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Subject:	Draft Council conclusions on the Future of the European Health Union: A Europe that cares, prepares and protects - <i>Exchange of views</i>

Delegations will find in Annex a revised draft Council conclusions on the above-mentioned subject following the meeting of the Working Party on Public Health on 24 May 2024.

Changes in comparison to document 9692/24 are in **bold/underline** for additions and in ~~strikethrough~~ for deletion.

The Future of the European Health Union: a Europe that cares, prepares and protects

Draft Council Conclusions

RECALLING THAT

1. Access to health-care and prevention is a fundamental right¹ and Article 168 TFEU provides that a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.
2. ~~In proclaiming the European Pillar of Social Rights, t~~The European Parliament, the Council of the European Union and the Commission have made a shared political commitment to ensure within their competencies that everyone has the right to “timely access to affordable, preventive and curative health care of good quality”² ~~(Principle 16).~~
3. **Solidarity is a fundamental principle of the European Union and a pillar on which the Health Union should be built. In this regard, Member States should promote solidarity in the field of health.**
4. The COVID-19 pandemic demonstrated that the EU is a crucial actor when dealing with cross-border health threats, and that European citizens expect the EU to have a more active and effective role in protecting their health and wellbeing, beyond crisis management.³
5. The Commission Communication on ‘Building a European Health Union: Reinforcing the EU’s resilience for cross-border health threats’⁴ recognises that a strong European Health Union will protect our way of living, our economies and societies. It establishes health as a

¹ Article 35 of the Charter of fundamental rights of the European Union, OJ C 326, 26.10.2012, p. 391–407, ELI: http://data.europa.eu/eli/treaty/char_2012/oj

² **Principle 16 of the European Pillar of Social Rights (2017/C 428/09), (EUR-Lex 32017C1213(01) - EN - EUR-Lex (europa.eu))**

³ European Parliament, Directorate-General for Communication, Zalc, J., Maillard, R., Uncertainty/EU/hope – Public opinion in times of Covid-19 – Second round, European Parliament, 2020. <https://data.europa.eu/doi/10.2861/784439>

⁴ Communication (COM) 2020/724 final from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Building a European Health Union: Reinforcing the EU’s resilience for cross-border health threats (<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0724>)

precondition for the well-functioning of our society and economy and the wellbeing of the European citizens. **The European Commission adopted the Communication “The European Health Union: acting together for people’s health”, which summarises the Union’s response to the COVID-19 pandemic and subsequent components of a comprehensive European Health Union, ensuring Member States are better prepared for and respond to future health crises, putting equity in access to healthcare and protecting EU citizens at its centre.**

6. The combined challenges of an aging population-, technological and innovation challenges, existing and emerging new health threats, climate change and CBRN threats/-bioterrorism, socio-economic disparities, ~~population~~-migrations, shortages of medicinal products and medical devices, and a context of growing budgetary pressure increasingly put the sustainability of our health systems at risk. These challenges are of a systemic nature and require cross-border cooperation between the EU and its Member States, as well as with international partners.
7. Health workforce shortages are a challenge in all Member States (especially nurses and primary care professionals), exacerbated by demographic challenges and an aging health workforce, skill mismatches and uneven health workforce distribution between countries and within them.⁵ This leads to significant pressure on the health workforce. In OECD countries, the share of medical doctors over 55 years of age increased from 20% in 2000 to 35% in 2019. These shortages are compounded by geographic disparities across the EU, with data showing a 5.6-fold difference between the regions with the lowest and the highest density of physicians.⁶ Mismatches in skills of health workers and the skills required in a modern health system need to be addressed to reflect emerging needs and boost new care models.

⁵ European Commission, Directorate-General for Health and Food Safety, The State of Health in the EU: Synthesis Report 2023, Publications Office of the European Union, Doi:10.2875/458883

⁶ European Commission, Directorate-General for Health and Food Safety, State of health in the EU – Companion report 2021, Publications Office of the European Union, 2022.
<https://data.europa.eu/doi/10.2875/835293>

