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Delegations will find in the annex the Council Conclusions on strengthening the European Health Union, as approved by the Council (EPSCO) at its 3834th meeting held on 7 December 2021.

ANNEX

Council Conclusions on strengthening the European Health Union

Introduction

The fight against the COVID-19 pandemic continues to be one of the key priorities all around the world and has put health high on the agenda of geopolitics, security and the economy. The crisis has highlighted the need for the EU and its Member States to better coordinate their preparedness and response mechanisms when faced with health emergencies, as part of a wider effort to work together towards building a strong and resilient European Health Union and to contribute, in collaboration with other countries, to improving global health security.

In the EU context, the COVID-19 pandemic has had a significant impact on the priorities of the Multiannual Financial Framework, for example more funding has been provided for health through the new EU4Health programme[1], the Recovery and Resilience Facility[2], Horizon Europe[3] and the Cohesion Policy funds[4]. Increased funding brings opportunities as well as a responsibility to use it in a more strategic way in order to strengthen EU capacities and ensure that investments in health systems are consistent with the national priorities of the Member States.

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1 Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (Text with EEA relevance) (OJ L 107, 26.3.2021, p.1-29)

2 Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 February 2021 establishing the Recovery and Resilience Facility (OJ L 57, 18.2.2021, p.17-75)

3 Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (Text with EEA relevance) (OJ L 170, 12.5.2021, p. 1-68), https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/coronavirus-research-and-innovation_en, https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/coronavirus-research-and-innovation/financing-innovation_en

4 https://ec.europa.eu/regional_policy/en/2021_2027/

Under the enormous pressure of the current COVID-19 pandemic, European health systems have demonstrated their capacity to innovate and adapt to evolving needs if certain conditions are met. For example, the use of telemedicine has accelerated significantly during the pandemic, demonstrating that substantial obstacles can be overcome. Nevertheless, by drawing on the lessons learnt during the COVID-19 crisis, the EU should create better conditions for responding to future challenges and enabling innovative solutions for strengthening its health systems including digital health.

Continuous and coordinated strategic investments in the improvement of health systems will strengthen their resilience and optimise healthcare in the future. While they play an essential role in addressing current and future health challenges, health systems are also crucial for the development of our societies and economies.

The COVID-19 pandemic serves as an important warning, also from the perspective of rising antimicrobial resistance. The current pandemic has also shown us that available, affordable, and accessible medicinal products are the cornerstone of the preparedness and resilience of a European Health Union, as recognised by the Pharmaceutical Strategy for Europe[5].

Given that non-communicable diseases account for 87% of the disease burden in the EU[6], and given the impact of the disruption in healthcare systems caused by COVID-19, further strengthening of health promotion as well as the prevention and treatment of non-communicable diseases such as cancer is needed. The Europe's Beating Cancer Plan[7] is one of the keys pillars of a strong European Health Union. It tackles every stage of the disease pathway, from prevention to the quality of life of cancer patients and survivors, focusing on actions spanning several policy areas. The implementation of the plan will contribute towards reversing the rising trend of cancer across the EU, as well as towards a healthier, fairer and more sustainable future for all, in line with the United Nations Sustainable Development Goals[8].

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5 Communication from the Commission, Pharmaceutical Strategy for Europe (COM/2020/761 final)

6 https://knowledge4policy.ec.europa.eu/health-promotion-knowledge-gateway/eu-burden- non-communicable-diseases-key-risk-factors_en

7 Communication from the Commission, Europe's Beating Cancer Plan (COM/2021/44 final)

8 https://sdgs.un.org/goals

The pandemic has also further underlined the need to step up the role of the EU in global health and to ensure that the EU and Member States are speaking with one voice. Along with a fairer distribution of vaccines, the immediate focus should also be on strengthening health systems around the world in partnership with international organisations. Stronger EU leadership in global health should be based on our strengths, such as shared values and traditionally strong health systems.

