatory pathways with divergent timelines, requirements, and systems. Notes in particular that key legislative texts, such as the Clinical Trials Regulation (CTR), In Vitro Diagnostic Regulation (IVDR), and Medical Devices Regulation (MDR), are interpreted and implemented inconsistently across Member States, undermining legal certainty and delaying innovation.

22. Highlights the potential of regulatory frameworks such as the hospital exemption to improve access to innovative therapies and foster research environments linked to clinical practice, thereby supporting the development of marketable innovations in collaboration with industry;

23. Highlights the importance of specific support schemes for orphan medicines, including frameworks for unmet medical needs, conditional authorisations, and health technology assessments;

24. Strongly supports shared public/private ownership of biotechnologies developed with the contribution of public funding; stresses the importance of fair and equitable pricing to ensure accessibility for all, particularly in the context of publicly funded research and innovation;

25. Monitors the use of next-generation regulatory and HTA sandboxes to test emerging biotechnologies in a secured, controlled, and adaptable framework that upholds EU standards of safety, efficacy, quality, public health, and bioethics; Stresses that sandboxes should not evolve into parallel regulatory systems and calls for EMA consultation and oversight in their design and assessment; Urges the Commission to expand their scope to include cross-sectoral innovations such as medicinal products, medical devices and IVDs, AI, and substances of human origin, while fostering EU-wide collaboration to enable mutual learning and supporting a product-centred regulatory approach that ensures continuity of knowledge from early clinical applications through to marketing authorisation.

26. Stresses the need for regulatory mechanisms that enable biological therapies, including biosimilars to evolve over their lifecycle, allowing updates to composition or manufacturing processes when supported by scientific or clinical evidence; Recalls the importance of improving interoperability and open access to drug and clinical trial databases to foster collaboration and scale up research; urges the creation of clear guidelines for the use of scientific and real-world evidence (RWE) in both regulatory and health technology assessment (HTA) decisions, ensuring transparency in how this data is generated and used;

27. Points out that while security standards must be the highest in all cases, audit requirements must be particularly strengthened when applying for public funding, and that this must be accompanied by accessibility commitments in return for the funding received; Calls on the Commission to publish a report on how current EU legislation on biotechnology and biomanufacturing is being implemented, including an assessment of existing gaps and regulatory barriers that may hinder the sector's growth and contribute to the EU's loss of clinical research market share to global competitors;

Digital Transformation of Healthcare through Biotechnology

28. Encourages the use of cloud-based technologies to support regulatory assessments throughout the process from clinical trial applications to marketing authorisation and its ongoing management;

29. Underlines that personalised medicine, particularly in rare diseases, represents a transformative advancement, with emerging therapies and biomarker-driven diagnostics enabling targeted interventions tailored to individual patient profiles; Notes the growing role of artificial intelligence (AI) in healthcare, particularly in personalised medicine, diagnostics, treatment, clinical research, and its integration into medical devices; Underlines AI's potential to contribute to bioprocess design, optimisation of metabolic pathways for biopharmaceuticals, and the development of more efficient and humane research methods; Calls on the Commission to develop sector-specific and harmonised ethical guidelines for the use of AI across the lifecycle of medicines, ensuring coherence with the AI Act; Ask the Commission to prioritise the use of open-source software and AI, ensuring transparency, security, and control in processing sensitive data without compromising clinical effectiveness; Recognises the value of real-world data in improving the evidence base on how medicines are used, how safe they are, and how effective they are in real-life settings, as a complement to data from clinical trials;

30. Calls for targeted support for initiatives such as the European Virtual Human Twins to enable low-cost early-stage therapeutics and improve translational readiness; encourages the development of EU standards for the validation of digital tools used in pre-clinical and clinical research, in coordination with EMA and HTA bodies; supports sustained investment in key research infrastructures, including biobanks and modelling databases; calls for the development of new approach methodologies (NAMs) for safety assessments of emerging biotechnologies; underlines the need for a common EU framework ensuring the secure, interoperable and ethical use of health data, aligned with the European Health Data Space and grounded in transparent bioethical rules.

