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From: Permanent Representatives Committee (Part 1)
To: Council

Subject: Draft Council Conclusions on Access to medicines and medical devices for
a Stronger and Resilient EU
- Approval

Delegations will find attached the draft Council conclusions on Access to medicines and medical devices for a Stronger and Resilient EU.

The text was endorsed by the Committee of the Permanent Representatives (Part 1) on 9 June 2021.

The Council (EPSCO) is invited to approve these Council Conclusions at its session on 15 June 2021.

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 medicinal products 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, the European Union should seek a holistic approach that addresses both EU and national developments as well as challenges towards a robust regulatory system for pharmaceutical and medical devices within the EU and its Member States. The aim is to ensure high standards of quality, safety, efficacy and equity, as well as public trust, promoting optimisation and flexibility, without prejudice to national competences.

Looking beyond the COVID-19 pandemic, there is a need to act on the structural needs. Although recognising the remarkable progress in many disease areas, societies face persistent challenges. Accordingly, there is a need to ensure that timely access to innovative medicines and medical devices delivers benefits both to patients and health systems. In addition, it is necessary to focus efforts on public health concerns, such as the development of new antimicrobials, or concerns relating to vulnerable populations such as the paediatric and elderly populations. It is also important to follow the multidisciplinary principles that the One Health Approach envisages, in order to tackle the emerging threat of antimicrobial resistance that impacts on human, environmental and animal health domains. This also applies in the context of the COVID-19 recovery plans.

The European medicines regulatory system needs to ensure that generics, biosimilars and 'older' products, that are essential to patients and healthcare systems, are available on markets to a sufficient extent.

Throughout this process, it is vital that the necessary actions and reforms to be implemented encompass the needs of the end-users of health technologies, 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 (TFEU), a high level of human health protection must be ensured in the definition and implementation of all Union policies and activities; that Union action, which needs to complement national policies, must be directed towards improving public health; that the Union should encourage cooperation between the MEMBER STATES in the field of public health and, if necessary, support their action; that the European Parliament and the Council must adopt measures setting high standards for the quality and safety of medicinal products and devices for medical use; and that Union action must 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, including the allocation of the resources assigned to them¹.
- b. that under Article 4(3) of the Treaty on European Union, the Union and the MEMBER STATES must, in full mutual respect, assist each other in carrying out tasks which flow from the Treaties, pursuant to the principle of sincere cooperation².
- c. that Article 35 of the Charter of Fundamental Rights of the European Union recognises the fundamental right to benefit from medical treatment under the conditions established by national laws and practices³.

¹ Consolidated version of the Treaty on the Functioning of the European Union, OJ C 115, 9.5.2008, p. 122

² Consolidated version of the Treaty on European Union, OJ C 115, 9.5.2008, p. 13

³ Charter of Fundamental Rights of the European Union, OJ C 326, 26.10.2012, p. 391

- d. the Presidency Conclusions of 19 and 20 June 2000, which reaffirmed the need to ensure a high level of protection of human health in the definition and implementation of all Union policies⁴.
- e. the Resolution of the European Parliament on Access to Medicines, adopted on 2 March 2017⁵.
- f. the Resolution of the European Parliament on the shortages of medicines and on how to address an emerging problem, adopted on 17 September 2020⁶.
- g. the Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its MEMBER STATES, adopted on 17 June 2016⁷.
- h. the Council conclusions on Encouraging MEMBER STATES-driven Voluntary Cooperation between Health Systems, adopted on 16 June 2017⁸.
- i. the European Council conclusions inviting the Commission to identify strategic dependencies in industrial ecosystems including health and to propose measures to reduce these dependencies, adopted in October 2020⁹.
- j. the Council conclusions on the Economy of Wellbeing, adopted on 26 November 2019¹⁰.

⁴ Santa Maria da Feira European Council (2000) Presidency Conclusions

⁵ European Parliament (2017) European Parliament resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(INI), P8_TA(2017)0061

⁶ European Parliament (2020) European Parliament resolution of 17 September 2020 on the shortages of medicines – how to address an emerging problem, P9_TA(2020)0228

⁷ Council conclusions on strengthening the balance in the pharmaceutical systems in the European Union and its Member States, OJ C 269, 23.7.2016, p. 31

⁸ Council conclusions on Encouraging Member States-driven Voluntary Cooperation between Health Systems, OJ C 206, 30.6.2017, p. 3

⁹ Council of the European Union (2020) Special meeting of the European Council (1 and 2 October 2020) – Conclusions, EUCO 13/20