8. The rapid evolution of digital technologies impacts healthcare systems. The acceleration of digital tools in healthcare, including telemedicine, medical devices software and remote patient monitoring, as well as ~~self-testing~~ **digital self-diagnosis**, have the potential to improve patient outcomes and enhance healthcare accessibility. At the same time, technological advancements, such as Artificial Intelligence, provide opportunities for research, policy making, gathering and using real world data, the development of new medicinal products- and medical devices, and innovation for public health, but also introduce complex ethical- and societal -challenges that requires - coordinated action at national, European and international levels.
9. Health data play a pivotal role in enhancing individual patient care, advancing medical research, and shaping public health policies. It is fundamental that citizens have the transparency over the use of their personal health information, ensuring protection and security, as well as raising awareness to foster trust and encourage data sharing for the greater good. The benefits of utilising health data in line with European values and patients' data protection rules for society are immense, including the potential for early disease detection, personalized medicine- and improved healthcare outcomes.
10. Evidence-based disease prevention and the promotion of health- are key elements to reduce the burden of non-communicable diseases in a cost-effective manner. Non-communicable diseases cause almost 90% of all deaths and account for 77% of the disease burden in the EU, and their prevalence is increasing, thereby negatively affecting the health and wellbeing of the population, especially of vulnerable groups, the workload of the health workforce and the resilience of our health systems. Additionally, the burden of some diseases, for example neurodegenerative diseases, including dementia, is expected to increase greatly over the coming decades, with significant social impact not only on individuals, but also on their, families, communities, societies and the workforce.
11. Non-communicable diseases should be addressed in a cross-sectoral and a holistic manner, **taking into account areas with a high burden of disease or a high mortality**, through evidence-based, affordable and cost-effective health promotion, preventive interventions and disease management strategies. Mental health is a key aspect of wellbeing and impacts a variety of sectors both socially and financially. Health promotion and disease prevention, early development of psychosocial skills, in addition to national, also at European level, as laid down in the Healthier Together initiative, can reduce the prevalence of non-

communicable diseases by as much as 70%.⁷ For this reason, investments in health promotion and disease prevention, **as well as in treatment and rehabilitation**, can lead to **a healthier population**, a healthier and increased workforce potential and economic gain for the Union in the long run.

12. Evidence-based disease prevention and management are key elements to reduce the burden of communicable diseases in a cost-effective manner. Communicable diseases in the EU account for an increasing disease burden. These include emerging and re-emerging infectious diseases and outbreaks, as well as sustained increases. Further, some infectious disease experiencing declining incidence still -do not reach elimination targets. The sustained increase of sexually transmitted infections is of particular concern as it affects the sexual and reproductive health, **especially** of the younger populations.
13. Health-related unmet patient and societal needs encompass both unmet needs arising from the direct impact of a health condition on patients' lives (patient needs) and unmet needs arising from social externalities induced by a health condition (societal needs). Patient and societal needs can relate to the health, healthcare and social impact of a condition. A holistic approach requires that besides treatment development, also prevention, diagnosis, coordination and organisation of care, and availability of information to patients, among others, is considered to meet health-related unmet patient and societal needs.
14. In a patient-centred healthcare system, research and development (R&D) focus on addressing high-priority health-related unmet patient and societal needs. Needs may relate e.g. to increased life expectancy, quality of life, healthcare-related costs and accessibility to healthcare services or preventive measures. While important efforts are being done to orient R&D towards rapidly changing -needs, current frameworks for innovation and supply of health interventions -partially fail to stimulate solutions for priority health-related needs both from the patients' and the societal point of view. This is due to a lack of evidence on what the highest unmet needs are, a lack of evidence on relevant expected outcomes or a lack of commercial or public interest in unheeded needs. Structured scientific evidence on what the highest unmet needs are, is thus necessary. This should make it possible to direct private and public R&D investments to the highest unmet needs.

⁷ European Commission, Directorate-General for Health and Food Safety, Healthier together – EU non-communicable disease initiative, Publications Office of the European Union, 2022, <https://data.europa.eu/doi/10.2875/195572>

15. ~~To address priority needs in healthcare and innovation policies a~~An independent needs-evidence database **can help to support addressing priority needs in healthcare and innovation policies** is necessary. This database should be governed by a research infrastructure at EU level and gather disease-specific, disease-overarching, and systems-level scientific evidence, collected in a standardised way, based on a framework with transparent needs criteria. This framework should be developed by independent researchers, taking into account input from stakeholders, including citizens, patients, healthcare providers, policy makers and developers- **Data from existing national and international databases, including from Eurostat, can, whenever relevant, be used to feed into the needs-evidence database.** ~~Other initiatives, e.g. initiatives such as the 1+ Million Genomes Initiative can~~ **contribute to realise the full potential of data sharing for wider health benefits, including developing possible solutions for identified unmet health-related needs, along with supporting research and health policy making.** ~~, in a next step, help to identify possible solutions for identified unmet health-related needs.~~
16. Targeted legislative initiatives and non-legislative measures have been taken to reduce the risk of shortages of medical devices and in-vitro diagnostic medical devices. The Regulations on medical devices and in-vitro diagnostic medical devices are necessary to ensure a high level of safety and health for European citizens, whilst supporting innovation and ensuring a smooth functioning internal market by establishing a robust, transparent, predictable and sustainable regulatory framework. Nonetheless, there are remaining challenges related to the implementation of the Regulations on medical devices and in-vitro diagnostic medical devices, including increased costs and length of conformity assessment procedures, notably for orphan devices, increasing risks of supply disruptions and withdrawal of some medical devices and in-vitro diagnostic medical devices from the EU market needed for appropriate patient care. This also affects the competitiveness and innovation capacity of the European medical device industry, in particular small and medium sized enterprises.