31. Recalls that valuable research in the EU has often been lost due to insufficient follow-up and weak links to market application; Stresses the need for fit-for-purpose mechanisms to ensure the traceability and effective translation of publicly funded research into marketable solutions; Underlines the importance of a cohesive EU life sciences ecosystem, encompassing academic and clinical research institutions, regulators, investors, start-ups and scale-ups, data and AI developers, manufacturers, clinicians, and distributors, to support biotechnology development at all stages and ensure that innovation translates into effective patient care; Reaffirms that commitment to basic research and scientific excellence is essential for a strong technological base;

32. Calls on the Commission and Member States to support the development of regional biotechnology innovation hubs integrating GMP manufacturing, regulatory expertise, clinical

infrastructure, and workforce training to accelerate the scale-up and delivery of advanced therapies;

33. Highlights the need for the EU Life Sciences Strategy and the Biotech Act to position Europe as the leading destination for investment in biotechnology R&D, manufacturing, and clinical trials, while ensuring tangible benefits for citizens; stresses the importance of stronger collaboration between universities, research centres, hospitals, patient organisations, start-ups, SMEs, and industry across all phases of biotechnology development, including biosimilars; emphasises the need to improve knowledge and technology transfer to translate EU-funded research into commercial and industrial applications, supported by public-private partnerships, development hubs, and a coordinated European biobanking infrastructure; calls for better coordination, long-term planning, and investment mechanisms, as outlined in the Draghi and Letta reports; underlines the importance of closing the gap between preclinical and clinical research to accelerate innovative diagnostics and treatments, particularly in areas of unmet medical need.

34. Stresses that the EU Life Sciences Strategy should be continuously evaluated through key performance indicators (KPIs) and adjusted to ensure it delivers both for citizens and EU competitiveness; Proposes patient-centric KPIs such as improved quality of life, longer lifespans, and better access to innovative and generic therapies, medical devices, and combination products, alongside competitiveness-oriented KPIs including patent production, foreign direct investment, faster time-to-market, translational research output, and capital raised for start-ups and scale-ups compared with other regions; Recalls, in this context, the need to support university ecosystems and research infrastructures, and to develop health centres of excellence to strengthen Europe's research networks;

Fostering Innovation, Investment and Financing

35. Encourages structured EU support to growing and connecting excellent biotechnology Innovation Districts in the EU with sufficient capacity, resources and scientific edge to promote new groundbreaking biotechnology discoveries, innovation and commercialisation.

36. Calls for a balanced innovation system that responds to public health needs, ensures data-sharing obligations and guarantees fairness and sustainability; Stresses that this must go hand in hand with timely market entry of biosimilar medicines on Day 1 after patent expiry, supported by a clarified and well-functioning Bolar exemption; Further underlines the importance of complementary reward mechanisms, such as subscription models, shared-risk approaches, and joint research or procurement programmes, to encourage investment, safeguard competitiveness, and ensure equitable and timely patient access to medicines;

37. Underlines the importance of adapting regulatory and access frameworks to the specific characteristics of emerging biological therapies, with proportionate pathways for clinical evidence, quality standards, and lifecycle management to ensure their safe and effective integration into healthcare systems; expresses concern about frequent delays that block access to more affordable treatments and place a financial burden on national healthcare systems; urges the Member States and the Commission to address the delays.

38. Underlines the need to increase public and private investment in biotechnology across the value chain, with particular focus on early-stage development where funding gaps for start-ups and scale-ups remain most acute; highlights the importance of directing these investments towards biotechnologies that address unmet medical needs, such as rare diseases, antimicrobial

resistance, and chronic conditions where traditional treatments have proven inadequate; Stresses the importance of dedicated instruments such as seed and venture capital, public–private co-investment vehicles, and risk-sharing mechanisms, as well as strong public funding for basic research; highlights that investment must take into account the long and complex timelines of biomedical projects, requiring structured phasing from research to commercialisation, and calls for progressive increases with the aim of reaching 3% of GDP by 2030; points out the need for a transparent regulatory framework that allows the evaluation of both European and foreign public investment in the development of medicines and medical products, ensuring such investment translates into improved accessibility; emphasises the importance of guaranteeing equitable access to biotechnological and digital therapies for all social groups, particularly persons with disabilities and vulnerable populations, by implementing accessible digital standards and reducing health system digital divides; recalls that much biopharmaceutical R&D is funded outside Europe and highlights the need for appropriate incentives to secure sustained investment and continued innovation within the EU.

