PRESS

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Council of the European Union

1. Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States

"The Council of the European Union

1. RECALLS 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 fully respect the responsibilities of the Member States for the organization and delivery of health services and medical care and allocation of the resources to them;

2. RECALLS that under Article 168(4)(c) of the Treaty on the Functioning of the European Union, the European Parliament and the Council can, in order to meet common safety concerns, adopt measures setting high standards of quality and safety for medicinal products and devices for medical use;

3. RECALLS that under Article 4(3) of the Treaty on European Union, the Union and the Member States shall assist each other in carrying out tasks which flow from the Treaties, pursuant to the principle of sincere cooperation;

4. RECALLS that under Article 5(2) of the Treaty on European Union, the Union shall act only within the limits of the competences conferred upon it by the Member States in the Treaties to attain the objectives set out therein and that competences not conferred upon the Union in the Treaties remain with the Member States;

5. RECALLS that under Article 3(1)(b) of the Treaty on the Functioning of the European Union, the Union has exclusive competence in relation to the competition rules necessary for the functioning of the internal market for medicinal products;

6. STRESSES that it is fully Member States' competence and responsibility to decide which medicinal products are reimbursed and at what price and that any voluntary cooperation on

pricing and reimbursement between Member States should remain Member States driven;

7. RECOGNISES that a balanced and strong, functioning and effective intellectual property environment, that is line with international commitments of the European Union, is important for supporting and promoting access to innovative, safe, effective and quality medicinal products in the European Union;

8. NOTES that the pharmaceutical sector in the European Union has the potential to be a major contributor to innovation and the health and life sciences sector, through the development of new medicinal products;

9. RECOGNISES that new medicinal products however may also pose new challenges to individuals patients and public health systems, in particular regarding the assessment of their added value, the consequences for pricing and reimbursement, the financial sustainability of health systems, their post-market surveillance and patient access and affordability;

10. UNDERLINES that Health Technology Assessment is an important tool in achieving sustainable health care systems and to promote innovation that delivers better outcomes for patients and society as a whole and RECOGNISES that EU cooperation in line with the Strategy for EU cooperation on Health Technology Assessment and the adopted work programme of EUnetHTA can support the decision-making of Member States, while acknowledging the potential added value of health technology assessments in the context of national health systems;

11. TAKES NOTE that the EU pharmaceutical legislation provides harmonised regulatory standards for the authorisation and supervision of medicinal products for human use and lays down certain regulatory schemes for the earlier marketing authorisation of medicines with less comprehensive data, such as the conditional marketing authorization or the authorisation under "exceptional circumstances";

12. RECOGNISES that the exact conditions for the inclusion of innovative and specialised medicinal products in the existing schemes of early marketing authorisation could be further clarified in order to improve transparency, to ensure a continuous positive benefit risk balance of medicinal products put on the market under special conditions and to focus on medicinal products of major therapeutic interest for public health or to meet unmet medical needs of patients;

13. BEARING IN MIND that specific legislation has been put in place promoting the development and marketing authorisation of medicinal products targeting - *inter alia* - products to treat patients suffering from rare diseases commonly known as orphan medicinal products, paediatric medicinal products and advanced therapy medicinal products, incorporating specific incentives, including supplementary protection certificates, data exclusivity or market exclusivity and protocol assistance for orphan medicinal products;

14. BEARING IN MIND that the incentives in this specific legislation need to be proportionate to the goal of encouraging innovation, improving patients' access to innovative medicines with therapeutic added value and budgetary impact, and it should be avoided that circumstances are created that might encourage inappropriate market behaviour of some manufacturers and/or hamper the emergence of new or generic medicinal products and in this way potentially limit pa-

tients' access to new medicines for unmet medical needs and that can affect the sustainability of health systems;

15. NOTES that there are indications that the post-market compliance with certain obligations for marketing authorization holders is not always optimal, which may cause that independent research data and information from patient registries are not structurally generated, collected and made available for research and proof of effectiveness and safety;

16. NOTES WITH CONCERN an increasing number of examples of market failure in a number of Member States, where patients access to effective and affordable essential medicines is endangered by very high and unsustainable price levels, market withdrawal of products that are out-of-patent, or when new products are not introduced to national markets for business economic strategies and that individual governments have sometimes limited influence in such circumstances;

17. NOTES the increasing trend of marketing authorisation of new medicinal products for small indications, including, in some cases, the authorisation of a single product for 'segmented' patient groups within a disease area and the authorisation of one substance for several rare diseases and in this respect NOTES WITH CONCERN that companies may seek very high prices while the added value of some of these products is not always clear;