Strengthening the European Health Union through innovative solutions for resilient health systems

THE COUNCIL OF THE EUROPEAN UNION,

1. RECALLS that Article 168 of the Treaty on the Functioning of the European Union (TFEU) states that Union action shall complement national policies, encourage cooperation between the Member States in the field of public health and, if necessary, lend support to their action.

2. NOTES that Article 168 TFEU states that Union action shall respect the responsibilities of the Member States for the organisation and delivery of health services and medical care; Article 168 TFEU also provides that a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

3. RECALLS the Council conclusions towards modern, responsive and sustainable health systems published on 8 July 2011[9] and the Council conclusions on encouraging Member States-driven Voluntary Cooperation between Health Systems published on 30 June 2017[10].

4. RECALLS the European Pillar of Social Rights[11] from 2017 and its 20 principles, which include the right to timely access to affordable, preventive and curative healthcare of good quality for everyone.

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9 OJ C 202, 8.7.2011, p. 10-12

10 OJ C 206, 30.6.2017, p. 3-7

11 https://ec.europa.eu/info/strategy/priorities-2019-2024/economy-works-people/jobs-growth- and-investment/european-pillar-social-rights/european-pillar-social-rights-20-principles_en

5. RECALLS the 2020 Social Protection Committee (SPC) Annual Review of the Social Protection Performance Monitor[12] (SPPM) and developments in social protection policies which highlight that strengthening the resilience, effectiveness and access of the health systems should remain a primary focus of Member States' efforts. The crisis has demonstrated the value of strong safety nets, along with the strategic importance of efficient coordination between social and healthcare systems for providing access to quality care for all.

6. RECALLS the Council conclusions on the Economy of Wellbeing[13], published on 24 October 2019, which point out that the Economy of Wellbeing is based on a sound and sustainable economic policy. The Economy of Wellbeing highlights the importance of investing in effective, efficient and equitable policy measures and structures ensuring access for all to public services including health and social services, long-term care, prenatal care, the promotion of health and preventive measures, social protection as well as education, training and life-long learning and stands for equal opportunities, gender equality and social inclusion.

7. RECALLS the Communication from the Commission on effective, accessible and resilient health systems[14] adopted on 4 April 2014, the Commission Communication on enabling the digital transformation of health and care in the Digital Single Market[15] adopted on 25 April 2018, the Commission Recommendation on a European Electronic Health Record Exchange format adopted on 6 February 2019[16], and the Commission Communication on building a European Health Union[17] adopted on 11 November 2020.

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12 https://socialprotection.org/discover/publications/2020-spc-annual-review-social-protection- performance-monitor-sppm-and

13 https://data.consilium.europa.eu/doc/document/ST-13432-2019-INIT/en/pdf

14 COM/2014/0215 final

15 COM/2018/233 final

16 OJ L 39, 11.2.2019, p. 18–27

17 COM/2020/724 final

8. RECALLS the Communication from the Commission on drawing the early lessons from the COVID-19 pandemic[18] adopted on 15 June 2021, which highlights that the capacity to cope with a pandemic depends on continuous and increased investment in health systems.

9. WELCOMES the High-level Conference on Implementing Innovative Solutions for Resilient Health Systems[19] held on 15 and 16 July 2021, which outlined the need for strategic investments in health systems and the opportunities for increased collaboration among the European Union, Member States and stakeholders.

10. WELCOMES the Policy Brief on the European Support for Improving Health and Care Systems[20] describing a number of EU tools that can support the strengthening of health systems. It outlines that making best use of these instruments typically requires combining various EU tools with different objectives over multiple stages of the change process. Furthermore, it highlights that the need to combine different tools creates a challenge for Member States i.e. being aware of many different tools and their potential to support health systems, and the challenge of aligning objectives and processes to health objectives and the requirements of different tools.