39. Highlights the role of funds and programs such as Horizon and EU4Health in supporting the development of the biotechnology sector and the research use of health data and the implementation of its solutions in our healthcare systems; Welcomes the STEP programme as a timely initiative to boost EU investment in health biotechnology, but notes with concern that funding and private investment in research, development, and innovation remain well below the levels of global competitors such as the United States and China; Advocates for increased private investment to complement public funds, alongside faster and more agile financing mechanisms, simplified regulatory and operational frameworks, and stronger interconnected value chains, in order to close the innovation gap and address the persistent challenges of scaling up and commercialising research results in Europe; Encourages the use of existing instruments such as InvestEU and the Innovation Fund to provide targeted support to early-stage biotechnology projects, particularly in the ATMP space;

40. Stresses the need to provide adequate and targeted resources to support groundbreaking research and calls for streamlined access to follow-up funding based on research results, in order to accelerate commercialisation, scale-up and the valorisation of innovative biotechnology-based medical products Underlines the importance of ensuring that future EU funding frameworks, including the next Multiannual Financial Framework and the post-2027 Horizon Europe programme, prioritise innovative research in biotechnology, life sciences, and digital health;

41. Underlines the importance of building an inclusive and equitable biotech ecosystem that supports both innovative and biosimilar medicines, recognising their role in patient access, healthcare sustainability, and industrial capacity; Stresses the need for appropriate policy support given the shared complexity of biotech manufacturing for patented and off-patent products; Calls for strengthened collaboration among Member States with Commission support, pooling knowledge and resources, and leveraging public and private investments to address neglected areas;

42. Stresses the need to ensure that Europe is adequately equipped and appropriately funds the continuous evolution, improvement and transformation of its biotech research, development and manufacturing ecosystem, including for emerging technological platforms and for follow-on biosimilar medicines, in line with the Innovation Principle.

43. Stresses the importance of ensuring that biotechnological therapies are developed in line with patient and societal needs, with patient involvement across all stages; Underlines the

necessity of facilitating their equal distribution and timely commercialisation in the EU and guaranteeing affordability for all, while ensuring fair pricing that reflects both public investment and the risks undertaken by producers; Emphasises the need for innovative regulatory and assessment frameworks, systemic investments to support the sustainable integration of advanced therapies into healthcare systems, and the continued development, production, and availability of biosimilar medicines;

Skills, Training and Talent Mobility

44. Stresses the need to promote career opportunities in life sciences and address the brain drain by offering better working conditions to retain and attract skilled workers and researchers in the EU. Underlines the importance of specialised academic training, biotechnology education, and professional development, including stronger links between academia and industry and the promotion of scientific careers, particularly among women; Calls on the Commission and Member States to invest in training and awareness, accelerate the mutual recognition of professional qualifications, and establish coordinated talent attraction mechanisms such as simplified and harmonised visa procedures, automatic work permits for top graduates, and one-stop-shops for global STEM talent. Welcomes initiatives such as Choose Europe for Science as strategic opportunities to position the EU as a global hub for scientific careers and innovation;

45. Recalls the need for continuous training and upskilling of healthcare and biotechnology professionals to address the increasing technologization of healthcare, support the safe handling of biotechnological products, and ensure their effective integration into clinical practice; Stresses that the biotech ecosystem must adopt a comprehensive skills strategy, based on public-private partnerships, to build a future-oriented workforce and redesign healthcare processes as new roles emerge; Underlines the importance of promoting gender equality in STEM education and career pathways, recognising the biotech sector as a key opportunity to enhance the participation of women in science, research, and innovation;

