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From:	General Secretariat of the Council
To:	Delegations
Subject:	Draft Council Conclusions on Access to medecines and medical devices for a Stronger and Resilient EU

Delegations will find in the Annex a Presidency proposal for Council Conclusions on the abovementioned subject to be examined at the informal videoconference of the members of the Working Party on Pharmaceutical and Medical devices on 18 May 2021.

ANNEX

DRAFT Council Conclusions
on Access to medicines and medical devices for a Stronger and Resilient EU

INTRODUCTION: The trinity of Accessibility, Availability, Affordability of medicines and medical devices

Access to medicines and medical devices, their availability, and affordability are paramount objectives which constitute major challenges to health systems in the European Union, in line with WHO principles to achieve universal health coverage. To manage this trinity in a balanced way, we need to reinforce the paradigm of a patient-centred health care system, while guaranteeing equitable and affordable access.

The COVID-19 pandemic has highlighted the problems of access and availability, exacerbating the growing problem of shortages for medicines and medical devices. In fact, it has been made clear that disruption of supply chains, both at global level and within EU, is a prominent feature of a pandemic. The root causes of shortages are multifactorial - they relate to manufacturing and quality issues, as well as economic ones. Therefore, both need to be addressed in a holistic and coordinated manner at national and European levels and throughout the whole supply chain.

In addition, the pandemic underlined the significance of cooperation between Member States, with the support of the European Commission, to better tackle the common challenges we face. There is a need to strengthen and reinforce our joint approach to cross-border health threats and, thus, of a European Health Union - that is our key lesson learned from the pandemic.

In the spirit of European solidarity, a joint coordination effort is needed to make sure that no one is left behind in the recovery from the COVID-19 pandemic. In the aftermath of COVID-19 there is a need to reinforce Europe's resilience and confidence in the European social model, promoting a Union based on the common values of solidarity, convergence and cohesion.

Looking beyond the COVID-19 pandemic, we need to act on the structural needs. Although recognising the remarkable results in many disease areas, governments face enormous challenges, as we need to ensure that timely access to innovative medicines and medical devices brings value to patients and health system. Moreover, the European system needs to safeguard that generics, biosimilars and older products that are essential to patients and health care systems are available.

It is essential to find sustainable solutions to manage the increasing expenditure, to improve transparency, for more robust decisions, to reinforce convergence of tools and methodologies, whilst taking measures to assess in an increasingly rigorous manner, the effectiveness of new and increasingly complex technologies.

Throughout this process it is fundamental that necessary measures and reforms encompass the needs of the end-users of health technologies users, namely health systems, health professionals, patients and citizens.

THE COUNCIL OF THE EUROPEAN UNION

1. RECALLS:

    a. that under Article 168 of the Treaty on the Functioning of the European Union a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities; that Union action, which shall complement national policies, shall be directed towards improving public health; that the Union shall encourage cooperation between the MEMBER STATES in the field of public health and, if necessary, lend support to their action, and that Union action shall fully respect the responsibilities of the MEMBER STATES for the definition of their health policy and for the organisation and delivery of health services and medical care as well as for the allocation of the resources assigned to them[1].

[1] Vd.: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A12008E168

b. that under Article 4(3) of the Treaty on European Union, the Union and the MEMBER STATES shall, in full mutual respect, assist each other in carrying out tasks which flow from the Treaties, pursuant to the principle of sincere cooperation[2].

c. that Article 35 of the Charter of Fundamental Rights of the European Union recognises the fundamental right of citizens to health and medical treatment.

d. the Presidency Conclusions of 19 and 20 June 2000 that reaffirmed the need to ensure a high level of protection of human health in the definition and implementation of all Union policies[3].

e. the Resolution of the European Parliament on Access to Medicines, adopted on 14 February 2017.

f. the Resolution of the European Parliament on the shortages of medicines – how to address an emerging problem adopted on 17 September 2020.

g. the Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its MEMBER STATES, adopted on 17 June 2016[4].

h. the Council conclusions on Encouraging MEMBER STATES-driven Voluntary Cooperation between Health Systems, adopted on 16 June 2017[5].

i. the Pharmaceutical Strategy for Europe launched on November 2020 that is, in the Commission's view, a fundamental pillar in building a stronger European Health Union.

j. the Health Ministers Council meeting on 9 December 2019, where the Council called for a European agenda on pharmaceutical policy for the legislative period of 2020-2024.