11. INVITES THE MEMBER STATES AND THE COMMISSION TO:

– facilitate and encourage the continuous voluntary exchanges[21] on health system innovation aimed at knowledge sharing and mutual learning in order to inform decision-making and support national policy actions based on Member States' needs;

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18 COM/2021/380 final

19 https://slovenian-presidency.consilium.europa.eu/en/events/implementing-innovative-solutions-for-resilient-health-systems/?__cf_chl_jschl_tk__=pmd_xB8ySgWRhCPB9APPyxuc2HlH9iJM7fwAsb9nU5FePVk-1629875480-0-gqNtZGzNAmWjcnBszQ1l

20 https://slovenian-presidency.consilium.europa.eu/media/0qonoilq/policybrief_slovenia_inside_pages_v2.pdf

21 https://ec.europa.eu/health/state/voluntary_exchanges_en

– review the process for the evaluation, diffusion and implementation of best practices and innovative solutions, in order to optimise their application and impact, as appropriate;

– facilitate and encourage collaboration among Member States for external peer evaluation of innovative solutions;

– encourage discussions on strategic approaches to strengthening the resilience of health systems, and taking into account the ageing of populations and the need to promote life-long policies, at existing or future Member State health fora, such as the Expert Group on Health Systems Performance Assessment (HSPA)[22] and the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases[23];

– continue and support further work of the Expert Group on HSPA in its role to improve our understanding on how to strengthen effectiveness of care, increase accessibility and improve the quality of care and safety of patients and explore the potential of this group to address strategic approaches to health system innovation and transformation;

– continue and encourage further the successful collaboration among Member States in the field of digital health, such as the eHealth Network[24] to support wider deployment of digital solutions and services that have a clear potential to strengthen the effectiveness, the accessibility and the resilience of health systems, while ensuring respect of privacy;

22 https://ec.europa.eu/health/systems_performance_assessment/policy/expert_group_en
23 https://ec.europa.eu/health/non_communicable_diseases/steeringgroup_promotionprevention_en
24 https://ec.europa.eu/health/ehealth/policy/network_en

– encourage and promote the use of the Technical Support Instrument[25] and other EU mechanisms to undertake reforms in order to enhance the resilience of health systems, including through innovation;

– support collaborative research and partnerships among Member States on transforming health and care systems to develop evidence-based strategies, policies and innovative ways of delivering care and maintaining population health;

– encourage collaboration and partnerships, where needed, with international organisations providing expert support to health system analysis, innovation development, knowledge sharing and the implementation of innovative solutions;

– support relevant civil society organisations in their endeavours to promote health and reach out to vulnerable groups.

12. INVITES THE COMMISSION TO:

– strengthen the coordination across the EU programmes and policies to support more effectively the implementation of national health systems reforms with all available EU mechanisms;

– explore the provision of an advisory service with a single point of access to assist Member States on request in optimising the use of EU funds, mechanisms and instruments to support the planning, financing and implementation of changes in their healthcare systems;

[25] https://ec.europa.eu/info/overview-funding-programmes/technical-support-instrument-tsi_en

– promote and support the opportunities for capacity building of professionals working on health systems, in particular for those in the early stages of their careers; the opportunities should increase their knowledge and skills of health system management and financing, and thus contribute to strengthening the resilience of health systems and a One Health approach.

Strengthening the European Health Union: improving accessibility to and availability of medicinal products and medical devices

13. WELCOMES the Joint meeting of EU Directors for Pharmaceutical Policy & Pharmaceutical Committee[26] held on 8 and 9 July 2021. This meeting underlined the importance of improving the accessibility and availability of medicinal products, especially where there may be a lack of commercial interest, such as in the case of certain antimicrobials, or in the case of repurposed generic or older medicinal products in oncology.

14. RECALLS the Council conclusions on Access to medicines and medical devices for a Stronger and Resilient EU[27], adopted on 15 June 2021, and the need to consider all the objectives set therein.

15. WELCOMES the EU4Health Programme, which sets out an ambitious response to the pandemic and healthcare systems' resilience, particularly the funding available for the sector to ensure the availability of medicines and medical devices, address shortages and ensure security of supply.

