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From: General Secretariat of the Council  
To: Delegations  
Subject: Draft Council Conclusions on Strengthening a European Health Union

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Delegations will find in the Annex a Presidency proposal for Council Conclusions on the above-mentioned subject to be examined at the informal videoconference of the members of the Working Party on Pharmaceutical and Medical Devices on 23 September 2021.

**Draft Council Conclusions on Strengthening a 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 moved health high on the agenda of geopolitics, security and 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.

In the EU context, the COVID-19 pandemic has had an important impact on the priorities of the Multiannual Financial Framework, for example more funding was assured for health through the new EU4Health programme<sup>1</sup>, the Recovery and Resilience Facility<sup>2</sup> and the Cohesion Policy funds<sup>3</sup>. Increased funding brings opportunities as well as a responsibility to use it in a more strategic way in order to strengthen health systems and build a stronger European Health Union.

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. However, learning from the COVID-19 crisis, we should create better conditions for responding to future challenges and allowing for innovative solutions for strengthening our health systems.

Continuous and coordinated strategic investments in the improvement of health systems will strengthen their resilience and optimise health care in the future. The pandemic has demonstrated the essential role of health systems in improving health outcomes. Investments in health systems should be recognised as investments in our societies and economies.

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<sup>1</sup> COM/2020/405 final

<sup>2</sup> COM/2020/408 final

<sup>3</sup> [https://ec.europa.eu/regional\\_policy/en/2021\\_2027/](https://ec.europa.eu/regional_policy/en/2021_2027/)

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.

With non-communicable diseases being responsible for 87% of the disease burden in the EU<sup>4</sup>, and considering the impact of the disruption in health care systems caused by COVID-19, further strengthening of health promotion as well as prevention and treatment of non-communicable diseases such as cancer is needed. The Europe's Beating Cancer Plan<sup>5</sup> is one of the keys pillars of a strong European Health Union. It tackles every stage of the disease pathway, from prevention to quality of life of cancer patients and survivors, focusing on actions spanning across several policy areas. The implementation of the plan will contribute towards reversing the rising trend of cancer across the EU and secure a healthier, fairer and more sustainable future for all, in line with the United Nations Sustainable Development Goals<sup>6</sup>.

The pandemic has also underlined the need to step-up the role of the EU in global health. Along with a fairer distribution of vaccines the focus should also be on strengthening health systems around the world to ensure a resilient global health prevention, detection and treatment of communicable and non-communicable diseases.

## **Strengthening a European Health Union: Implementing 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.

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<sup>4</sup> [https://knowledge4policy.ec.europa.eu/health-promotion-knowledge-gateway/eu-burden-non-communicable-diseases-key-risk-factors\\_en](https://knowledge4policy.ec.europa.eu/health-promotion-knowledge-gateway/eu-burden-non-communicable-diseases-key-risk-factors_en)

<sup>5</sup> COM/2021/44 final

<sup>6</sup> <https://sdgs.un.org/goals>

2. NOTES that Article 168 TFEU states that Union action shall fully respect the responsibilities of the Member States for their 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” adopted on 8 July 2011<sup>7</sup> and those on “encouraging Member States-driven Voluntary Cooperation between Health Systems” adopted on 30 June 2017<sup>8</sup>.
4. RECALLS the European Pillar of Social Rights<sup>9</sup> from 2017 and its 20 principles, which include the right to timely access to affordable, preventive and curative health care of good quality for everyone.
5. RECALLS the 2021 SPC Annual Review of the Social Protection Performance Monitor<sup>10</sup> (SPPM) and developments in social protection policies which highlights 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.

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<sup>7</sup> OJ C 202, 8.7.2011, p. 10–12

<sup>8</sup> OJ C 206, 30.6.2017

<sup>9</sup> [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](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)

<sup>10</sup> <https://socialprotection.org/discover/publications/2020-spc-annual-review-social-protection-performance-monitor-sppm-and>

6. RECALLS the Council conclusions on the “Economy of Wellbeing”<sup>11</sup>, adopted on 24 October 2019, which point out that the Economy of Wellbeing is based on a sound and sustainable economic policy. They highlight 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.
7. RECALLS the Communications from the Commission on “effective, accessible and resilient health systems”<sup>12</sup> adopted on 4 April 2014, on “enabling the digital transformation of health and care in the Digital Single Market”<sup>13</sup> adopted on 25 April 2018, and on “building a European Health Union”<sup>14</sup> adopted on 11 November 2020.
8. RECALLS the Communication from the Commission on “drawing the early lessons from the COVID-19 pandemic”<sup>15</sup> adopted on 15 June 2021, which highlights that the capacity to cope with a pandemic depends on the continuous and increased investment in health systems.
9. WELCOMES the High-level Conference on “Implementing Innovative Solutions for Resilient Health Systems”<sup>16</sup> 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.