46. Emphasises the need to retain and attract scientists and highly skilled professionals in order to safeguard the sustainability of the healthcare system and reinforce Europe's research capacity, while benefiting from an open, international and dynamic research environment; highlights the importance of attracting human capital to European universities, early encouragement of research careers through the education system, and the implementation of a gender perspective in STEM careers; Highlights the importance of strengthening programmes that promote women's leadership in biotechnology and consolidating intergenerational mentoring networks;

47. Points out the importance of funding university careers through public support mechanisms and the relevance of scholarships for students without resources to advance their university careers, as well as promoting scientific and academic mobility not only through projects but also with scholarships and funding mechanisms for students and academics;

48. Urges the Commission to explicitly address skills shortages in the context of the EU Biotech Act, notably through the strengthening of education, training, and lifelong learning initiatives, including the 'Union of Skills';

49. Highlights the importance of strategic international cooperation in biotechnology; calls on the Commission to support global research initiatives, promote regulatory convergence with like-minded non-EU partners, and diversify partnerships to include a broad range of countries and actors, while facilitating European SMEs' access to new healthcare markets;

50. Calls for the simplification and harmonisation of submission data requirements for manufacturing processes and encourages the EMA to provide up-to-date guidance on biotechnology-derived products, particularly where patient safety may be at risk;

Support for biotech start-ups, scale-ups & SMEs

51. Recognises the challenges biotechnology companies, particularly start-ups and SMEs, face in navigating the EU regulatory framework, and underlines the need for support mechanisms such as the EU Biotech Hub or Biotechnology Platform; Insists that these support mechanisms must prioritise public health, safety, environmental protection, and democratic oversight; Encourages the development of regulatory innovations and early communication between developers and regulators to address regulatory and market barriers; Supports efforts to facilitate the establishment and scale-up of companies in Europe, while reaffirming the importance of maintaining high safety and quality standards as a key competitive advantage of EU-approved products.

52. Notes that biotechnology is mainly developed in universities and research centres but also highlights the role of SMEs thanks to their agility and innovation, which foster the exploration and practical application of new ideas; highlights, however, that these SMEs face a significant and costly regulatory burden when developing and distributing their products.

53. Highlights the unique challenges which biotechnology SMEs, face due to the high-risk nature of their research and development, as well as patent fragmentation across the Union ;Stresses the importance of dedicating support and flexible financing models to assist them from early research to commercialisation; further stresses the need to increase access for SMEs to private investment in research, development and innovation to complement public funding and close the innovation gap with other leading countries

54. Underlines the importance of providing early and proactive scientific advice and regulatory guidance from the European Medicines Agency to innovative biotech SMEs, to help accelerate safe and timely market access; Encourages the establishment of targeted funding mechanisms for SMEs developing novel biological therapies, including bacteriophage-based treatments, given their public health importance, especially in combating antimicrobial resistance ; Calls on the Commission to promote public-private partnerships involving start-ups, SMEs, academic groups, and clinical partners, fostering access to shared tools, datasets, and digital validation frameworks like the European Virtual Human Twins, and to strengthen collaboration through platforms such as STEP;

55. Underlines the importance of tailored regulatory and competitive intellectual property (IP) framework to support biotechnology SMEs in the EU taking into account global competitiveness with other geo-economic blocs ; Stresses the need to evaluate potential IP rights extensions within the biotechnology sector, including exploring data exclusivity enhancements as an alternative incentive to patent-based exclusivities where appropriate , while ensuring that biosimilar medicines can enter the market after the expiration of relevant IP rights to guarantee timely and equitable access for patients; Encourages the facilitation of administrative and regulatory procedures and the establishment of mechanisms to mobilise public and private capital to better support biotechnology SMEs , and emphasises the value of providing incentives to promote stronger integration between universities and business programmes, fostering the commercial development of innovations;