18. RECOGNISES that special attention should be given to the access to medicines for patients in smaller Member States;

19. UNDERLINES the importance of timely availability of generics and biosimilars in order to facilitate patients' access to pharmaceutical therapies and to improve the sustainability of national health systems;

20. STRESSES that both public and private investments are essential for the research and development of innovative medicinal products. In those cases where public investment has played a major role in the development of certain innovative medicinal products, a fair share of the return on investment in such products should preferably be used for further innovative research in the public health interest for example through agreements made on benefit sharing during the research phase;

21. STRESSES that the functioning of the pharmaceutical system in the EU and its Member States depends on a delicate balance and a complex set of interactions between marketing authorisation and measures to promote innovation, the pharmaceutical market, and national approaches on pricing, reimbursement and assessment of medicinal products and that several Member States expressed concerns that this system may be imbalanced and that it may not always promote the best possible outcome for patients and society;

22. RECALLS the Council Conclusions on the reflection process on modern, responsive and sustainable health systems adopted on 10 December 2013[1], the Council Conclusions on the economic crisis and healthcare adopted on 20 June 2014[2], the Council Conclusions on innovation for the benefit of patients adopted on 1 December 2014[3] and the Council Conclusions on

personalised medicine for patients adopted on 7 December 2015[4];

23. RECALLS the discussion at the Informal Meeting of Ministers of Health in Amsterdam on 18 April 2016 on “Innovative and Affordable Medicines” which highlighted the important role of the life sciences industry in Europe, in particular, in developing effective new treatments for patients with high unmet medical needs. At the same time challenges in the pharmaceutical system in the EU and its Member States were noted and that several Member States may wish to cooperate and take action on a voluntary basis to face common challenges identified by those several Member States to the sustainability of national healthcare systems, which may be linked to a number of potential factors, for example the affordability of medicinal products related to high prices, possible unintended or adverse consequences of incentives and the lack of leverage of individual Member States in negotiations with industry;

24. WELCOMES the discussion during the informal meetings of relevant high level representatives of the Member States responsible for pharmaceutical policy on 11 December 2015 and 26 April 2016, who met for the first time and recognised the added value of an informal reflection and exchange of views on strategic policy level between Member States;

25. RECOGNISES that a number of Member States have expressed interest in pursuing voluntary cooperation between two or more Member States in the field of Health Technology Assessment as well as in exploring voluntary cooperation in different areas, for example on issues related to pricing and reimbursement of medicinal products, activities aimed at 'horizon scanning', the exchange of information and knowledge, the collection and exchange of price data such as the EURIPID collaboration, and in some cases by bringing together of facilities and resources as well as instruments for joint price negotiations and the conducting of early dialogue with companies developing new products; all these activities should remain to be voluntary, focused on clear added value, shared interests and objectives;

26. RECOGNISES that further analysis to examine the current functioning of the pharmaceutical system in the EU and its Member States would be useful, in particular in relation to the impact of certain incentives in EU pharmaceutical legislation, the use thereof by economic operators and the consequences for the innovation, availability, accessibility and affordability of medicinal products for the benefit of patients including as regards innovative treatment solutions to common diseases that cause a heavy burden for individuals and health systems;

27. RECALLS also the relevant findings of the European Commission's 2009 Pharmaceutical Sector Inquiry Report[5], which stressed that a healthy and competitive market for medicinal products benefits from vigilant competition law scrutiny;

28. UNDERLINES the importance of a continuing open and constructive multi-stakeholder dialogue with pharmaceutical industry, patient organizations and other stakeholders, which is necessary in order to ensure future developments of new and innovative medicinal products as well as the sustainability of the pharmaceutical system in the EU and its Member States, while reinforcing, at the same time, public health interests and guaranteeing the sustainability of the EU Member States health systems;

29. RECOGNISES that the pharmaceutical system in the EU and its Member States, which

is characterised by a division of competences between Member States and the EU level, can benefit from dialogue and a more holistic approach regarding pharmaceutical policy, by enhancing voluntary cooperation between Member States aimed at greater transparency, to safeguard common interests, ensuring access of patients to safe, effective and affordable medicinal products as well as the sustainability of national health systems;

30. RECALLS the Report on the implementation of the EMA-EUnetHTA three-year work plan 2012-2015 [6] published by the European Medicines Agency and EUnetHTA;

31. RECOGNISES potential benefits of the exchange of information across Member States on implementation and application of Managed Entry Agreements;

32. RECOGNISES that while these Council conclusions mainly refer to medicinal products, given the specific nature of the sector, the same concerns regarding sustainability and affordability, as well as considerations regarding research and development and HTA, are also applicable to medical devices and *in-vitro* diagnostic medical devices.