[26] https://ec.europa.eu/health/documents/pharmaceutical-committee/human-meeting_en
[27] OJ C 269I , 7.7.2021, p. 3–10

16. NOTES that improving the accessibility, development and the availability of off-patent and new antimicrobials, and off-patent repurposed medicinal products in oncology, as well as radiotherapy and medical technology, can positively influence the effectiveness and the resilience of health systems, while it is important to promote the prudent and appropriate use of all antimicrobials.

17. UNDERLINES that the accessibility and the availability of antimicrobials is a matter of priority, in terms of both stimulating innovation and addressing the reasons for shortages and withdrawal of existing antimicrobials, finding ways to ensure their prudent and appropriate use and to deal with market failures.

18. RECOGNISES that the repurposing of already approved, off-patent medicinal products, including in the field of oncology, where a significant unexploited potential exists, should be explored further as a possible means for effective and affordable medicinal products to treat patients in areas of unmet needs, and ACKNOWLEDGES the important contribution of non-commercial stakeholders, such as academic and research institutions and not-for-profit organisations in achieving this goal.

19. SUPPORTS the planned pilot project of the Safe and Timely Access to Medicines for Patients (STAMP)[28] repurposing framework for the interaction of not-for-profit organisations with medicinal products regulators and marketing authorisation holders as a way to gain experience and valuable information to advise as necessary on any relevant EU steps to facilitate the repurposing of off-patent medicinal products, including for cancer.

[28] https://ec.europa.eu/health/documents/pharmaceutical-committee/stamp_en

20. WELCOMES the fact that the Europe's Beating Cancer Plan provides for an EU platform to improve access to cancer medicinal products to support the repurposing of existing medicinal products.

21. ACKNOWLEDGES that the European Health Union, the Pharmaceutical Strategy for Europe, the Europe's Beating Cancer Plan, the newly launched European Health Emergency Preparedness and Response Authority and the announced European Health Data Space[29] offer an opportunity for common actions at EU level in response to public health needs; CALLS for an adequate involvement of Member States in the work of HERA, also in the "preparedness phase".

22. ACKNOWLEDGES the concerns expressed during the meeting of the Heads of Medicines Agencies (HMA), held under the Slovenian Presidency of the Council of the EU on 15 and 16 September 2021, in relation to the anticipated update of the rules on fees payable to the European Medicines Agency and its potential implications for the national competent authorities (NCA) responsible for medicinal products. The concerns expressed were, *inter alia*, that the cost-based fee proposal would reduce existing centralised human medicines fees for NCAs at a time of stretched resources and increased pressure for input into the centralised system, would not reflect the value of services delivered, would be based on out-of-date information and would recognise only some of the costs incurred by NCAs; INVITES the Commission to pay due attention to the concerns expressed in order to avoid causing damage to national competent authorities and to safeguard and strengthen the EU regulatory system for medicinal products, including the scientific contributions made by national competent authorities.

[29] https://ec.europa.eu/health/ehealth/dataspace_en

23. TAKES NOTE OF the European Parliament Resolution of 17 September 2020 on the shortage of medicines – how to address an emerging problem[30], which states that "an efficient strategy should cover measures to mitigate medicine shortages, but also to prevent them from happening, looking at the multiple root causes of shortages", and, among others, "notes that another way to ensure the EU's strategic autonomy in health is by including the pharmaceutical production of certain products in the IPCEI programme (Important Projects of Common European Interest)", and, *inter alia*, "calls on the Commission and the Member States to examine the possibility of creating one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture medicinal products of health and strategic importance for healthcare, in the absence of existing industrial production, in order to complete and guarantee security of supply and prevent possible shortages of medicines in cases of emergency"; and NOTES that these as well as other possible initiatives identified under the Pharmaceutical Strategy could also be examined in the context of ensuring the supply of medicinal products in all Member States experiencing market failures in the supply of medicinal products. This includes the supply of medicinal products in relation to the future handling of health crises of a scale similar to the current COVID-19 pandemic.