56. Calls on the Commission to explore the creation of an EU Biotech Innovation Fund to support researchers, academia, start-ups and SMEs conducting R&D and innovation in healthcare biotechnologies, while ensuring complementarity with existing EU instruments such as Horizon Europe and the EIC, the fund should also allocate resources to the European Medicines Agency (EMA) and national competent authorities to support regulatory modernisation and the enhancement of interoperable digital tools and databases; stresses the need to accelerate the implementation of the Unitary Patent System to reduce costs, improve predictability, and increase the value of European intellectual property; stresses the importance of ensuring close alignment between the future EU Biotech Act and the broader Pharmaceutical Package, including both Regulation 2023/0131 and Directive 2023/0132, particularly with regard to incentive mechanisms for innovation in antimicrobials, regulatory sandbox approaches, lifecycle management of biologics, and the application of technical, scientific, and safety standards, as well as safeguards for the accessibility of medicinal products;

Ensuring Ethical Standards and Fundamental Rights

57. Highlights the importance of strong ethical oversight in biotechnology, including for AI-based tools;

58. Recognises that biotechnological advancements bring both opportunities and challenges, and may entail risks of misuse, unintended consequences or raise ethical concerns; Calls on the Commission and Member States to adopt a regulatory approach that is precautionary yet innovation-enabling, fostering responsible innovation while maintaining the highest standards of safety and reliability in line with scientific knowledge, safeguarding public trust, human rights, and strong EU ethical standards;

59. Calls for ethical coordination to be guided by the shared constitutional traditions of the Member States, the Charter of Fundamental Rights of the EU, the European Convention on Human Rights, and relevant international human rights instruments; calls on the Commission to promote cooperation among national ethics committees, ensuring impartiality, transparency, and the involvement of all relevant stakeholders, while encouraging the exchange of best practices and fostering cross-border dialogue on emerging bioethical issues;

60. Stresses the need for strong ethical oversight in the field of biotechnology in healthcare that enables advanced innovation, ensures it is always used in favour of patients, underlines the need to safeguard human dignity, promote inclusiveness, and prevent discrimination ; Underlines the importance of integrating principles of social justice, gender equality, and environmental sustainability into ethical assessments of biotechnological development and use; Encourages open dialogue with civil society, patients and experts to ensure broad societal support for emerging technologies, including gene therapies;

61. Stresses the need for transparent and clear communication on ethical considerations and science-based decision-making; underlines the importance of building and maintaining public trust in modern science and the biotechnology sector by strengthening health literacy, including through accessible formats for communicating new technologies, both for the general population and as part of healthcare professional training; Emphasises that biotechnology in healthcare should be directed exclusively towards therapeutic purposes; Rejects any attempt to impose global uniformity in bioethics at the expense of national traditions and values; Calls for tailored regulatory and financial support to improve their market access and strengthen competition, while upholding high standards of patient safety;

62. Warns against the use of genetic tests for purposes that lack clinical utility and recalls their prohibition in the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes;

63. Emphasises that the commercialisation of genetic tests without a clear health-related purpose is often accompanied by personal data collection practices that may not comply with EU standards on informed consent, data processing, and data sharing; urges the Commission to develop mechanisms to monitor and address such practices and ensure full compliance with EU data protection law.

64. Highlights that the growing use of crowdsourced and smartphone-based health data poses challenges to the consistency of health information and the effectiveness of informed consent; underlines that healthcare professionals must be involved in data collection processes to ensure data quality and patient rights are upheld; stresses the need for adequate training for these professionals, both in understanding the nature of the data collected and the legal and ethical rights of patients;

65. Stresses the importance of addressing ethical and legal considerations related to emerging gene editing technologies such as CRISPR; emphasises the need for ongoing dialogue with the scientific community, ethics bodies and the public to ensure responsible and transparent governance of these technologies; Notes that germline modifications are banned in the EU and considers that human embryos and gametes cannot be treated as commercial or industrial products; Calls on the Commission to assess the broader impact of biotechnology on the environment, to re-evaluate medical research practices involving animals, and to incorporate a gender perspective in biomedical research.

