



Brussels, 26 November 2015
(OR. en)

14393/15

SAN 390

NOTE

From: General Secretariat of the Council
To: Permanent Representatives Committee/Council

Subject: **Employment, Social Policy, Health and Consumer Affairs Council**
meeting on 7 December 2015
Draft Council conclusions on Personalised medicine for patients
- Adoption
(Public debate in accordance with Article 8(2) of the Council's Rules of
Procedure [proposed by the Presidency])

1. The Working Party on Public Health discussed and agreed the draft Council conclusions as set out in the Annex.
2. COREPER is invited to confirm the Working Party's agreement and submit the draft conclusions to the Council (EPSCO) for adoption at its meeting on 7 December 2015.
3. The Council is invited to adopt the draft conclusions and forward them for publication in the Official Journal of the European Union.

**Draft Council conclusions on
Personalised medicine for patients**

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, and that Union action, which is to complement national policies shall be directed towards improving public health. The Union shall encourage cooperation between the Member States in the field of public health and, if necessary, lend support to their action. Union action shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care, including allocation of the resources assigned to them;
2. RECALLS the Council conclusions on common values and principles in European Union health systems adopted on 2 July 2006¹, which define a set of operating principles shared across the European Union, especially regarding patient involvement and quality and safety of care, and which emphasise in particular that all European Union health systems aim to be patient-centred;
3. RECALLS the Council conclusions on innovation in the medical device sector adopted on 6 June 2011², which recognise that innovative medical devices could improve health and quality of life for patients and could contribute to addressing the sustainability of healthcare systems, and that innovation should be increasingly patient-centred;
4. RECALLS the Council recommendation of 8 June 2009 on an action in the field of rare diseases (2009/C 151/02) and the incentives offered by Regulation (EC) No 141/2000 of the European Parliament and of the Council on orphan medicinal products which are also used to encourage the development and authorisation of medicinal products for small populations;

¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2006:146:0001:0003:EN:PDF>.

² OJ C 202, 8.7.2011, p. 7.

5. RECALLS the Council conclusions on the reflection process on modern, responsive and sustainable health systems adopted on 10 December 2013³, the Council conclusions on the economic crisis and healthcare adopted on 20 June 2014⁴, as well as the Council conclusions on innovation for the benefit of patients adopted on 1 December 2014⁵, which, while stressing the need to fully respect areas of Member States competence, advocate the need for cooperation on strategies to effectively manage expenditure on pharmaceuticals and medical devices, while ensuring equitable access to effective medicines within sustainable national healthcare systems; the Council conclusions on innovation for the benefit of patients have been followed-up by work in the Working Party on Public Health at Senior Level, including possible topics to serve as a basis for future discussions⁶;
6. TAKES NOTE of the European Commission Staff Working Document on the use of ‘-omics’ technologies in the development of personalised medicine⁷, which highlights the potential and issues in the development of personalised medicine and concludes that the development of personalised medicine offers through the use of ‘-omics’ technologies new opportunities for the treatment of patients in the European Union. It proposes that through this approach, healthcare providers may be able to offer better-targeted treatment, avoid medical errors and reduce adverse reactions to medicinal products. It also identifies several challenges to the implementation and uptake of personalised medicine in health systems;
7. TAKES NOTE of the World Health Organisation (WHO) 2013 Priority Medicines Report⁸, that discusses the role and the current limitations of personalised medicine, called ‘stratified medicine’ in the context of the report, and recommends investments to further strengthen research in and knowledge of stratified medicine and pharmacogenomics;

³ OJ C 376, 21.12.2013, p. 3.

⁴ OJ C 217, 10.7.2014, p. 2.

⁵ OJ C 438/12, 6.12.2014.

⁶ 9869/15 (Innovation for the benefit of patients: Follow-up to the Council’s conclusions) 11039/1/15 REV1 (Outcome of proceedings of the Working Party on Public Health at Senior Level on 15 July 2015).

⁷ European Commission Staff Working Document, October 2013.

⁸ http://www.who.int/medicines/areas/priority_medicines/MasterDocJune28_FINAL_Web.pdf.

8. NOTES that there is no commonly agreed definition of the term “personalised medicine”. However, it is widely understood that personalised medicine refers to a medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention. Personalised medicine relates to the broader concept of patient-centred care, which takes into account that, in general, healthcare systems need to better respond to patient needs;
9. NOTES that, as DNA sequencing technologies, and other advanced ‘-omics’ technologies for the identification of multiple biomarkers are developing rapidly, there is the expectation that these developments could make it possible to use detailed risk profiling as an additional tool for targeted interventions, aiming at and potentially improving health outcomes and over time allowing for a more cost-efficient use of healthcare;
10. NOTES that, with the development of personalised medicine, individuals and health systems face new challenges, including balancing its risks and benefits while also considering its ethical, financial, social and legal implications, particularly regarding pricing and reimbursement, data protection and public interest in processing personal data;
11. NOTES that the development and implementation of personalised medicine goes hand-in-hand with the development of relevant diagnostics;
12. NOTES WITH CONCERN that not all patients have access to innovative methods of better-targeted prevention, diagnosis and treatments and that a significant challenge for Member States consists in promoting appropriate uptake in healthcare systems, in order to ensure integration into clinical practice in line with the principles of solidarity and universal and equal access to high quality of care, while fully respecting Member States competences, and ensuring the sustainability of their national health systems;