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2 Vd.: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:12008M/TXT

3 https://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/ec/00200-r1.en0.htm

4 https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-balance-pharmaceutical-system/

5 https://data.consilium.europa.eu/doc/document/ST-10381-2017-INIT/en/pdf

k. the Council conclusions on COVID-19 lessons learned in health, adopted on 17 December 2020.

l. the World Health Assembly (WHA) 72.8 Resolution on Improving the transparency of markets for medicines, vaccines, and other health products.

m. the Conference "Availability, Accessibility and Affordability of Medicines and Medical Devices for a Stronger and Resilient EU" held under the Portuguese Presidency of the Council of the European Union on the 29th and 30th April 2021.

2. RECOGNISES as an important output of the pandemic context a closer cooperation between Member States and the European Commission in guaranteeing affordable and equitable access to medicines and medical devices, building on the experience of joint negotiation and joint procurement.

3. ACKNOWLEDGES Regulation (EU) 2021/522 of the European Parliament and the Council of 24 of March[6], 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", which constitutes the main financial instrument for health policies, paving the way to achieve the European Health Union. EU4Health will contribute for the post-COVID-19 recovery by making the EU population healthier, strengthening the resilience of health systems to face future health threats, and promoting innovation in the health sector.

4. NOTES that the European Commission and Member States are pledged to ensure that safe vaccines reach every country in the world and their commitment to the global initiative ensuring equitable access to COVID-19 vaccines, COVAX. NOTES that the EU is the "World's Pharmacy" where 400 million doses of COVID-19 vaccines have been produced and 50% has been exported to 90 countries around the world.

6 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2021.107.01.0001.01.ENG

RECOMMENDATIONS

5. INVITES THE MEMBER STATES and THE COMMISSION to establish a close and collaborative work on the measures necessary for the implementation of the Pharmaceutical Strategy that enables a European agenda on pharmaceutical policy.

6. INVITES THE MEMBER STATES and THE COMMISSION to set up a forum facilitated by the European Commission where the various stakeholders – from Member States, Governments, patients and consumers, health professionals, industry and academia - would debate the policy options to feed a European agenda on pharmaceutical and medical device policies.

7. INVITES THE MEMBER STATES AND THE COMMISSION to strive to building a crisis proof system, working together to contribute to a resilient and equitable system thereby reinforcing the trust of citizens. One of the pillars of this structure should be the guarantee of equitable access and availability of medicines and medical devices.

AVAILABILITY:

8. UNDERLINES the essential role of medicines and medical devices in the health systems and the need to ensure their adequate and continuous availability in the EU.

9. WELCOMES the patient-centred Pharmaceutical Strategy for Europe, fostering accessibility and affordability of medicines. Supporting sustainable innovation, access to generic and biosimilars, promote a flexible system, supporting the competitiveness of the health sector and the need to enhance the resilience of the sector by diversifying and securing supply chains and better equip the Union in crisis preparedness.

10. WELCOMES the ongoing study by the European Commission on the root causes of shortages and assessment of the legal framework, with a view to better understand the problem and adopt adequate and coordinated measures at European level.

11. WELCOMES the Structured Dialogue Initiative to better understand the functioning of global supply chains and identify the causes and drivers of vulnerabilities and dependencies that pose a threat to the supply of critical medicines and APIs, to ensure the diversification of supply chains.

12. NOTES that regulatory flexibility and simplification is a long-standing aim for operational excellence and measures like the one related to the approval of vaccines implemented during the COVID-19 pandemic should be further explored in the upcoming process for the revision of the pharmaceutical legislation. Sustainability of the regulatory system and the need for reinforcing scientific and regulatory capacity and capability of the network is key to an adequate and sound implementation of the new Pharmaceutical Strategy.