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

12 COM/2014/0215 final

13 COM/2018/233 final

14 COM/2020/724 final

15 <https://ec.europa.eu/info/sites/default/files/communication150621.pdf>

16 [https://slovenian-presidency.consilium.europa.eu/en/events/implementing-innovative-solutions-for-resilient-health-systems/?\\_cf\\_chl\\_jschl\\_tk\\_=pmd\\_xB8ySgWRhCPB9APPyxuc2HIH9iJM7fwAsb9nU5FePVk-1629875480-0-gqNtZGzNAmWjcnBszQ1l](https://slovenian-presidency.consilium.europa.eu/en/events/implementing-innovative-solutions-for-resilient-health-systems/?_cf_chl_jschl_tk_=pmd_xB8ySgWRhCPB9APPyxuc2HIH9iJM7fwAsb9nU5FePVk-1629875480-0-gqNtZGzNAmWjcnBszQ1l)

10. WELCOMES the Policy Brief on the “European Support for Improving Health and Care Systems”<sup>17</sup> that described that the EU also has many 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 across multiple stages of the change process and that the need to combine different tools creates a challenge for Member States of being aware of many different tools and their potential to support health systems, and to align objectives and processes between health objectives and the requirements of different tools.

11. INVITES THE MEMBER STATES AND THE COMMISSION TO:

- facilitate and encourage the continuous voluntary exchanges<sup>18</sup> aiming at knowledge sharing and mutual learning in order to inform decision making and support national policy actions based on Member States’ needs;
- review the process for the evaluation, diffusion and implementation of best practices or innovative solutions, in order to optimise their application and impact;
- consider establishing a new forum for Member States to discuss strategic approaches to strengthen health systems;
- continue making use of the Technical Support Instrument to undertake reforms in order to enhance the resilience of health systems through innovation;
- continue and support further work of the Expert Group on Health Systems Performance Assessment (HSPA)<sup>19</sup> in their role to improve our understanding on how to strengthen effectiveness of care, increase accessibility and improve the safety of patients;

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<sup>17</sup> [https://slovenian-presidency.consilium.europa.eu/media/0qonoilq/policybrief\\_slovenia\\_inside\\_pages\\_v2.pdf](https://slovenian-presidency.consilium.europa.eu/media/0qonoilq/policybrief_slovenia_inside_pages_v2.pdf)

<sup>18</sup> [https://ec.europa.eu/health/state/voluntary\\_exchanges\\_en](https://ec.europa.eu/health/state/voluntary_exchanges_en)

<sup>19</sup> [https://ec.europa.eu/health/systems\\_performance\\_assessment/policy/expert\\_group\\_en](https://ec.europa.eu/health/systems_performance_assessment/policy/expert_group_en)

- continue and encourage further the successful collaboration among Member States in the field of digital health, such as the eHealth Network<sup>20</sup> to support wider deployment of digital solutions that have a clear potential to strengthen the effectiveness, the accessibility and the resilience of health systems;
- continue and encourage partnerships with international organisations providing expert support to health system analysis, innovation development, knowledge sharing and implementation of innovative solutions.

12. INVITES THE COMMISSION TO:

- strengthen the coordination across the EU programmes and policies in order to support more effectively the implementation of national reform processes in health systems;
- provide an advisory service for those responsible for health systems within Member States with a single point of access, on the use of all relevant EU programmes and instruments for reforms and investments in health systems in order to assist Member States in optimising the use of EU funds, mechanisms and instruments to support the planning and the implementation of changes in their health care systems;
- promote and support the opportunities for capacity building of professionals working in health authorities and in health systems, in particular those at early stages of their careers, to increase their knowledge and skills regarding health system management and financing, and thus contribute to strengthening and the resilience health systems.

**Strengthening a European Health Union: Improving Accessibility to and Availability of Medicinal Products**

13. WELCOMES the Joint meeting of EU Directors for Pharmaceutical Policy & Pharmaceutical Committee<sup>21</sup> 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.