24. ACKNOWLEDGES that the future Regulation on strengthening cooperation on Health Technology Assessment (HTA) can support Member States in their decisions to secure access to innovative health technologies and improves complementary voluntary cross-border cooperation.

[30] https://www.europarl.europa.eu/doceo/document/TA-9-2020-0228_EN.html

25. ACKNOWLEDGES that effective implementation of the medical device regulation (MDR)[31] and *in vitro* diagnostic medical device regulation (IVDR)[32] is key to ensure availability of high quality, safe and well-performing medical devices (MDs) and *in vitro* diagnostic medical devices (IVDs).

26. ACKNOWLEDGES that MDs and IVDs have played a critical role in the EU's response to the pandemic and RECOGNISES that the MD and IVD sectors had to address unprecedented challenges caused by the COVID-19 pandemic, which required increased availability of critical MDs and IVDs across the EU, whilst continuing to ensure a high level of protection for patient health and safety.

27. WELCOMES the Commission Proposal for a Regulation amending Regulation 2017/746 on *in vitro* diagnostics medical devices, as regards additional transitional provisions, for certain *in vitro* diagnostics devices, as a timely response to the call made in the Council conclusions adopted at the EPSCO Council in June 2021[33].

28. ENCOURAGES ambitious Commission policy proposals and future innovative and sustainable solutions to address the issue of security of supply, in particular as regards older medicinal products, including off-patent antimicrobials and oncological medicinal products.

29. SUPPORTS continuing collaboration among Member States to secure adequate supply and access to affordable vaccines, medicinal products and diagnostics against pandemic diseases such as COVID-19.

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31 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance) *(*OJ L 117, 5.5.2017, p. 1–175)

32 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance) (OJ L 117, 5.5.2017, p. 176–332)

33 Council Conclusions on Access to medicines and medical devices for a Stronger and Resilient EU (OJ C 269I , 7.7.2021, p. 3–10)

30. INVITES MEMBER STATES AND THE COMMISSION TO:

– find ways to improve the accessibility and the availability of medicinal products, notably of antimicrobials and of repurposed medicinal products for the treatment of unmet medical needs, where a lack of commercial interest is a hindering factor;

– support further elaboration and piloting of a 'pull' incentive mechanism for antibiotic procurement in the EU as proposed by the EU Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI)[34] as an option to be explored in order to address the persisting challenges of access and delayed availability of antimicrobials, to better understand its implications for Member States, such as the impact of these incentives on the sustainability of their health systems, and to determine the possibility of participation by countries beyond the EU, while keeping an open strategic autonomy for raw materials for medicines and medical devices;

– support the training of health workers in the human, animal and environment sectors in antimicrobial resistance, infection prevention and control, rational use of antibiotics and appropriate antibiotic waste disposal and promote population awareness;

– engage, within the framework of the Network of Competent Authorities on Pricing and Reimbursement (NCAPR), in the exchange of best practices in order to optimise access to repurposed medicinal products, particularly those that are intended to fulfil an unmet medical need;

[34] https://slovenian-presidency.consilium.europa.eu/media/gmulwi3x/policy-brief-improving- access-to-essential-antibiotics.pdf

– ensure that longstanding technical cooperation on HTA among Member States' authorities is taken to the next step in an effective and timely manner, in accordance with the Member States-driven approach outlined in the future Regulation on Health Technology Assessment;

– consider proposing legislation that supports repurposing efforts to obtain clear evidence of the safety and efficacy of the medicinal product, also in cases where there is no direct commercial interest. Legal requirements for marketing authorisation holders may include labelling changes for repurposed medicinal products to cover additional indications after a positive assessment of the clinical data submitted by third parties;

– explore the potential for reliance on adaptive platform trials, innovative trial designs for clinical research in repurposing to complement the clinical research efforts, including by taking into account Real-World Evidence, while ensuring that the data generated in clinical trials are of high quality, reliable and robust;

– consider addressing the need for repurposing of medicinal products in paediatric indications in order to avoid off-label use, to the benefit of this most vulnerable population;

– strengthen the governance linked to the implementation of the new regulations for MD and IVMD and develop the European expertise in this field for the benefit of EU patients.