17. The European Centre for Disease Prevention and Control (ECDC) estimates that 35,000 people die each year in the EU from antimicrobial-resistant infections. Meanwhile, the total consumption of antibacterials for systemic use has decreased by only 2.5% since the baseline year of 2019, indicating slow progress towards the EU target reduction of 20% by 2030.⁸ Therefore, more efforts to promote the prudent use of antibiotics are needed.
18. Climate change -health-related hazards, exposures, vulnerabilities, and risks from climate change are showing clear, accelerating trends in Europe.⁹ Climate change leads to increased risks of both communicable and non-communicable diseases, creating new vulnerabilities and exacerbating existing inequalities by disproportionately affecting vulnerable population groups. Climate and public health policies can have important synergies. This should be seen in line with the One Health approach recognising the strong interlink between the health of humans, animals, and the environment. Efforts to decarbonize the European Union, and in particular efforts to decarbonize European healthcare systems must, **while taking into account the impact on availability and affordability,** continue in order to limit these effects.
19. The EU's capacity to conduct public, large scale multinational clinical trials is essential for the generation of reliable evidence on safety and effectiveness of interventions, and to strengthen Europe as a hub for development and manufacturing. During the pandemic, an unprecedented number of academic clinical trials were launched in the EU to accelerate COVID-19 treatment and prevention. Strengthening future initiatives through more efficient coordination across Member States and among national ethic committees is key, since the lack thereof resulted in numerous underpowered trials that could not provide meaningful results and a duplication of research activities. Moreover, the lack of clarity about the interface with related legislation such as Regulations on medical devices and in-vitro diagnostic medical devices is an obstacle to the efficient conduct of clinical trials. The creation of the MedEthicsEU group is supported by the Commission to promote cooperation between national ethics committees involved in clinical trials and to promote progress in the coordination for the implementation of the Clinical Trials Regulation as

⁸ European Centre for Disease Prevention and Control, Merk, H. Diaz Högberg, L. Pachouras, D. et al., Assessing the health burden of infections with antibiotic-resistant bacteria in the EU/EEA, 2016-2020. ECDC; 2022. <https://data.europa.eu/doi/10.2900/73460>

⁹ European Environment Agency, Is Europe on track towards climate resilience? - Status of reported national adaptation actions in 2023, Publications Office of the European Union, 2023, <https://data.europa.eu/doi/10.2800/112091>

developed in the Clinical Trials Coordination and Advisory Group (CTAG). It is also important to continue to pursue the efforts with a view to enabling a smooth operation of the coordinated assessment procedure relating to clinical investigations and performances studies.

20. A coherent, transparent and effective EU institutional framework is key to strengthening preparedness and crisis response at EU level in an all-hazards and whole-of-society approach in line with the European Council conclusions of 21 and 22 March 2024. Health emergency prevention, preparedness and response is indispensable to prepare for future crises. EU preparedness contributes to global health security and EU's role in global health. The European Union adopted numerous reforms in the emergency governance structure which remain yet to be fully implemented and tested, including the implementation of the serious cross-border threats to health Regulation, extension of the ECDC and European Medicines Agency (EMA) mandates and the establishment of the EC service Health Emergency Preparedness and Response Authority (HERA). The 2023 State of Health Preparedness Report outlines the level of implementation already achieved and where further action and efforts are needed to ensure its proper implementation.
21. Shortages of medicinal products-put the health and wellbeing of citizens at risk. The delocalisation of the manufacturing of medicinal products and Active Pharmaceutical Ingredients (API) to a limited number of locations outside the EU has accentuated concerns about security of supply inside the EU. Addressing vulnerabilities in the supply chain of critical medicinal products is a key action for the resilience of EU healthcare systems. The need to address vulnerabilities was recognised by the European Council Conclusions of June 2023, the Leaders' Declaration in Granada in October 2023 and the Commission Communication on 'Addressing medicine shortages in the EU' of that same month, which puts forward a set of short-term and longer-term actions to address shortages of critical medicinal products and enhance their security of supply in the EU.
22. To improve access to medicinal products, medical devices and in-vitro diagnostic medical devices under the current legal framework, and as the European Council indicated in its conclusions of 17 and 18 April 2024, it is important to ensure the cross-border movement of goods, including of strategic goods such as medicinal products, while addressing transparency in supply chain. ~~To this effect, respecting the principle of solidarity, it is key~~