INVITES THE MEMBER STATES TO:

33. Consider further development of exclusively Member States driven voluntary cooperation between relevant authorities and payers from Member States, including cooperation within groups of Member States, that share common interests in relation to pricing and reimbursement of medicinal products and to explore possible areas in which such voluntary cooperation can contribute to higher affordability and better access to medicinal products. Where relevant and appropriate, groups of Member States that would like to explore cooperation on a voluntary basis, may also make use of international expertise, with full respect of Member States' competences. This voluntary cooperation could include activities such as:

- Assessment of future introduction of new medicinal products with a possibly significant financial impact on health systems at an early stage through so called 'joint horizon scanning', which entails a forward looking scan of emerging trends and future developments in pharmaceutical research and development aimed at better anticipating the arrival of new, expensive, innovative medicinal products that might potentially affect current policy and practice;
- Pro-active exchange of information between Member States (e.g. national pricing and reimbursement authorities), particularly in the pre-launch phase, with due respect for existing national rules and frameworks, e.g. in relation to business confidentiality;
- Exploring possible strategies on voluntary joint price negotiations in coalitions of Member States, that have expressed interest to do so;
- Consider reinforcing existing cooperation schemes and initiatives to foster agreement on approaches to address unavailability of medicinal products and market failure situations.

34. Exchange HTA-methodologies and assessment outcomes through EUnetHTA and the HTA Network as already foreseen under the Joint Action EUnetHTA, while recognizing that financial impact and pricing must be addressed separately from the HTA, and that the applicability of HTA results need to be assessed by national health systems.

35. Without prejudice to existing cooperation in the context of EUnetHTA, and where appropriate, further explore closer voluntary cooperation on HTA between two or more Member States as a Member States' initiative, such as mutual recognition of HTA reports and/or joint HTA reports.

36. Consider organising during each EU Presidency an informal meeting of relevant high level representatives from the Member States responsible for pharmaceutical policy (e.g. national directors of pharmaceutical policy), encouraging strategic reflection and discussion on current and future developments in the pharmaceutical system in the EU and its Member States, thereby avoiding duplication and respecting the division of competences. These discussions are purely informal and, where relevant and appropriate, can be used as an input for further reflection in the appropriate EU fora, in particular the Working Party on Pharmaceuticals and Medical Devices when areas of EU competence are concerned.

37. The Presidency-trio (the Netherlands, Slovakia and Malta) is invited to identify with the Member States a set of mutual experienced concerns and challenges which could be considered and/or modified by the future Presidencies in the period from 2017-2020, with full respect for Member States' and EU level competences.

38. Where appropriate, these common concerns and challenges will be followed up concretely through dialogue, exchange and (international) cooperation as well as through information exchange, monitoring and research at Member States and EU level in the appropriate fora and, in particular, when EU competences are concerned, through the Working Party on Pharmaceuticals and Medical Devices, with the input from Member States, existing technical and policy fora and, where relevant, the European Commission.

INVITES THE MEMBER STATES AND THE COMMISSION TO:

39. Explore possible synergies between the work of regulatory bodies, HTA bodies and payers, whilst respecting their specific responsibilities in the pharmaceutical chain and fully respecting Member States competences, in order to ensure timely and affordable access of patients to innovative medicinal products that reach the market especially through EU regulatory tools of accelerated assessment, marketing authorisation in exceptional circumstances and conditional marketing authorisation while also analysing the effectiveness of these tools and examining possible clear and enforceable (pre-) conditions and exit options for the products that enter the market through these mechanisms in order to ensure high level of quality, efficacy and safety of the respective medicinal product. These products will therefore continue to be appropriately evaluated and examined with regard to their benefits and risks and appropriateness to be included in these tools.

40. Foster enhanced cooperation between Member States under the 3rd Joint Action of the European Network for Health Technology Assessment (EUnetHTA) as adopted and to reflect about the future of HTA cooperation at European level for the period beyond 2020 when the current Joint Action comes to an end.

41. Improve and strengthen existing dialogue and cooperation between Member States and at EU level, in particular through and within existing fora and technical working bodies and by

continuing investment in and facilitating the work of the Network of Competent Authorities on Pricing and Reimbursement (NCAPR), the Pharmaceutical Committee and the Expert Group on Safe and Timely Access to Medicines for Patients (STAMP).