66. Emphasises that biosecurity risks must be managed alongside advances in biotechnology and biomanufacturing, ensuring the responsible access to and use of synthetic biology tools, gene-editing technologies, and biological materials; Calls for enhanced international cooperation on biosecurity *lex artis*, including the adoption of coordinated screening recommendations, attribution and traceability protocols and database integrity, that shall be managed by an European Union public body, aligned with global state of the art, so that EU-based biotech companies can benefit from international best practices while preserving their competitiveness;

67. Supports cross-border collaboration and regulatory harmonisation to speed up patient access to safe and effective biotech products; calls for early dialogue between developers, health technology assessment (HTA) bodies and payers;

68. Emphasises the critical role of high-quality biomedical and genetic data in accelerating research and personalised medicine; calls on the Commission to strengthen data governance frameworks that ensure privacy, security, and interoperability, enabling trusted and responsible cross-border data sharing for research and innovation; underlines the strategic importance of the European Health Data Space (EHDS) as a cornerstone for enabling secure access and secondary use of health data across the EU, and calls for its effective implementation to support biomedical innovation and improve patient outcomes.

69. Highlights the legal and ethical challenges of processing biomedical data in AI systems; stresses the importance of human oversight and dynamic validation of AI, adapted to the specificities of the sector and aligned with existing EU rules and ethical frameworks; underlines the need to address risks linked to AI systems operated from outside the Union, particularly

where data protection standards do not meet EU requirements, given the sensitive nature of health and genetic data. Calls on the Commission to ensure the smooth functioning of the Single Market for life sciences and biotechnology, working closely with Member States to prevent regulatory fragmentation and to guarantee legal certainty, predictability, and timely pathways to market for innovative products. Further calls on the Commission to facilitate long-term and practical international data-sharing agreements to enable global collaboration in AI-driven biomedical research and innovation.

70. Stresses the importance of developing human capital with expertise in biotechnology, promoting cross-border recognition of qualifications, and supporting the mobility of highly specialised professionals; calls for stronger partnerships between universities, research centres, and technology-based SMEs and start-ups to foster biotech entrepreneurship and accelerate innovation capacity across the EU.

Cross-Sectoral Dimensions of Biotechnology

71. Highlights the importance of assessing the long-term health and environmental impacts of biotechnologies, particularly in areas such as food and agriculture, engineered microbes, and other emerging applications beyond the healthcare sector.

72. Calls for ecosystem impact assessments to be included in the evaluation of biotechnologies, especially in agriculture; emphasises that environmental changes linked to the use of technologies like GMOs may have important long-term consequences for public health;

73. Emphasises that biotechnologies must be developed within a holistic and forward-looking framework, encouraging synergies with digital, AI, and other key technologies; Stresses that biotechnologies should work alongside other technologies, fostering parallel development to achieve more effective solutions and innovation, in line with a technology-neutral and forward-looking approach; emphasises the importance of encouraging synergies between biotechnology, digital technologies, artificial intelligence, and other emerging fields.

Ensuring a simplified and future-proof regulatory environment for European Biotech

74. Stresses the need to simplify, align, and better coordinate clinical approval processes across the EU, which are currently fragmented due to multiple, disconnected regulatory pathways with divergent timelines, requirements, and systems; Notes in particular that key legislative texts, such as the Clinical Trials Regulation (CTR), In Vitro Diagnostic Regulation (IVDR), and Medical Devices Regulation (MDR), are interpreted and implemented inconsistently across Member States, undermining legal certainty and delaying innovation.

75. Points out that accountability in biotechnology must be ensured through risk assessment and auditing mechanisms; whenever possible, these should be integrated directly into data management model and supported by reliable third-party certification schemes; calls for the development of integrated biosecurity applications as part of biotechnology promotion programmes; Urges the Commission to propose, within the framework of the future European Biotech Act, a comprehensive and integrated approach covering all key biotechnology sectors, in order to foster innovation and enhance the competitiveness of the European biotech ecosystem; Calls for stronger alignment between the EU's industrial, innovation, and health policies, to ensure that access and regulatory pathways can keep pace with scientific progress;

supports early dialogue between regulators, Health Technology Assessment (HTA) bodies, and developers to improve efficiency and patient access.