~~that national measures aimed at ensuring public health interests, including availability of medicinal products, take into account the impact on the availability in other markets.~~

23. Strategic investments in health are crucial to reinforce the sustainability and resilience of European health systems. The EU provides multiple funding streams at the disposal of Member States and stakeholders. However, Member States face challenges finding and accessing existing EU funds to support impactful investment in national health system transformations. It is of great importance that the work programmes of the EU existing funding instruments promoting research & innovation and those supporting implementation of policy initiatives are in synergy with national priorities in the health area and the nexus between research, innovation, policy and funding instruments is upheld.

THE COUNCIL OF THE EUROPEAN UNION

STRESSES the urgent need to continue to build upon and improve the European Health Union in light of the systemic challenges our health systems are facing today,

INVITES the MEMBER STATES and the EUROPEAN COMMISSION in close cooperation and in accordance with their respective competences to:

I. address the health workforce crisis

INVITES the MEMBER STATES and the EUROPEAN COMMISSION to:

24. ~~SUPPORT~~ **CONSIDER PRIORITISATION of** investments in the health workforce through national investments and the use of existing EU funds and technical support, **in order to facilitate targeted investments in the health workforce.**
25. SUPPORT the development and uptake of innovative digital tools that can assist health professionals in their everyday clinical practice, as well as the integration of digital competences in ~~the curricula~~ **training and further education**, and the development of digital health literacy.

26. ENHANCE EU-level collaboration in order to support- knowledge sharing between Member States on national health workforce strategies, in line with and complementing the new Action plan to tackle labour and skills shortages presented in March 2024¹⁰.
27. IDENTIFY an appropriate forum composed of Member States, the Commission and stakeholders, including the EU social partners of the healthcare sector where appropriate, to discuss appropriate actions at EU-level in coordination with actions at national level.

INVITES the EUROPEAN COMMISSION to:

28. DEVELOP a comprehensive approach on health workforce at EU level that supports Member States and their strategies, in line with the Framework for action on the health and care workforce in the WHO European Region 2023–2030 and WHO Global Code of Practice on the International Recruitment of Health Personnel, taking into account all relevant dimensions such as planning and forecasting, national and international recruitment and training, continuous professional development, retaining staff, sustaining mental and physical health of healthcare workers, working conditions, the challenges of skill mix, life-long training and retraining, including on digital competences- and- leadership skills, and surge capacity to cope with crisis situations.
29. IDENTIFY elements, instruments and good practices to support national strategies, such as the development of common goals, exchanging good practices and information, setting up joint actions taking into account the lessons learned and outcomes of the current and previous actions, including joint actions, on health workforce and enhanced access to existing EU funding mechanisms to enable the proposed actions.
30. ASSESS the effects of the ~~internal market~~ legal frameworks at EU level **regarding the regulation of the qualifications of health professionals and that impact the organisation of health professions**, to address the health workforce crisis, **whilst preserving the mobility of health professionals and** in respect of Member States' and Union competences. This assessment should be based on a consultation of Member States health authorities, social partners and civil society actors as well as take into account the ageing population and a correspondingly ageing health workforce.

¹⁰Communication from the Commission COM(2024) 131 final to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Labour and skills shortages in the EU: an action plan
<https://ec.europa.eu/social/BlobServlet?docId=27473&langId=en>

31. CONSIDER, where appropriate and necessary, and based on the above-mentioned assessment, actions to ensure that these legal frameworks can enhance national health system goals and national health workforce strategies, in line with Single Market principles.

II. address priority needs in healthcare and innovation policies

INVITES the MEMBER STATES and the EUROPEAN COMMISSION to:

32. STRENGTHEN synergies between existing and upcoming infrastructures and programmes in Member States and at EU level to set up an independent needs-evidence database, which identifies health-related unmet patient and societal needs ~~to support EU policies and~~ using a scientific approach.
33. CONSIDER to set up a voluntary Member State driven mechanism for the appraisal and prioritisation of the highest disease-specific, disease-overarching, and systems-level, health-related unmet patient and societal needs, based on the scientific evidence about the disease-specific needs and using transparent assessment criteria.