31. INVITES THE COMMISSION TO:

– include a comprehensive end-to-end optimised regulatory framework of evidence-based, holistic and future-proof proposals in the context of the Pharmaceutical Strategy for Europe, with the aim of improving the affordability, availability and accessibility of medicinal products and, in particular, antimicrobials, personalised, advanced therapy medicinal products, therapies for (very) small patient groups and repurposed medicinal products, while fully respecting Member States' competence;

– develop specific joint EU research capacities that would also facilitate cooperation with national/academic research institutions and offer support in translating research findings into the development of antimicrobials for clinical practice, while also reinforcing the use of Union-wide clinical trials networks and data-sharing platforms and, as appropriate, learning from e.g. the Innovative Medicines Initiative project ENABLE[35];

– analyse what is needed to ensure the availability and development of today's and tomorrow's medicines and therapies within the EU and assess the potential costs and benefits as well as the market implications of organising manufacturing facilities at EU level in addition to existing financial arrangements, including publicly financed or not-for-profit manufacturing facilities, bearing in mind their potential market-distorting effects and well-known limitations, to ensure the availability of antimicrobials in the case of lack of commercial interest, or in emergency situations, and assess the costs and benefits of other possible initiatives identified in the work under the Pharmaceutical Strategy, in addition to mechanisms supporting innovation, leading to breakthrough methods of manufacturing that result in sustainable production of affordable medicines;

[35] https://www.imi.europa.eu/projects-results/project-factsheets/enable

– continue to prioritise the implementation of the MDR and IVDR, including through the provision of targeted support to Member States, to secure smooth implementation and thus contribute to the accessibility and availability of MDs and IVDs for the benefit of EU patients;

– address the aspects that impact the competitiveness of the European pharmaceutical industry with a view to mitigating security of supply concerns and to promoting open strategic autonomy in the EU, notably for the production of off-patent APIs and medicinal products;

– consider, in cooperation with Member States, and also taking into account the outcomes of the pilot project of the STAMP repurposing framework, a central repurposing coordinator at EU level to support the cooperation and coordination among different stakeholders and to assist with the development of the scientific arguments required to obtain the regulatory approval for repurposed financially unattractive medicinal products;

– specifically consider the repurposing potential for unmet medical needs in the context of the announced European Health Data Space, taking full advantage of trustworthy Artificial Intelligence and Big Data in a responsible manner, also with the aim of supporting the successful selection of candidates;

– consider creating possibilities for and supporting the repurposing of existing medicinal products by facilitating the gathering of data on off-label use of medicinal products in rare cancers, including paediatric cancers, in the context of the Knowledge Centre on Cancer[36].

[36] https://knowledge4policy.ec.europa.eu/cancer_en

32. INVITES THE COMMISSION, THE EUROPEAN MEDICINES AGENCY AND PARTICIPATING BODIES TO:

– encourage the implementation of the planned piloting of the STAMP repurposing framework, which has been delayed due to the COVID-19 pandemic.

33. INVITES THE ECONOMIC OPERATORS TO:

– cooperate and share available data on shelved products that are no longer protected by patents with academic institutions and not-for-profit organisations in the interest of repurposing them in order to address unmet medical needs.

Strengthening the European Health Union: beating cancer

34. RECALLS that the health, economic and social insecurities due to the COVID-19 pandemic had negatively impacted mental health and spurred detrimental lifestyle habits and has disrupted health promotion and prevention programmes.

35. RECALLS that COVID-19 negatively impacted access to early diagnosis and treatment of cancer at times of severe pressure on hospital facilities. This can have detrimental effects on the incidence and survival of cancer.

36. WELCOMES the Communication from the Commission on Europe's Beating Cancer Plan to turn the tide against cancer while addressing health determinants through the 'Health in All Policies' approach. The plan is an important and ambitious stepping stone towards a stronger European Health Union and a more secure, better-prepared and more resilient EU.