76. Stresses the need to build a coherent and accessible European framework for biotechnology that enhances regulatory clarity, improves cross-border patient access, and fosters innovation while maintaining high safety, ethical and environmental standards;

77. Calls on the Commission to include a clear and operational definition of biotechnology in the upcoming EU Biotech Act, to provide clarity for regulators, researchers, and industry stakeholders; urges the Commission to promote the acceleration of authorisation, permitting, and licensing processes across the EU for biotechnology-related activities, while ensuring regulatory coherence and harmonisation among Member States; Further urges the acceleration of clinical trial assessment timelines, to enhance the EU's global competitiveness and enable European patients to participate in multi-country trials; Stresses that efforts to streamline regulatory procedures must not compromise public health, long-term safety monitoring, or environmental sustainability; highlights the importance of maintaining the EU's strong record on environmental protection and sustainable water management. Calls on the Commission to promote the implementation of the Clinical Trials Regulation through projects that empower and streamline the conduct of multi-country trials in the EU, making it a more competitive region, including for the development of advanced therapies and personalised medicine.

78. Encourages the development of regulatory science capacities and dedicated guidance to support the quality, safety and effectiveness assessment of emerging biological therapies, including the use of real-world evidence where appropriate; Underlines the urgent need for greater transparency in clinical trials; notes that the lack of publicly available data holds back scientific progress, as it prevents researchers from learning from past studies, including those with negative or inconclusive results; Warns that this lack of transparency leads to duplication of efforts, waste of resources, and missed opportunities for innovation; Calls, therefore, for full disclosure of all clinical trial outcomes as a key element of a strong evidence base and of public health-driven research;

79. Stresses the need for the Commission to enforce the Cross-Border Healthcare Directive and to support Member States in applying its provisions to advanced cell and gene therapies (ATMPs), in order to improve patient access to specialised treatments across the EU; Recognises that many Member States lack national capacity in this field and that relying on a limited number of specialised centres at EU level is the most cost-effective and equitable solution;

80. Calls on the Commission to issue guidance on reimbursement pathways that would enable broader access to life-saving therapies. Encourages the Commission to make use of voluntary joint public procurement to pilot voluntary EU-level coordination for the procurement of medical products and ATMPs targeting ultra-rare conditions, where national access may currently be constrained by limited patient cohorts.

81. Calls for the revision of the Cross-Border Healthcare Directive to ensure greater patient access to treatment, in particular as regards orphan drugs and advanced therapies (ATMPs), across borders with a single set of authorisation rules and a single appeal system for rejections that may be unwarranted.

82. Calls on the Commission to support the creation of a dedicated EU matchmaking platform to connect translation-ready academic research with investors, manufacturers, and experienced developers, with the goal of accelerating the clinical development and commercialisation of promising biotechnology discoveries; Highlights that institutions should act as enablers of health-related biotechnology innovation, including off-patent-led advances in technology, manufacturing, and medicinal products; Emphasises that innovation should serve the public interest, uphold the highest standards of safety and ethics, and apply the precautionary principle where appropriate; Underlines the importance of democratic governance, independent oversight, and public participation in guiding the development and responsible use of biotechnologies in healthcare; Further stresses the role of institutions in promoting the integration of health-related innovations into healthcare systems to ensure that patients can effectively benefit from biotechnological progress.

83. Emphasises that biotechnology must be accessible to all EU citizens, regardless of their place of residence, socioeconomic status, or other barriers to healthcare access; Stresses the importance of strengthening European Reference Networks (ERNs) and establishing swift, simplified, and efficient cross-border healthcare mechanisms, particularly for innovative therapies that, due to their cost, complexity, or rarity, cannot be made available in all Member States; underlines the strategic importance of the upcoming negotiations on the Multiannual Financial Framework;

84. Calls for an ambitious budget that allocates sufficient resources to research, health, and innovation, enabling Europe to remain globally competitive while addressing societal challenges through cutting-edge science.

85. Calls on the Commission to support Member States in launching attractive programmes for health-related biotechnology companies, providing a collaborative environment for development through initiatives such as ecosystem hubs, innovation campuses, industrial parks, incubators, and technology transfer offices at universities and research centres; Further calls for the development and implementation of national biotechnology strategies to integrate biotech into healthcare systems, including clear plans for modernising the role of biotechnology in healthcare, strengthening research networks, and connecting them to the European Health Data Space.