INVITES the EUROPEAN COMMISSION to:

34. EXAMINE the need for an EU initiative to coordinate and direct public support, within Union competence, to adequately and effectively address the most pressing health-related unmet patient and societal needs. This initiative ~~should consider that different types of (health)interventions, including treatments optimisation, may provide a solution to the identified health-related unmet patient and societal needs, taking into account the potential of the EU cooperation on health technologies~~ assessments.
35. CONSIDER the identified most pressing health-related needs in priority setting for the ~~next~~ EU framework programmes in the field of research, innovation and health, and the EU health programme once the database contains sufficient information.

INVITES the MEMBER STATES to:

36. ENHANCE the voluntary exchange of information and best practices on national approaches on reimbursement policies in existing fora with the aim to provide predictability to healthcare developers as to how health-related unmet patient and societal needs are

considered in decisions about including cost-effective health interventions in the national benefit package.

37. CONSIDER the identified most pressing unmet health-related patient and societal needs when deciding on national research funding and incentives.

III. take action in the field of prevention of non-communicable diseases

INVITES the MEMBER STATES and the EUROPEAN COMMISSION to:

38. STRENGTHEN EU policies on health promotion, including mental health and the prevention of non-communicable diseases, thereby addressing the disease groups responsible for more than 80% of the disease burden in the EU countries and the leading causes of avoidable premature deaths¹¹ in line with the health in all policies approach.
39. PROMOTE healthy environments and communities that encourage and enable healthy lifestyle choices, addressing tobacco and related products and alcohol, unhealthy diets, physical inactivity, psychosocial and environmental factors including climate change.
40. CONTINUE **and STRENGTHEN the work of the Healthier together - EU Non-Communicable Diseases Initiative** ~~supporting~~ **by implementing and completing in a stepwise manner an overarching, integrative,** comprehensive, **and** multi-sectoral ~~and prevention-oriented EU-level~~ **approach** actions, based on and completing the framework of the 'Healthier Together' EU non-communicable diseases initiative, to support the implementation of effective policies in the area of NCDs, **including as strands, action plans on health determinants, cancer, cardiovascular diseases, chronic respiratory diseases, diabetes, mental health and neurological disorders, and rare diseases.**

¹¹ The EU 'Healthier Together' Non-Communicable Diseases Initiative.
https://health.ec.europa.eu/document/download/18238342-e8a8-493a-8afe-ed44da987800_en?filename=ncd_initiative_factsheet.pdf

INVITES the EUROPEAN COMMISSION to:

41. ADOPT the legislative proposals and continue to work on non-legislative measures announced under Europe's Beating Cancer plan, with a special focus on the initiatives related to determinants of health including socioeconomic and commercial determinants such as legislative and non-legislative measures announced for achieving a tobacco-free Europe, reducing harmful alcohol consumption and improving health promotion through access to healthy diets and physical activity.
42. CONTINUE to work on the ~~non-legislative~~ measures of the Healthier together – EU NCD Initiative.
43. CONSIDER additional action to ensure a better protection of health of European citizens from environmental risk factors.
44. **ADDRESS the issue of the marketing of addictive substances towards children on social media and develop a framework that puts greater responsibility on social media providers for advertising of addictive substances aimed at children and that are illegal in Member States.**
45. **CONSIDER how the negative mental and physical health effects on children of extended use of social media and screen based technologies can be addressed in order to improve the well-being of children in Europe.**

IV. effectively combat antimicrobial resistance

INVITES the MEMBER STATES and the EUROPEAN COMMISSION to:

46. IMPLEMENT the Council recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach.¹²
47. WORK towards a more integrated one-health approach in the monitoring and the surveillance of antimicrobial resistance **in organisms associated with** humans, animals, plants and the environment and consumption of antibiotics by humans and animals.

¹² Council recommendation (2023/C 220/01) on stepping up EU actions to combat antimicrobial resistance in a One Health approach OJ C 220, 22.6.2023, p.1-20. [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023H0622\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023H0622(01))

48. STRENGTHEN coordinated cooperation of the EU and its Member States with third countries to exchange and disseminate best practice, in line with the One Health approach, related to infection prevention and control, diagnostics, surveillance, access to effective antibiotics, as well as use and stewardship of antimicrobials, including antibiotic medicinal products and veterinary medicinal products.

INVITES the EUROPEAN COMMISSION to:

49. DEVELOP guidelines, in close collaboration with Member States and relevant agencies, to support evidence-based cost-effective policies to reduce inadequate and inappropriate consumption of antimicrobials as well as guidelines for addressing environmental aspects in AMR National Action Plans within the framework of the One Health approach and guidelines for infection prevention policies, especially for healthcare, veterinary and environment workforce.
50. FURTHER EXPLORE and IMPLEMENT **an EU funded Union pull incentive from existing EU funds** ~~multi-country pull incentive schemes~~ in order to improve innovation, the development of new antimicrobials and access to existing and new antimicrobials in line with the Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach ~~and to establish a dedicated budget for the implementation of the most suitable scheme.~~

INVITES the MEMBER STATES to:

51. ENHANCE and REINFORCE more performance-based antimicrobial stewardship and infection prevention and control in all related sectors.