13. TAKES NOTE OF the May 2021 update of the Industrial Strategy for Europe, creating an environment for a competitive and efficient European Pharmaceutical Industry. UNDERLINES the interlinkage between the Industrial Strategy for Europe with the Pharmaceutical Strategy and the creation of necessary financial incentives to promote API production and reinforce manufacturing capacity to strengthen the EU Health sovereignty.

14. WELCOMES the EU Health Union package that has been put forward on 11 November 2020. The package encompassed a series of proposals to strengthen the EU's health security framework, to reinforce the crisis preparedness and readiness as well as the response role of key EU agencies, including the European Medicines Agency (EMA) and the European Centre for Diseases Control (ECDC).

15. WELCOMES, in the context of the European Health Union package, the impact assessment for a proposal for the creation of the European Preparedness and Response Authority (HERA), with the mission of strengthening the EU's preparedness and response in terms of medical countermeasures for serious cross-border health threats. HERA will address the entire value chain, from assessing the threat to conceptualisation and implementation. “HERA Incubator” will aid - against the COVID-19 variants, with the aim of bringing together researchers, manufacturers, regulators and authorities to monitor variants, exchange data and cooperate in adapting vaccines to prepare and respond to health crisis and ensure the availability of affordable and innovative health care.

16. HIGHLIGHTS the need of strengthening the joint work between EMA and the Member States in order to better monitor the availability of medicines and medical devices, to prevent and manage shortages as well as to provide scientific advice relevant for crisis preparedness and management.

17. NOTES the need for Member States to be adequately prepared for the application of the Clinical Trials Regulation. This regulation fosters an environment that is favourable to conducting clinical trials in the EU, promoting the highest standards of safety for participants and increased transparency of trial information via the Clinical Trials Information System. This envisages innovation in clinical trials to support innovative clinical trial designs and methodologies.

18. RECOGNISES that the medical devices and *in vitro* diagnostic medical devices (IVD) regulations play a vital role in guaranteeing availability and access to safe and innovative devices to the European patients and healthcare professionals, being of paramount importance the existence of the appropriate tools and resources to the adequate application such as the capacity of notified bodies, the implementation of European Database on Medical Devices (EUDAMED) and the operability of new scientific bodies. STRESSES the need to continuously monitor the implementation and exploring the full potential of these regulations.

19. ACKNOWLEDGES that IVD Regulation will bring several major improvements, that sets high standards of quality and safety for *in vitro* diagnostic medical devices in order to meet common safety concerns as regards such products. TAKES NOTE of the fact that there is a change on the paradigm concerning the risk classification of IVDs, leading to a significant increase of the IVDs that need the intervention of a notified body in their conformity assessment.

RECOMMENDATIONS

20. INVITES MEMBER STATES AND THE COMMISSION to continue their efforts for the timely and adequate application of the MD and IVD Regulations, in order to assure the availability and accessibility of MD and IVDs in the European market.

21. INVITES MEMBER STATES AND THE COMMISSION to reinforce collaboration and coordination within the regulatory network, early communication strategies on possible supply disruptions between all stakeholders within the supply chain, identification of additional sources of supply, while considering a patient-oriented strategy, namely in crisis situations. NOTES that forecasting is of the utmost importance, and SUGGESTS the implementation of tools such as an EU platform to monitor manufacturing stock levels and the establishment of a list of critical medicines and medical devices for public health emergencies.

22. ENCOURAGES THE COMMISSION to develop a full inventory of Europe's manufacturing capacities. ENCOURAGES THE COMMISSION to strengthen the long-term resilience of supply chains, particularly of off-patent medicinal products, where Europe's dependency from third countries is higher.