¹⁰ Council conclusions on the Economy of Wellbeing, OJ C 400, 26.11.2019, p. 9

- k. the Pharmaceutical Strategy for Europe launched by the Commission on 25 November 2020¹¹ which constitutes a fundamental pillar in building a stronger European Health Union. The Strategy, through a number of legislative and non-legislative actions, aims to promote patient access to innovative and affordable medicines in the EU.
 - l. the Health Ministers Council meeting on 9 December 2019, in which some Members of the Council called for a European Union agenda on pharmaceutical policy for the 2020-2024 legislative period.
 - m. the Council conclusions on COVID-19 lessons learned in health, adopted on 28 December 2020¹².
 - n. 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 29 and 30 April 2021.
2. RECOGNISES, as an important result in the context of the COVID-19 pandemic, a closer cooperation between the Member States and the European Commission in the area of availability and access to medicines and medical devices, building on the experience and challenges of joint negotiation and joint procurement.
 3. ACKNOWLEDGES Regulation (EU) 2021/522 of the European Parliament and the Council of 24 March¹³, establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-2027, which constitutes the main financial instrument for health policies. EU4Health will contribute to the post-COVID-19 recovery by strengthening the resilience of health systems to face future challenges posed by health threats, and by promoting security of supply and innovation in the health sector.

¹¹ Communication from the Commission Pharmaceutical Strategy for Europe, COM/2020/761 final

¹² Council conclusions on COVID-19 lessons learned in health, OJ C 450, 28.12.2020, p. 1

¹³ 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) No282/2014, OJ L 107, 26.3.2021, p. 1

4. NOTES that the European Commission and Member States, in accordance with their possibilities, can contribute to ensuring that safe and effective vaccines, diagnostic tests and therapies are available in every country in the world and, where these countries have committed to contributing to the global initiative ensuring equitable access to COVID-19 tools, to ensuring access to the COVID-19 Tools Accelerator, including its vaccine pillar COVAX.
5. INVITES THE COMMISSION and THE MEMBER STATES to closely collaborate on the measures necessary for the implementation of the Pharmaceutical Strategy, which enables a holistic approach in the development of the European pharmaceutical policy and to facilitate timely solutions, in particular regarding shortages of critical medicines.
6. INVITES MEMBER STATES AND THE COMMISSION to facilitate the dialogue between all Member States, patients and consumers, health professionals, industry and academia in the pharmaceutical and medical device areas, taking into account existing mechanisms.
7. INVITES THE MEMBER STATES AND THE COMMISSION to strive on building a more crisis-proof system and to work together to contribute to a resilient and equitable system, thereby increasing citizens' trust. One of the pillars of this structure should be the efforts of Member States to join forces to improve access to and the availability of effective medicines and medical devices in all Member States, therefore supporting the preparedness and resilience in pharmaceutical development and production in the EU.

AVAILABILITY:

8. HIGHLIGHTS the essential role of medicines and medical devices in the health systems and the need to ensure their adequate and continuous availability in all EU Member States, in particular in smaller markets, in accordance with their needs, and to ensure that authorised products reach all EU countries. For this purpose, it is important to understand the reasons behind the timing to market of medicinal products in some countries and to learn from the pilot project on the market launch of Centrally Authorised Products.

9. WELCOMES the patient-centred Pharmaceutical Strategy for Europe, promoting the accessibility, availability and affordability of medicines. SUPPORTS sustainable innovation and access to generics, biosimilars, and other well established products. PROMOTES flexible solutions and upholds the sustainability of the health sector and competitiveness of the European pharmaceutical industry. STRESSES the need to enhance the resilience of the sector by diversifying and securing supply chains and by better equipping the Union and its Member States for crisis preparedness.
10. LOOKS FORWARD to the results of the ongoing study by the European Commission on the root causes of shortages and its assessment of the legal framework, with a view to better understanding the problem and to adopting adequate and coordinated measures at EU level. TAKES NOTE OF the Commission's initiatives to strengthen the mandate of the European Medicines Agency (EMA) in crisis preparedness and management, to review pharmaceutical legislation and to look into ways in which to secure supply so as to mitigate the problems posed by shortages.
11. NOTES the Structured Dialogue Initiative which aims to develop a better understanding of the functioning of global supply chains, to identify the causes and drivers of vulnerabilities and dependencies that pose a threat to the supply of critical medicines (including their starting materials and Active Pharmaceutical Ingredients (APIs)) and to ensure the diversification of supply chains. This initiative aims to propose solutions designed to ensure the security of medicines supplies to patients within the EU. INVITES MEMBER STATES to continue to provide input on the Structured Dialogue initiative to better cover the regulatory and health system perspective and Member States' needs.
12. NOTES that regulatory flexibility and simplification is a long-standing aim for operational excellence and measures such as those taken on the approval of vaccines during the COVID-19 pandemic that have contributed to accelerated access. However, this approach should be further explored with caution and focus on needs, particularly in the context of a crisis.