<sup>20</sup> [https://ec.europa.eu/health/ehealth/policy/network\\_en](https://ec.europa.eu/health/ehealth/policy/network_en)

<sup>21</sup> [https://ec.europa.eu/health/documents/pharmaceutical-committee/human-meeting\\_en](https://ec.europa.eu/health/documents/pharmaceutical-committee/human-meeting_en)

14. NOTES that improving the accessibility and the availability of antimicrobials and off-patent repurposed medicinal products in oncology can positively influence the effectiveness and the resilience of health systems, while it is important to promote the prudent use of all antimicrobials.
15. UNDERLINES that the accessibility and the availability of antimicrobials is a matter of priority, both in terms of stimulating innovation as well as finding ways to ensure their prudent use and to deal with market failures.
16. RECOGNISES that the repurposing of already approved, off-patent medicinal products, particularly in the field of oncology, where a significant unexploited potential exists, is an opportunity for effective and affordable medicinal products to treat cancer in areas of unmet needs, and ACKNOWLEDGES the important contribution of non-commercial stakeholders, such as academic institutions and not-for-profit organisations in achieving this goal.
17. SUPPORTS the planned pilot project of the Safe and Timely Access to Medicines for Patients (STAMP)<sup>22</sup> 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.
18. WELCOMES 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.
19. ACKNOWLEDGES that the European Health Union, the Pharmaceutical Strategy for Europe<sup>23</sup>, the Europe's Beating Cancer Plan and the announced European Health Data Space offer the opportunity for common actions at EU level in response to public health needs.

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<sup>22</sup> [https://ec.europa.eu/health/documents/pharmaceutical-committee/stamp\\_en](https://ec.europa.eu/health/documents/pharmaceutical-committee/stamp_en)

<sup>23</sup> COM/2020/761 final

20. RECALLS that the European Parliament, in its Resolution of 17 September 2020 on the shortage of medicines – how to address an emerging problem<sup>24</sup>, 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.
21. ENCOURAGES ambitious Commission policy proposals and future innovative solutions to address the issue of security of supply, in particular as regards older, off-patent antimicrobials and oncological medicinal products.
22. INVITES MEMBER STATES AND THE COMMISSION TO:
- pay due attention to finding 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 the 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)<sup>25</sup> to address the persisting challenges of access and delayed availability of antimicrobials, in order to better understand its implications for Member States, and to determine possibilities of participation of countries beyond the EU;
  - engage in the framework of the Network of Competent Authorities on Pricing and Reimbursement (NCAPR) in the exchange of best practices and in defining the pathways to engage the Health Technology Assessment bodies and payers in the early dialogue in order to achieve the appropriate access to the repurposed medicinal products;

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<sup>24</sup> [https://www.europarl.europa.eu/doceo/document/TA-9-2020-0228\\_EN.html](https://www.europarl.europa.eu/doceo/document/TA-9-2020-0228_EN.html)

<sup>25</sup> <https://slovenian-presidency.consilium.europa.eu/media/gmulwi3x/policy-brief-improving-access-to-essential-antibiotics.pdf>

- consider proposing legislation that supports repurposing efforts 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 lower the burden in clinical research efforts, including by taking into account Real-World Evidence;
- address 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, especially in treating rare cancers.

### 23. INVITES THE COMMISSION TO:

- include a comprehensive end-to-end framework of proposals in the context of the Pharmaceutical Strategy for Europe, with an aim to improve the affordability, the availability and the accessibility of medicinal products and, in particular, antimicrobials and repurposed medicinal products;
- assess the possibility of developing 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;
- assess the potential benefit as well as the market implications of organising at EU level publicly financed or not-for-profit manufacturing facilities in case of lack of commercial interest, to ensure the availability of antimicrobials;
- define a central repurposing coordinator at EU level to support the cooperation and coordination among different stakeholders and assist with the development of the scientific arguments required to obtain the regulatory approval for repurposed financially unattractive medicinal products;
- pay special attention to the repurposing potential for unmet medical needs in the context of the announced European Health Data Space, taking full advantage of Artificial Intelligence and Big Data, also with an aim to support the successful selection of candidates;

- create possibilities and support 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.

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

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

25. 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 for addressing unmet medical needs.