23. INVITES THE COMMISSION to propose the adoption of regulatory or legislative measures to guarantee availability, particularly of critical medicines in periods of crisis of significant increases in demand. RECOMMENDS an early and systematic information sharing between EU national competent authorities and the Commission on the reasons of shortages linked to quality and manufacturing issues, particularly when they have a high impact in public health and production issues in other Member States and/or third countries.

ACCESSIBILITY

24. ACKNOWLEDGES the importance to balance the market exclusivity with timely competition and uptake of generic and biosimilars, to ensure access to essential older medicinal products, and the need for tailored incentives.

25. NOTES that the Pharmaceutical Strategy foresees the revision of the current basic pharmaceutical legislation and UNDERLINES the opportunity to adapt the EU regulatory framework to improve access to medicines of the highest quality, efficacy and safety to EU citizens.

26. RECOGNISES all the improvements brought by the medical devices and IVD regulations, with room for further enhancing coordination at European level, including market surveillance and vigilance.

27. ACKNOWLEDGES that IVD regulation (IVDR) brought several major improvements, that sets high standards of quality and safety for IVD in order to meet common safety concerns as regards such products. TAKES NOTE of the fact that the regulation introduces enormous changes to the sector, including concerning the risk classification of IVDs, leading to a significant increase of the IVDs that need the intervention of a notified body in their conformity assessment.

28. RECOGNISES the impact of COVID-19 on the already challenging implementation of the IVDR. WELCOMES the priority given by the Medical Device Coordination Group (MDCG) to ensure effective implementation of IVDR, including the endorsement of a Joint Implementation Plan in May 2021, but remains concerned about the level of preparedness as well as the capacity of IVDR designated notified bodies.

RECOMMENDATIONS

29. INVITES MEMBER STATES to continue the work on off patent products, namely in the repurposing initiative as a tool to stimulate research and facilitate marketing authorisation, particularly in neglected areas.

30. INVITES THE MEMBER STATES AND THE COMMISSION to discuss regulatory routes and set of commonly accepted criteria applicable to orphan and paediatric medicinal products and to consider new mechanisms and incentives for drug development according to the level of unmet medical needs in order to grant access in all Member States.

31. INVITES MEMBER STATES and THE COMMISSION to discuss, in the context of the Pharmaceutical Committee, new ways to invest in the development of new medicines to tackle unmet medical needs. NOTES that, under the public leadership, HERA could have a pivotal role on incentivising research and development for new medicines to address UMNs, antimicrobial resistance (AMR) and cancer.

32. INVITES MEMBER STATES and THE COMMISSION to collaborate on models to define and identify UMNs, as well as areas of public health concern, such as AMR, in order to guarantee that public funding is driven for the emergent needs. NOTES the lack of understanding of the concept of UMNs and the efforts to reach a definition that is agreed upon by all Member States and the European Commission.

33. INVITES THE COMMISSION AND MEMBER STATES to prioritise and continue their efforts to adequately implement the IVD Regulation and to assure the availability and accessibility of safe IVDs on the European market. INVITES THE COMMISSION AND MEMBER STATES to continue to monitor the level of preparedness, to work closely together with all actors involved to ensure progress and to reflect on how to best address remaining challenges.

34. INVITES THE COMMISSION and MEMBER STATES to explore synergies and increase the dialogue between medicines and medical devices sectors with regards to the innovative healthcare paradigms resulting from the convergence of technologies, as these are constantly evolving, as shown under the COVID-19 pandemic. Expertise is required to face the challenges of health technologies and the need to provide scientific advice to academy/start-ups.

35. INVITES THE COMMISSION and MEMBER STATES to strengthen the regulatory system with adequate tools to deal with convergent technologies and combined products having in consideration of the overall product lifecycle. UNDERLINES the speed of innovation and also the challenges of convergence products and their co-development, which requires the proper expertise and a more collaborative approach between medical devices and medicines sectors.

36. INVITES THE COMMISSION AND MEMBER STATES at CAMD and MDCG level to work together in the development of pathways to an effective coordination, namely on market surveillance and vigilance, in order to assure a uniform access to conform and safe medical devices in all Member States and for an efficient management of their resources.