V. strengthen the EU ecosystem for ~~public~~ clinical trials

INVITES the MEMBER STATES and the EUROPEAN COMMISSION to:

52. ESTABLISH a coordination mechanism to prioritise and streamline the funding of clinical trials by the EU and the national funders to be implemented in the EU for an optimal preparedness and response to public health infectious diseases emergencies.
53. IMPROVE EU-level public clinical trial databases, notably by connecting the Clinical trials in the European Union portal with the future EUDAMED and additional databases,

where appropriate, and, with the common goal of improving visibility of ongoing and future clinical trials, **streamlining** ~~creating the~~ functional programming interface for uptake into **of** national clinical trial databases, where appropriate and in line with European values and data protection regulations.

54. ESTABLISH an EU collaborative effort for enhanced public-private partnerships around the recruitment into clinical trials.
55. COORDINATE trial funding processes between the EU and national funders in terms of scope, review process and accelerated approvals when justified, where appropriate.
56. STRENGTHENS research and clinical trial governance across Member States through enhanced coordination of regulatory and ethical review across Member States.
57. ESTABLISH a European partnership on pandemic preparedness to better coordinate pandemic preparedness research and innovation along the whole research continuum including the consolidation of an EU-wide network of ever-warm clinical trial sites.
58. SUPPORT collaboration at national level and between Member States to facilitate the conduct of clinical trials of medicinal products combined with performance studies of in-vitro diagnostic-medical devices or clinical investigations of medical devices Additionally, continue providing support to initiatives intended to improve the ~~interface~~ **synergies between** the IVDR/MDR/CTR, such as Combine project.

INVITES the MEMBER STATES to:

59. STREAMLINE data collection **principles** to ~~secure~~ **enhance** access, linkage and sample sharing between different **clinical research** databases and **data from clinical** trials, nationally, **at** European **level** and internationally in line with European values and data protection standards.

VI. take actions in the fields of preparedness and communicable diseases

INVITES the EUROPEAN COMMISSION to:

60. ENSURE to keep preparedness and response to cross border health threats high on the agenda.
61. ORGANISE sectorial exercises followed by a large scale simulation exercise on health crisis management in the EU between all relevant actors at national and European level, taking into account an all-hazard and whole-of-society approach.
62. CONDUCT a thorough evaluation of the post-pandemic EU health emergency governance framework and, where necessary, subsequently clarify the relations between relevant entities involved in crisis preparedness and management. The evaluation should take into account the results of the evaluation of the Regulation on serious cross-border threats to health and of the review of the operations of HERA, the role of the EMA and the ECDC in crisis preparedness and management, as well as taking into account the results of the sectorial exercises. This evaluation should also consider new crisis scenarios impacting public health such as climate change-related, hybrid, cyber or security threats.

INVITES the MEMBER STATES and the EUROPEAN COMMISSION to:

63. STRENGTHEN and PRIORITISE EU and national policies on health promotion and the prevention and management of communicable diseases as well as those strengthening the continuum of preparedness including prevention and societal resilience.
64. PROMOTE healthy and stigma-free environments and engaged communities that encourage healthy ~~and~~ lifestyle choices, addressing the promotion of vaccination, as well as other primary prevention measures to prevent communicable diseases, **such as sexually transmitted infections**, the impact of environmental factors, migration and climate change.
65. **STRENGTHEN the fight against mis- and disinformation on health, by implementing, when available, models for evidence-based awareness-raising campaigns, by supporting research on this topic, and by promoting transparency on targeted campaigns against vaccination, including on social media.**

VII. improve the security of supply for and access to medicinal products, and the security of supply for medical devices and in-vitro diagnostic medical devices

INVITES the EUROPEAN COMMISSION and the MEMBER STATES to:

66. CONTINUE the work on addressing vulnerabilities in the supply chains of critical medicinal products, including in the Critical Medicines Alliance and, where appropriate, make suggestions to improve their security of supply with a focus on strengthening EU-wide manufacturing of critical medicinal products, while ~~and ensuring~~ better access to medicinal products in all Member States and an innovative and competitive pharmaceutical sector.
67. CONTINUE the work on mitigating critical medicine shortages in the context of crisis preparedness and management, and addressing supply chain vulnerabilities of critical medicinal products in the MSSG provided for in Regulation (EU) 2022/123 and beyond.
68. CONTINUE monitoring closely the implementation of the Regulations on medical devices and in-vitro diagnostic medical devices, to ensure they achieve their stated objectives in practice which include ensuring a high level of safety and health for European citizens, whilst supporting innovation. All necessary measures should be taken to maximise the availability of data on the supply and demand of medical devices throughout the EU, in line with European values and data protection rules, and on this basis to secure the availability of devices needed for maintaining a high level of patient safety and care, to allocate the resources necessary for an effective management of the regulatory system and to call on all actors, in particular manufacturers and notified bodies, to make full use of the extended transitional periods provided for in the Regulations and non-legislative measures to ensure timely transition to the Regulations.
69. STRENGTHEN collaboration -and early involvement of - competent authorities responsible for medical devices and in-vitro diagnostic medical devices and other stakeholders in developing and meeting environmental requirements applicable to those devices.
70. PROMOTE the voluntary exchange of data, in line with European values and data protection rules, in order to get an overview, on the supply and demand of critical medicinal products on the EU market, the manufacturing site of critical medicinal products and their active substances and the vulnerabilities and strategic dependencies of medicinal

products. Duplication of data exchange for the national authorities and the pharmaceutical industry should be avoided.

71. DEVELOP a common strategic approach on a voluntary basis to ~~monitor~~ stockpiling for preparedness for cross-border health emergencies and impactful supply disruptions, giving due consideration to sensitive aspects such as national defence stocks, in line with the Commission Communication introducing HERA and -the Commission Communication on Addressing medicine shortages, while- taking into account -solidarity between Member States and their experiences.
72. ENCOURAGE a worldwide level playing field in environmental rules applying to the manufacturing of medicinal products, excipients and active substances, ~~e.g. by gradually implementing a substantiated environmental risk assessment covering the manufacturing of all medicinal products medicines and implementing MEAT criteria, where appropriate, with the focus of diversity and long-term security of supply in public procurement considering EU-based manufacturing,~~ while respecting WTO law (GPA) and other binding international commitments.¹³.
73. MAKE USE of existing tools within the current legal framework in order to improve access to medicinal products and medical devices in Member States facing challenges, in particular where there are low volumes, such as in the case of orphan medicines, with voluntary participation of Member States in such initiatives.

INVITES the EUROPEAN COMMISSION to:

74. CONSIDER to propose ~~the need for~~ a Critical Medicines Act, taking into account, amongst others, the findings of the Critical Medicines Alliance, to provide a legal framework to address supply chain vulnerabilities of critical medicinal products, with the aim to strengthen EU production and diversify vulnerable supply chains of critical medicinal products which could include state aid and public procurement measures, while respecting Member State competences and WTO law (GPA) and other binding international commitments (e.g. trade agreements with relevant public procurement chapters).

¹³

75. PROPOSE a comprehensive medicinal products roadmap in order to help competent authorities and other relevant stakeholders, including manufacturers, in addressing the environmental risks identified in the manufacturing process, in the upstream supply chain and across the lifecycle of these products to increase sustainability, to reduce greenhouse gas emissions and meeting environmental requirements applicable to those products.
76. ~~CONSIDER a new legislative tool that would allow for the Joint Procurement Agreement mechanism to be used for purchases of medicinal products, medical devices and in-vitro diagnostic medical devices that do not fall within the definition of medical countermeasures as stated in Decision 1082/2013/EU on serious cross-border threats to health, especially of those for rare diseases.~~
77. EXAMINE remaining challenges related to the implementation of the legislation on medical devices and in-vitro diagnostic medical devices with a specific focus on its performance to ensure a high level of safety and health for EU citizens, whilst supporting innovation and also -ensure- the availability of devices for small patient populations (especially ‘orphan devices’ or ‘pediatric devices’) and to fostering the development and availability of innovative and affordable devices in the EU; special attention should be given to the governance system, the additional resource and expertise requirements as well as- the costs and administrative burdens stemming from the implementation of the legislation, especially for SMEs; if appropriate, come up with a legislative proposal to address any identified shortcomings with a view to making the EU regulatory system sustainable in the medium- and long-term to ensure it is implemented as originally intended and agreed and to ascertain a high level of patient care and safety in the EU.

INVITES the MEMBER STATES to:

78. CONTINUE the work of the EU voluntary solidarity mechanism within the Medicine Shortages Steering Group (MSSG) while considering national requirements.
79. ASSESS the need to **for financial aid as well as dedicated instruments** ~~set up a special Important Projects of Common European Interest (IPCEI)~~ to support sustainable production of critical medicinal products **in the EU**.