13. NOTES that the sustainability of the regulatory system, the need to strengthen scientific and regulatory capacity and the capability of the Member States and the European medicines regulatory network are key to an adequate and sound implementation of the new Pharmaceutical Strategy. STRESSES the need to advance the revision of the fee regulation¹⁴ to support the sustainability of the regulatory system network.
14. TAKES NOTE OF the May 2021 update of the Industrial Strategy for Europe¹⁵, 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 necessity to promote the diversification of API suppliers and reinforce manufacturing capacity of critical medicines within the EU to diversify supply lines to strengthen the EU open strategic autonomy.
15. WELCOMES the discussions on the EU Health Union package that the Commission submitted on 11 November 2020. The package comprises a series of proposals to strengthen the EU's health security framework, monitor shortages during crises, strengthen crisis preparedness and readiness, and enhance response capability and the extended role of the EMA and the European Centre for Diseases Prevention and Control (ECDC).
16. WELCOMES Europe's Beating Cancer Plan¹⁶, presented by the Commission as a key pillar of the European Health Union package. WELCOMES the SAMIRA¹⁷ Action plan which is aimed at the security of supply of medical radioisotopes for cancer diagnosis and care and the development of innovative cancer therapies.

¹⁴ Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products, OJ L 35, 15.2.1995, p. 1

¹⁵ Communication from the Commission Updating the 2020 New Industrial Strategy: Building a stronger Single Market for Europe's recovery, COM/2021/350 final

¹⁶ Communication from the Commission, Europe's Beating Cancer Plan, COM(2021) 44 final

¹⁷ Commission Staff Working Document on a Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA), SWD(2021) 14 final

17. NOTES the need to strengthen cooperation between the EMA and the Member States to better monitor the availability of medicines and medical devices. This also needs to entail cooperation with the Medical Device Coordination Group (MDCG). Such cooperation will also help prevent and manage shortages during a crisis, as well as provide scientific advice relevant for crisis preparedness and management, where necessary.
18. NOTES the need for Member States to be adequately prepared for the full implementation of the Clinical Trials Regulation¹⁸. This regulation aims to promote an environment that is favourable to the conduct of clinical trials in the EU, and which promotes the highest standards of safety for participants and increased transparency of trial information via the Clinical Trials Information System. This entails innovation in clinical trials to support innovative clinical trial designs and methodologies.
19. 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 patients and healthcare professionals in the EU. RECOGNISES that they are of paramount importance in terms of the availability of appropriate tools and resources and in terms of adequate application. This is relevant for the capacity of notified bodies, the implementation of European Database on Medical Devices (EUDAMED) and the operability of new scientific bodies (EU Reference Laboratories and expert panels). STRESSES the need for a functioning implementation and for exploring the full potential of these regulations on public health, whilst ensuring adequate coordination at EU and national level.

¹⁸ Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (Text with EEA relevance), OJ, L 158, 27.5.2014, p. 1

20. ACKNOWLEDGES that the IVD Regulation (IVDR) will deliver a number of major improvements, setting high standards of quality and safety for *in vitro* diagnostic medical devices with a view to meeting common safety concerns on such products. TAKES NOTE of the fact that there is a paradigm shift on the risk classification of IVDs, which will lead to a significant increase in IVDs needing a notified body to intervene in their conformity assessment.
21. CALLS ON MEMBER STATES AND THE COMMISSION to continue their efforts as regards the timely and adequate application of Medical Devices and IVD Regulations, in order to ensure the availability and accessibility of medical devices and IVDs in the European market.
22. INVITES MEMBER STATES AND THE COMMISSION within their available capacities, to support 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 sustainable health systems and a patient-oriented strategy, namely in crisis situations.
23. URGES the Commission to table a proposal for a revision of the fee regulation which would allow the EMA and national competent authorities to further invest in strengthening the scientific and regulatory capacity and capability of the network.
24. ENCOURAGES THE COMMISSION to develop a full inventory of the Europe Union's potential and existing global manufacturing capacities for critical medicines, medical devices and other medical products.
25. INVITES THE COMMISSION to propose measures to facilitate availability in all Member States where there is a demand, particularly of critical medicines in periods of crisis and where there are significant increases in demand. In this respect, TAKES NOTE of the EU Strategy on COVID-19 Therapeutics.