AFFORDABILITY & REAL-WORLD EVIDENCE:

37. NOTES that robust evidence along the life cycle of the health care products is central to support the decision-making process, particularly at regulatory, HTA, pricing and health care decision-makers. HIGHLIGHTS that to align evidence requirements amongst stakeholders, a systematic and permanent dialogue between regulators, HTA, Payers, patients and health care professionals is needed.

38. RECOGNISES that Real-World Evidence (RWE) complements regulatory knowledge, reduce evidence gaps in HTA/Payer decisions and support medical decisions on best treatment options. WELCOMES the European Health Data Space (EHDS) initiative to promote digital health and to leverage data quality, establishing a strong infrastructure and interoperability within the MEMBER STATES, developing a system of data governance and rules for data exchange and also WELCOMES the Data analytics and Real-World Interrogation Network (DARWIN EU) as a synergic tool for this initiative.

39. RECOGNISES the change in business models from blockbusters to "niche-busters", such as advanced therapy medicinal products. Niche products are frequently authorised through accelerated procedures with limited evidence at the time of approval, but that can generate a higher potential benefit for patients. HIGHLIGHTS that this uncertainty on outcomes should be reflected on prices.

40. UNDERLINES the need for a better preparedness of Member States to predict hurdles and anticipate strategies, when dealing with high-cost emergent technologies, through investment in Horizon Scanning activities. WELCOMES the International Horizon Scanning Initiative, that aims to empower decision-makers and payer organisations to drive for better pricing in medicinal products.

41. UNDERLINES that Member States and the European Commission, also through the Pharmaceutical Strategy, aims at fostering cooperation in a group of competent authorities, based on mutual learning and best-practice exchange on pricing, payment and procurement policies, to improve affordability and cost-effectiveness of medicines and health system's sustainability. RECOGNISES the need to enhance transparency, including the public contributions to R&D.

42. TAKES NOTE of the progress achieved in cross-border HTA collaboration with EUnetHTA. This collaboration settles the pillars for the HTA regulation that will establish a framework to support Member States' cooperation on joint clinical assessment and joint scientific consultations of medicinal products, IVD medical devices and medical devices. The implementation of the HTA regulation will support Member States in promoting an equitable and timely access to health technologies in the EU, respecting national competences.

RECOMMENDATIONS

43. INVITES MEMBER STATES AND THE COMMISSION to IMPLEMENT an EU Real-World data collection and evidence generation action plan, promoting a better alignment amongst ongoing national and cross border initiatives. This would include the development of a robust framework and methodologies in a multi-stakeholder approach, to recognise RWE as a complement to evidence from clinical trials, to support HTA/Payers decision-makers as well as health care professionals, particularly on highly innovative technologies with clinical uncertainty.

44. INVITES MEMBER STATES AND THE COMMISSION to take the opportunity of digital transition benefiting from the EHDS to optimise data collection, in a more integrated way and cooperate to transform this data into knowledge that can support regulators, HTA, payers and clinical decision making to pursue better patient health outcomes.

45. INVITES MEMBER STATES AND THE COMMISSION to enhance cooperation by reinforcing the role of the National Competent Authorities and Pricing Reimbursement Group (NCAPR), that would allow development of concrete actions to support national decision making, in full respect of Member States competencies. PROMOTE the strategic alignment and synergies between transparency, pricing and reimbursement initiatives, including regional initiatives, and also with other partners (e.g., WHO, OECD, EMA).

46. ENCOURAGES MEMBER STATES to reinforce the regional cross-border collaborations in order to make a more efficient use of health technologies and public resources, paving the way for a more equitable and sustainable health care system.

47. INVITES MEMBER STATES AND THE COMISSION to collaborate in studying and implementing new and transparent payment mechanisms for innovative products, particularly to UMNs and those aimed at specific populations, as well as older medicinal products. These models should reflect new ways to foster innovation whilst ensuring access to generic and biosimilars and safeguarding that older products remain on the market rewarding the value these medicines bring to the health system.