### **Strengthening a European Health Union: Beating Cancer**

26. RECALLS that the COVID-19 pandemic had a strong impact on lifestyle determinants, health promotion and prevention programmes, and access to early diagnosis and treatment of cancer, which can have detrimental effects on forthcoming incidence and survival of cancer.

27. WELCOMES the Communication from the Commission on Europe's Beating Cancer Plan<sup>26</sup> as a political commitment to turn the tide against cancer while addressing health determinants through the “Health in All Policies” approach. The plan is an important steppingstone towards a strong European Health Union and a more secure, better-prepared and more resilient EU.

28. WELCOMES the significant support for implementing the Plan through several financial mechanisms and programmes, such as the EU4Health Programme, Horizon Europe<sup>27</sup> and the Recovery and Resilience Facility.

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<sup>26</sup> COM/2021/44 final

<sup>27</sup> [https://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe\\_en](https://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en)

29. INVITES THE COMMISSION TO:

- implement the Actions of the Europe's Beating Cancer Plan and explore the instruments and tools to support Member States in implementing them;
- take a comprehensive approach on health promotion and prevention of cancer, by which also other non-communicable diseases can be prevented;
- consider submitting a proposal for an update of the Council recommendation on cancer screening<sup>28</sup>.

30. INVITES THE MEMBER STATES AND THE COMMISSION TO:

- invest in sustainable cancer prevention by addressing health determinants of cancer as an intersectoral challenge through a "Health in All Policies" approach; developing and implementing cost effective interventions targeting tobacco use, harmful alcohol use, unhealthy diets, and physical inactivity; promoting vaccination, early detection, and screenings;
- explore innovative approaches in health promotion and integration of prevention activities as an integral part of health care 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 regards to children and young adults;
- integrate the conclusions and recommendations from The Innovative Partnership for Action Against Cancer (iPAAC) Joint Action<sup>29</sup> into 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.

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<sup>28</sup> OJ L 327, 16.12.2003, p. 34–38

<sup>29</sup> <https://www.ipaac.eu/en/about/>

## Strengthening a European Health Union: The Role of the EU in Global Health

31. RECALLS the Communication from the Commission on the EU Role in Global Health<sup>30</sup> in 2010 which established the strong legitimacy of 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.
32. RECALLS Council conclusions on the role of the EU in strengthening the World Health Organization<sup>31</sup> adopted 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.
33. RECALLS that the European Council conclusions on COVID-19 adopted on 25 May 2021<sup>32</sup> 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.
34. RECALLS that the European Council, at its meeting on 24 and 25 June 2021<sup>33</sup>, has welcomed the decision adopted by the 74th World Health Assembly to set up a special session of the World Health Assembly in November 2021 on a Framework Convention on Pandemic Preparedness and Response.
35. WELCOMES 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<sup>34</sup> presented in September 2021 and its objective to invest in strong, resilient, and inclusive national health systems.

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<sup>30</sup> COM/2010/0128 final

<sup>31</sup> OJ C 400, 24.11.2020, p. 1–3

<sup>32</sup> <https://www.consilium.europa.eu/en/press/press-releases/2021/05/25/european-council-conclusions-24-25-may-2021/>

<sup>33</sup> <https://www.consilium.europa.eu/en/press/press-releases/2021/06/25/european-council-conclusions-24-25-june-2021/>

<sup>34</sup> <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>

36. WELCOMES the Conference on strengthening the role of the EU in the context of global health<sup>35</sup>, held on 25 March 2021. The conference outlined the need for holistic, inclusive and coordinated strategy, as well as the importance of global solidarity in the response to common threats.

37. INVITES MEMBER STATES AND THE COMMISSION TO:

- explore how the EU could have a more strategic approach in global health as part of the stronger European Health Union and how the EU could lead the way in post-pandemic discussions at global level;
- establish a platform to support regular exchange of information, thematic discussions on cross-sectoral issues relevant to global health and timely and efficient coordination to establish EU positions;
- promote and support educational opportunities in the field of global health diplomacy;
- encourage closer cooperation and active involvement of civil society and non-governmental organisations to contribute to One Health;
- prepare a review of mechanisms and instruments through which the EU, its Member States and non-state actors support health systems strengthening globally to help identify gaps and enhance the role of the EU in global health and health security;
- continue and encourage partnerships providing support to health systems development beyond EU.

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<sup>35</sup> <https://www.2021portugal.eu/en/events/conference-on-strengthening-the-role-of-the-eu-in-the-context-of-global-health/>