ACCESSIBILITY

26. ACKNOWLEDGES the importance of the balance in terms of regulatory incentives in order to promote the development of and ensure adequate access to innovative medicinal products, as well as generics and biosimilars and 'older' medicinal products. RECOGNISES the opportunity to increase competition within the market, taking into consideration relevant tools and the need for tailored incentives in cases of unmet medical needs (UMNs). INVITES the Commission, in the context of the Pharmaceutical Strategy, to study the various aspects and impact in relation to incentives.
27. NOTES that the Pharmaceutical Strategy foresees the revision of the current basic pharmaceutical legislation. STRESSES the need to adapt the EU regulatory framework to improve market access for medicines of the highest quality, efficacy and safety.
28. RECOGNISES all the improvements delivered by the Medical Devices and IVD Regulations, and the scope for further enhancing coordination at EU level, also in terms of market surveillance and vigilance.
29. RECOGNISES the impact of COVID-19 on the already challenging implementation of the IVDR and including the need to ensure that safe and effective *in vitro* diagnostic medical devices can be legally placed on the Union market after May 2022. WELCOMES the priority given by the MDCG to ensure effective implementation of the IVDR, including the Joint Implementation Plan endorsed in May 2021, but remains concerned about the level of preparedness as well as the capacity of IVDR designated notified bodies, which are at a critical point from the perspective of the applicability of IVDR and CALLS ON THE COMMISSION to take legislative action allowing a swift and legally sound answer to this challenge.
30. INVITES the Member States and the Commission to continue exploring the issues affecting off-patent products. These include withdrawals from the market for commercial reasons, for example, via the repurposing initiative used as a tool to stimulate research and facilitate access, particularly in neglected areas and in cases of UMNs.

31. INVITES THE MEMBER STATES AND THE COMMISSION to discuss regulatory routes and a set of commonly accepted criteria for UMN applicable to orphan and paediatric medicinal products, medical devices and IVDs. INVITES THE MEMBER STATES AND THE COMMISSION to consider revised mechanisms and incentives for medicinal products development in line with the level of UMN, while ensuring access in all Member States.
32. INVITES MEMBER STATES AND THE COMMISSION to discuss, where appropriate, new ways in which to invest in the development of new medicines. INVITES THE MEMBER STATES AND THE COMMISSION to enable collaboration between scientific disciplines by involving regulators, academia, healthcare professionals, patients' organisations and healthcare deliverers and payers at early stages of R&D. INVITES THE MEMBER STATES AND THE COMMISSION to reflect on principles of licensing, taking into account social aspects regarding public research institutions and its potential impact on accessibility and affordability.
33. INVITES MEMBER STATES AND THE COMMISSION to collaborate on identifying UMN and their causes, as well as to collaborate on areas of public health concern, such as antimicrobial resistance and the environmental impact in terms of pharmaceutical manufacturing, in order to ensure that patients' needs are met. NOTES the lack of an agreed understanding of the concept of UMN. WELCOMES the efforts to identify and agree on a common set of criteria or principles for UMN.
34. INVITES THE COMMISSION AND MEMBER STATES to prioritise and continue their efforts to adequately implement the IVDR and to ensure the availability and accessibility of safe and effective IVDs on the European market. CALLS ON THE COMMISSION AND MEMBER STATES to continue monitoring the level of preparedness, to work closely together with all actors involved to ensure sufficient progress and to address the current challenges ahead of the date of application of the IVDR.

35. INVITES THE COMMISSION AND MEMBER STATES to strengthen the regulatory system with adequate tools to deal with convergent technologies and combined products, taking into consideration the overall product lifecycle. UNDERLINES that research priorities should be aligned to the needs of patient and health systems, the speed of innovation and the challenges associated with convergence products and their co-development. These require proper expertise and a more collaborative approach between medical devices and medicines sectors, for instance, in relation to personalised therapies.
36. INVITES THE COMMISSION AND MEMBER STATES to work together at MDCG level to promote effective coordination, namely in relation to market surveillance and vigilance, in order to assure access to legally compliant and safe medical devices in all Member States and to ensure the efficient management of their resources.