42. Assess the relevance and functioning of the various technical bodies operating at EU level within the EU pharmaceutical framework, including those operating under the auspices of the European Commission, to clarify and confirm existing tasks, roles and mandates with the aim to avoid duplication and fragmentation of work, and to give Member States a better insight and overview of ongoing developments and discussions in these fora.

43. Consider further investments at national and EU level in the availability of registries and in the developments of methods to assess the effectiveness of pharmaceuticals including through the use of relevant digital means. The implementation of means to inform on post-marketing effectiveness of medicines should allow exchange of information between Member States although in full respect of individual competences, applicable legislation on data protection and other legislation.

44. Consider further investments at national and EU level in the development of innovative medicines for clearly defined unmet medical needs, in particular also through Horizon 2020 and the Innovative Medicines Initiative (IMI) and with the involvement of the European Medicines Agency, whilst promoting open access to research data while fully respecting applicable legislation on data protection and, where applicable, the information that is considered commercially confidential, and considering conditions such as equitable licensing to ensure a fair return on investment for publicly funded research that delivered a major contribution to the development of successful medicinal products.

45. Explore obstacles for deploying existing methods and consider new solutions to address market failure, in particular also in small markets, when established products become unavailable or new products are not introduced to national markets, for example for business economic reasons.

INVITES THE EUROPEAN COMMISSION TO:

46. Pursue the ongoing activities to streamline the implementation of the current legislation on orphan medicinal products and to ascertain correct application of the current rules and fair distribution of incentives and rewards and if necessary consider revision of the regulatory framework on orphan medicinal products without discouraging the development of medicinal products needed for the treatment of rare diseases.

47. Prepare as soon as possible and with the close involvement of the Member States, while fully respecting Member States competences, the following:

a. an overview of the current EU legislative instruments and related incentives that aim to facilitate the investment in the development of medicinal products and the marketing authorization of medicinal products given to the holders of a marketing authorisation as implemented within the EU: Supplementary Protection Certificates (Regulation EC 469/2009), medicinal products for human use (Directive 2001/83/EC and Regulation EC 726/2004), orphan medicinal products

(Regulation EC 141/2000) and paediatrics (Regulation EC 1901/2006);

b. an evidence based analysis of the impact of the incentives in these EU legislative instruments, as implemented, on innovation, as well as on the availability, *inter alia* supply shortages and deferred or missed market launches, and accessibility of medicinal products, including high priced essential medicinal products for conditions that pose a high burden for patients and health systems as well as availability of generic medicinal products. Among those incentives, particular attention should be given to the purpose of supplementary protection certificates as defined in the relevant EU legislative instrument and the use of the “Bolar” patent exemption[7], the data exclusivity for medicinal products and the market exclusivity for orphan medicinal products.

Where relevant, the analysis of impacts should also address - *inter alia* - the development of medicinal products and the effects of the pricing strategies of industry in relation to these incentives.

The Commission will conduct the analysis on the basis of the information that is made available or gathered, including from the Member States and other relevant sources.

To this end, the Commission should prepare by the end of 2016 a timetable and methodology for conducting the analysis as mentioned in this paragraph.

48. Continue and where possible intensify, including through a report on recent competition cases following the pharma sector inquiry of 2008/ 2009, the merger enforcement pursuant to the EC Merger Regulation (Regulation 139/2004) and the monitoring, methods development and investigation - in cooperation with national competition authorities in the European Competition Network (ECN) - of potential cases of market abuse, excessive pricing as well as other market restrictions specifically relevant to the pharmaceutical companies operating within the EU, such in accordance with Articles 101 and 102 of the Treaty on Functioning of the European Union.

49. Based on the above mentioned overview, analysis and report in paragraphs 39 and 40, and taking into account the international commitments of the EU and - *inter alia*- also the needs of the patient, health systems and the competitiveness of the EU based pharmaceutical sector, discuss the outcome and possible solutions proposed by the Commission in the Working Party on Pharmaceuticals and Medical Devices and, when public health issues are concerned, the Working Party on Public Health at Senior Level."

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[1] OJ C 376, 21.12.2013, p. 3, with Corrigendum in OJ C 36, 7.2.2014, p.6
[2] OJ C 217, 10.7.2014, p.2
[3] OJ C 438, 6.12.2014, p.12
[4] OJ C 421, 17.12.2015, p. 2
[5] 12097/09 + ADD1 + ADD2
[6] http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/04/WC500204828.pdf
[7] Article 10.6 of the Directive 2001/83/EC of 6 November 2001 on the Community code

relating to medicinal products for human use.

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