37. WELCOMES the significant support for implementing the Plan through several financial mechanisms and programmes, such as the EU4Health Programme, Horizon Europe[37], the Recovery and Resilience Facility as well as Cohesion Policy Funds and the InvestEU Programme.

38. INVITES THE COMMISSION TO:

– ensure, as appropriate, effective implementation of the actions in the Europe's Beating Cancer Plan, and support Member States in implementing effective cancer control actions, by means of appropriate instruments and tools;

– take a comprehensive approach to health promotion and prevention of cancer, in order to ensure that best practices developed in cancer prevention and control can benefit other non-communicable diseases;

– consider submitting a proposal for an update of the Council recommendation on cancer screening[38].

39. INVITES THE MEMBER STATES AND THE COMMISSION TO:

– collaborate effectively on the implementation of the Europe's Beating Cancer Plan and make best use of the available EU funding;

– invest in sustainable cancer prevention by addressing health determinants of cancer as an intersectoral challenge through a 'Health in All Policies' and 'One Health' approach; develop and implement cost-effective interventions targeting tobacco use, alcohol use, physical inactivity and unhealthy diets by developing and implementing strategic actions as well as facilitating cooperation between Member States, existing EU agencies and fora such as the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases (SGPP);

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37 https://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en

38 OJ L 327, 16.12.2003, p. 34–38

– promote vaccination, early detection, and screenings based on evidence and European recommendations for the quality assurance of screening programmes;

– explore innovative approaches in health promotion and integration of prevention activities as an integral part of healthcare services delivery;

– encourage an active role of health professionals, patient groups and other relevant non-governmental organisations and other stakeholders in the implementation process of the Europe's Beating Cancer Plan;

– implement comprehensive approaches to the challenges of survivorship related to the quality of life of cancer survivors, with special regard for children and young adults and with reference to the established right to be forgotten;

– build on the conclusions and recommendations from The Innovative Partnership for Action Against Cancer (iPAAC) Joint Action[39], as appropriate, in the forthcoming activities of the implementation of the Europe's Beating Cancer Plan. This applies in particular to recommendations for new screening programmes, for updated recommendations on screening, amended datasets on population cancer registries, approaches to complex treatments for cancers as well as governance issues, such as comprehensive cancer centres, quality indicators, comprehensive cancer care networks and patient pathways. Existing networks and expertise such as the European Reference Network (ERN) should be taken into account to avoid duplication and overlapping;

[39] https://www.ipaac.eu/en/about/

– strengthen the cooperation between the Commission and the Member States through cross-sector actions that build bridges between the objectives of health systems and those of sustainable and healthy food systems. Our common aim is to ensure healthy nutrition and a reduction in diet-related non-communicable diseases in line with the objectives of the Europe's Beating Cancer Plan and recommendations from the Joint Action on Implementation of Validated Best Practices in Nutrition (BestReMap)[40];

– collaborate to secure the future supply of medical radioisotopes, in order to be self-sufficient in the EU and to make full use of the potential of nuclear medicine for the diagnosis and treatment of European patients with cancer in line with the Commission Staff Working Document on a Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA)[41] adopted on 5 February 2021. A more coordinated approach and sustainable funding of European production capacity is particularly important in the light of the ageing European production infrastructure.

Strengthening the European Health Union: the Role of the EU in Global Health

40. RECALLS the Communication from the Commission on the EU Role in Global Health[42] in 2010 which established the strong legitimacy of the EU to act on global health due to its leading role in international trade, global environmental governance and in development aid, as well as its values and experience of universal and equitable quality healthcare.

41. RECALLS Council conclusions on the role of the EU in strengthening the World Health Organization[43] published on 24 November 2020 which outlined the commitment of the EU and its Member States to take a leadership role in global health, while supporting the leading and coordinating role of the WHO in global health.