80. **STRENGTHEN voluntary collaboration and accelerate regional initiatives to enhance access to innovative medicines, taking stock of the experiences achieved, sharing best practices in joint negotiations and, increasing transparency and expertise among collaborating Member States.**

VIII. address the impact of climate change and on health

INVITES the MEMBER STATES and the EUROPEAN COMMISSION to:

81. ESTABLISH in collaboration with Member States an EU agenda on climate and health following the One Health approach on both the adaptation and mitigation side. This agenda should take account of the EU research agenda on climate and health. It should consider the impact of extreme temperatures, synergies between temperature and air pollution, vector borne diseases, extreme weather events such as floods and droughts, water quality and food security. The agenda should address the health benefits of mitigation measures and promote the development and availability of effective medical countermeasures to respond to climate-sensitive infectious diseases.
82. ENCOURAGE cooperation in terms of early-signalling, monitoring and response to climate-related health threats, where EU coordinated action can have a beneficial and complementary role on the work already being done in the Member States.
83. WORK TOWARDS reducing the impacts of healthcare systems on climate and the environment in the EU. Ensure that national strategies, EU legislation, existing tools and funds enable the health and care sector to manage the transition to decarbonised health care systems, taking into account the importance of the sustainability of the healthcare sector, **the impact on availability and affordability**, and the reduction of its climatic footprint.

IX. improve EU implementation tools

INVITES the MEMBER STATES and the EUROPEAN COMMISSION to:

84. INITIATE an in depth discussion in the EU4Health Steering Group in order to make the mechanism of joint actions more effective and sustainable in addressing future trends in health and Member States needs to implement priority areas within the EU Health Union.

85. STRENGTHENING the coordination between policy and funding instruments, ensuring that available EU funding - continues to be used in a strategic, effective and sustainable manner, in line with health priorities of Member States and taking into account technical support, with a focus on implementing transformations with long-term impact.
86. ASSESS the current landscape of EU funds and its corresponding legislative framework to better align EU funding with Member States national health policy priorities.

INVITES THE EUROPEAN COMMISSION TO:

87. ESTABLISH an EU Health investment Hub **in consultation with Member States and taking into consideration the lessons learnt from the Technical Support Instrument project “EU Resources Hub for sustainable investing in health”**, to provide on-demand, tailored and fit-for-purpose support to Member States in accessing and using existing EU funds delegated to Member States for the planning, financing and implementation of national health projects of high interest and impact and within the context of national health reforms and health care transformation processes, as well as identifying opportunities - from different EU programmes for projects with objectives that span across multiple EU funding instruments and their priorities;
88. IMPROVE and update the ~~tools offered~~ **procedures** to **facilitate** access **to existing** fundings.
89. CONTINUE to work on the consolidation of the initiatives already launched under Europe’s Beating Cancer Plan that have demonstrated their potential, to ensure **sustainable progress for the benefit of cancer patients in Europe**, ~~robust and sustainable structures, in order to fully harness their impact and consolidate the progress achieved since 2021.~~

1. EU Interinstitutional

- Article 168 of the Treaty on the Functioning of the European Union
- The European Pillar of Social Rights

2. Council:

- Council conclusions on Common values and principles in European Union Health Systems, approved on 22 June 2006
- Council conclusions on investing in Europe's health workforce of tomorrow: Scope for innovation and collaboration, approved on 7 December 2010
- Council conclusions towards modern, responsive and sustainable health systems approved on 8 July 2011
- **Council conclusions on the economy of wellbeing, approved on 24 October 2019**
- Council conclusions on strengthening the European Health Union, approved on 20 December 2021
- Council conclusions on Access to medicines and medical devices for a Stronger and Resilient EU, approved on 15 June 2021
- Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach, adopted on 13 June 2023
- Council conclusions on mental health, approved on 30 November 2023

3. European Council

- European Council conclusions of 30 June 2023
- European Council conclusions of 21 and 22 March 2024
- European Council conclusions of 17 and 18 April 2024

4. European Commission

- Commission legal proposals for a ~~reform~~ ~~revision~~ of the EU pharmaceutical legislation (COM/2023/193 final and COM/2023/194 final) **and Commission Communication on**

Reforming of the pharmaceutical legislation and measures addressing antimicrobial resistance COM(2023) 190 final

- Commission Communication on Addressing shortages in the EU, published on 24 October 2023, **COM(2023) 672 final**
- **Commission Communication on The European Health Union: acting together for people's health, published on 22 May 2024, COM(2024) 266 final**