86. Encourages the integration of environmental and ethical impact assessments in biotech development strategies, ensuring alignment with the Union's sustainability goals.

87. Calls for the diverse needs of the medical biotechnology sector to be addressed from a broad and forward-looking approach; Stresses the importance of tackling supply chain and operational challenges, including dependence on third countries for critical technologies, access to raw materials, essential equipment, and a skilled workforce, through coordinated EU action that fosters a resilient and innovation-driven environment;

88. Recognises that while AI systems and computing can significantly accelerate research and lead to new innovations—enabling better computational designs of biological systems and faster methods to design DNA and genomes of organisms—they can also lower the barrier to biological threats; therefore, calls for a robust governance framework to address these threats;

89. Stresses the importance for Member States to update their national action plans on rare diseases, in cooperation with the European Commission, academic institutions, and relevant stakeholders from the biotech sector; emphasises that the drafting of these plans should be

aligned with best practices exchanged among Member States and encourages that these be discussed within the Commission's expert groups;

90. Highlights the de-funding and staff reductions at the Food and Drug Administration (FDA) in the United States that undermine its role as the leading global medicines regulator, and which are likely to degrade EU patient access to innovative medicines and undermines global access to vaccines; underlines in this regard the urgent need to ensure that the European Medicines Agency (EMA) becomes the world-leading medicines regulator;

91. Stresses the urgent need to strengthen the capacity and resourcing of the EU regulatory network for medicines, namely the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) to ensure the timely and efficient evaluation of innovative therapies and to ensure that the EU is seen as the most attractive region globally to launch new medical products;

92. Stresses that appropriate funding and in-house expertise for the EMA and HMA is fundamental both for the development of new vaccines and novel antimicrobials as well as for EU preparedness for health emergencies including viral threats and anti-microbial resistance (AMR); underlines that the EMA should be appropriately resourced as to proactively provide scientific advice and provide clarity on the regulatory path to market and time to market to innovative biotech companies, including SMEs and developers of novel antimicrobials;

93. Recalls the ongoing backlog of Good Manufacturing Practice (GMP) inspections due to the COVID-19 pandemic which must be urgently addressed, whereas the mutual recognition agreement with non-EU regulators such as the U.S. Food and Drug Administration (FDA) are important to resolve this backlog; underlines that the EU inspections backlog now risks growing given the latest U.S. administration decisions to defund the FDA and to prioritise GMP inspections in the U.S.; stresses in this regard EU vulnerability in its ability to inspect manufacturing facilities, which is a major challenge to increasing biotech manufacturing capacity and therefore EU competitiveness and strategic autonomy in public health; calls in this regard for the conclusion of additional mutual recognition agreements with like-minded partner countries;

94. Stresses the need to urgently restore close collaboration between the European Medicines Agency and the UK Medicines and Healthcare products Regulatory Agency (MHRA) in order to strengthen innovation in biotech and life sciences in all of Europe, including but not limited to the EU;

95. Call for better coordination between key agencies and regulators including the EMA, the ECDC, DG SANTE and DG HERA, and work to ensure that the EU is seen as the best place in the world to invest in life sciences and biotechnology R&D, manufacturing and clinical trials;

COMPROMISE AMENDMENT 2

Compromise amendment covering AMs 191, 192, 193, 195, 196, 198, 199.

1. Acknowledges that advances in biotechnology, particularly in the fields of medically assisted reproduction and genetic testing for therapeutic and preventive purposes, represent a major opportunity to strengthen individual freedoms, improve reproductive health outcomes and support responses to fertility challenges in Europe, including the demographic decline in some Member States ; reaffirms, in line with its resolution of 24 June 2021 on the situation regarding sexual and reproductive health and rights in the European Union, that all persons must have equal and unequivocal access to medically assisted reproduction, free from any form of discrimination ; underlines the need for inclusive, rights-based and non-discriminatory policies in this field; encourages the development and transparent oversight of genetic innovations for therapeutic purposes, notably as a tool to help prevent the transmission of serious, debilitating or life-threatening hereditary conditions, in full respect of autonomy, informed consent and fundamental rights.