40 https://bestremap.eu/
41 https://ec.europa.eu/energy/sites/default/files/swd_strategic_agenda_for_medical_ionising_radiation_applications_samira.pdf
42 COM/2010/0128 final
43 OJ C 400, 24.11.2020, p. 1–3

42. RECALLS that the European Council conclusions on COVID-19 adopted on 25 May 2021[44] had called for work to be stepped up to ensure global equitable access to COVID-19 vaccines and supported COVAX's leading role in that respect.

43. RECALLS that the European Council, at its meeting on 24 and 25 June 2021[45], welcomed the decision adopted by the 74th World Health Assembly to set up a special session of the World Health Assembly in November 2021 dedicated to considering the benefits of developing a WHO convention, agreement or other international instrument on pandemic preparedness and response.

44. TAKES NOTE OF the final report of the Pan-European Commission on Health and Sustainable Development: Drawing light from the pandemic: A new strategy for health and sustainable development[46] presented in September 2021 and its objective to invest in strong, resilient, and inclusive national health systems; Also TAKES NOTE OF the important findings and recommendations of the Independent Panel for Pandemic Preparedness and Response, the Review Committee for the International Health Regulations, the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme and the G20 High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response, which all made valuable contributions and proposals to improve pandemic preparedness and response and to strengthen the global health security architecture.

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44 https://www.consilium.europa.eu/en/press/press-releases/2021/05/25/european-council-conclusions-24-25-may-2021/

45 https://www.consilium.europa.eu/en/press/press-releases/2021/06/25/european-council- conclusions-24-25-june-2021/

46 https://www.euro.who.int/en/health-topics/health-policy/european-programme-of-work/pan- european-commission-on-health-and-sustainable-development/publications/drawing-light- from-the-pandemic-a-new-strategy-for-health-and-sustainable-development-2021

45. WELCOMES the Conference on strengthening the role of the EU in the context of global health[47], held on 25 March 2021. The conference outlined the need for a holistic, inclusive and coordinated strategy, as well as the importance of global solidarity in the response to common threats.

46. WELCOMES the Conference on 'The Role of the European Union in Strengthening Health Systems Resilience Globally' held on 20 October 2021, which outlined the opportunities and the need for a strategic reinforcement of health systems globally.

47. INVITES MEMBER STATES AND THE COMMISSION TO:

– further explore how the EU, in the context of the stronger European Health Union, could have a more strategic approach in global health, including through a possible new Joint Action on global health;

– demonstrate a leadership role in global health, and in the post-pandemic negotiations at global level including through the negotiation of an important instrument on pandemic preparedness and response;

– explore how to further improve existing mechanisms of coordination to support regular exchange of information, and in particular between EU and Member States' representatives and experts based in national capitals, Brussels, Geneva and New York, to allow cooperation in establishing EU positions on health issues in a timely and efficient manner;

47 https://www.2021portugal.eu/en/events/conference-on-strengthening-the-role-of-the-eu-in- the-context-of-global-health/

– encourage collaboration on non-health issues that impact global health and the well-being of the population, including thematic discussions on cross-sectoral issues relevant to global health;

– promote and support educational opportunities in the field of global health and global health diplomacy;

– encourage closer cooperation and active involvement of relevant stakeholders, including civil society and non-governmental organisations to contribute to global health, including health security and a comprehensive ‘One Health approach’;

– encourage the use of existing EU mechanisms and instruments such as EU4Health, to strengthen the role of the EU in Global Health as well as to draw benefits from international cooperation, particularly in the field of pandemic preparedness and response, including antimicrobial resistance;

– prepare a review of mechanisms and instruments through which the EU, its Member States and non-state actors support the strengthening of health systems globally in order to help identify gaps and enhance the role of the EU in global health and health security;

– continue and encourage partnerships and networks that provide support in strengthening health systems globally in terms of preparedness, capacity building, health promotion, health research and development, and digital health;

– keep in mind the importance of avoiding unnecessary duplication and overlap with the work of other international actors and institutions and ensure coherence and complementarity with existing mechanisms and initiatives.