AFFORDABILITY (& REAL-WORLD EVIDENCE):

37. HIGHLIGHTS the fact that improved data requirements in relation to stakeholders may benefit from a dialogue between regulators, Health Technology Assessment (HTA)/payers, patients and health care professionals, at the appropriate level.
38. RECOGNISES that randomisation can provide more robust evidence compared with observational data. In particular, coded electronic health records based or registry-based randomised trials or platform trials can compare treatment options with usual care in a routine patient population with patient-relevant outcomes.

39. RECOGNISES that Real-World Evidence (RWE) can complement regulatory knowledge, reduce evidence gaps in HTA and payer decisions, and support medical decisions on best treatment options. WELCOMES the future proposal for a European Health Data Space (EHDS) to promote digital health and to leverage data quality. This establishes a strong infrastructure and interoperability, while promoting data privacy within the MEMBER STATES and at EU level, and develops a system of data governance and rules for data access and exchange with emphasis on data privacy. WELCOMES the Data analytics and Real-World Interrogation Network (DARWIN EU) as a synergic tool for this initiative.
40. HIGHLIGHTS that long-term dilemmas such as the increasing tension on the affordability of health systems due to rising prices, the introduction of increasingly complex and targeted therapies, as well as urgent health emergencies, such as the COVID-19 pandemic, have highlighted a pressing need for data by manufacturers and robust predictive information. RECOGNISES that there is an opportunity for comprehensive horizon scanning where it can effectively serve the needs of the EU and its Member States in predicting hurdles and developing strategies at national and EU level, when dealing with high-cost emergent technologies. TAKES NOTE of the International Horizon Scanning Initiative, that aims to empower national decision-makers and payer organisations to drive informed pricing decisions for medicinal products.
41. STRESSES that the Member States and the European Commission, also through the Pharmaceutical Strategy, aim to promote cooperation within a group of competent authorities, based on mutual learning and best-practice exchange on pricing, payment and procurement policies, so as to improve affordability and cost-effectiveness of medicines and health systems sustainability. RECOGNISES the need to further reflect on the transparency on the cost calculation on prices, including R&D investments, as an instrument to allow for better informed pharmaceutical policy and public debate.

42. TAKES NOTE of the progress achieved in cross-border HTA collaboration with EUnetHTA. This collaboration has contributed to the cooperation on joint clinical assessment and joint scientific consultations of medicinal products, IVD and medical devices.
43. INVITES MEMBER STATES AND THE COMMISSION to explore the possibility of establishing an EU Real-World data collection and evidence generation action plan, which will promote better collaboration between ongoing national and cross-border initiatives. This may include the development of a robust framework and methodologies in a multi-stakeholder approach. The aim is to recognise RWE as a complement to evidence from clinical trials, to support regulators and HTA/payers' decision-making and to support health care professionals, particularly in relation to highly innovative technologies with limited evidence.
44. INVITES MEMBER STATES AND THE COMMISSION to use the digital transition within the EHDS to optimise data collection, in a more integrated way, and to cooperate so as to transform this data into evidence to support regulators, HTA/ payers, clinical decision-making and patients to pursue better care and patient outcomes.
45. INVITES MEMBER STATES AND THE COMMISSION to further develop cooperation on a voluntary basis within the Network of Competent Authorities on Pricing and Reimbursement (NCAPR). This would allow for information exchange and the development of concrete initiatives to support national decision-making and take into account divergent situations, including different GDPs within the EU, in full respect of Member States competencies. PROMOTES synergies between all initiatives that aim to stimulate a debate on transparency, affordability, pricing and reimbursement initiatives, including regional initiatives, also involving other partners (e.g. WHO, OECD, EMA). HIGHLIGHTS the need to continue efforts, in order to stimulate competition through the exchange of best practices, including on the uptake of generics and biosimilars.

46. ENCOURAGES MEMBER STATES to enhance regional cross-border collaboration in order to improve capacity with regard to innovative health technologies in the context of sustainable health care systems.
47. INVITES MEMBER STATES AND THE COMMISSION to exchange ideas on payment mechanisms for innovative products, particularly with regard to UMN and those aimed at specific populations, as well as for older medicinal products, where this can contribute to improving access and affordability. These models should reflect new ways in which to promote innovation, whilst ensuring access to generic and biosimilars and ensuring that older products remain on the market in recognition of the value of these medicines to patients and the health system.
48. INVITES the MEMBER STATES AND when appropriate, the COMMISSION to explore the added value of setting up a voluntary and not exclusive multilateral joint procurement mechanism, taking into consideration EU joint procurement experiences gained in the pandemic and considering specific therapeutic areas.
49. NOTES that incentives for innovation can support the development of new effective and accessible medicines and medical devices.