13. NOTES that personalised medicine is becoming a reality in research, particularly following the support of the Seventh Framework Programme for research, technological development and demonstration activities, which dedicated over EUR 1 billion to underpin personalised medicine for the period 2007-2013⁹. Funding research for personalised medicine will continue through the Framework Programme for Research and Innovation, Horizon 2020¹⁰, including through actions carried out under the Innovative Medicines Initiative (IMI)¹¹;
14. WELCOMES the high-level conference of 8 July 2015 “Making Access to Personalised Medicine a Reality for Patients”, which addressed obstacles to the integration of personalised medicine into European Union healthcare systems, identified best practices and their added value, and outlined the potential benefits of personalised medicine for public health and its impact on policy-making in the European Union. Involving public health decision-makers, regulators, payers and patients, the conference also underlined the need to define a patient-centred approach to personalised medicine at European Union level, as well as a comprehensive approach integrating the different phases along the life cycle of personalised medicine products in such a way as to facilitate its integration into clinical practice.

INVITES THE MEMBER STATES TO:

15. SUPPORT access, as appropriate, according to national provisions, to clinically effective and financially sustainable personalised medicine by developing patient-centred policies including, as appropriate, patient empowerment and the integration of patient perspectives in the development of regulation processes, in cooperation with patient organisations and other relevant stakeholders;
16. USE genomics information with a view to integrating advances in human genomics into public health research, policy and programs, in compliance with existing national provisions concerning personal data and genomics;

⁹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:i23022>

For example the project PerMed (www.permed2020.eu).

¹⁰ http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/fp/h2020-eu-establact_en.pdf.

¹¹ <http://www.imi.europa.eu/>.

17. DEVELOP OR STRENGTHEN, if necessary, public health communication strategies, based on available, objective, balanced and non-promotional data to increase public awareness as regards both the benefits and risks of personalised medicine, as well as the citizens' role and rights, thus supporting appropriate access to innovative diagnostic methods and better-targeted treatment;
18. PUT in place information and awareness strategies for patients, based on available, objective, balanced and non-promotional data, in order to improve health literacy and access to reliable, relevant and understandable information on existing treatment options, including expected benefits and risks, thus enabling patients to actively cooperate with healthcare professionals in choosing the most appropriate treatment strategies;
19. PROVIDE education, training and continuing professional development for health professionals in order to equip them with the necessary knowledge, skills and competences to make the most of the benefits that personalised medicine brings to patients and healthcare systems;
20. FOSTER cooperation in the collection, sharing, management and appropriate standardisation of data necessary for effective research into, and development and application of personalised medicine, in compliance-with data protection legislation;
21. PROMOTE cross-disciplinary interaction, notably between specialists in genetics, in using statistical methodologies, bio- and health informatics and epidemiology and among health professionals, in order to ensure better understanding of the available data, more efficient integration and interpretation of information from multiple sources and appropriate decision-making on treatment options;
22. DEVELOP OR ADJUST, where necessary, procedures aiming to evaluate the impact of personalised medicine, in particular health technology assessment (HTA) procedures, to the specific nature of personalised medicine, taking into account, inter alia, added value from the patients perspective as well as enhanced cooperation and exchange of best practices, while fully respecting Member States competences;

23. RECOGNISE the potential of clinical and population-based biobanks for accelerating the discovery and development of new medicinal products; support the standardisation and networking of biobanks to combine and share resources, in compliance with data protection legislation;
24. CONSIDER exchange of information and best practices within the existing fora, which could support both appropriate access for patients to personalised medicines, as well as the sustainability of health systems;
25. CONSIDER developing long-term, patient-centred, strategic approaches on how to meet, with a public health perspective, the challenges associated with access to personalised medicine, while ensuring the sustainability of national health systems and fully respecting Member States competences;
26. EXCHANGE best practices in the field of personalised medicine and facilitate its appropriate use in health care practice.

INVITES THE MEMBER STATES AND THE COMMISSION TO:

27. CONTINUE voluntary joint work, including the development of guidance and the definition of criteria, to support HTA on personalised medicine in accordance with the HTA strategy¹², while fully respecting Member States competences;
28. FOSTER enhanced cooperation between Member States within the HTA Network established in accordance with the Directive on the application of patients' rights in cross-border healthcare and HTA bodies under the future Joint Action;
29. PROMOTE the interoperability of electronic health records to facilitate their use for public health and research, through the eHealth Network established in accordance with the Directive on the application of patients' rights in cross-border healthcare, taking advantage of the support from the Connecting Europe Facility¹³;

¹² http://ec.europa.eu/health/technology_assessment/docs/2014_strategy_eucooperation_hta_en.pdf.

¹³ <http://ec.europa.eu/digital-agenda/en/connecting-europe-facility>.

30. DEVELOP common principles on data collection based on standards and a sound legal framework and enabling the processing of patient data and the availability of comparable data at European Union level, allowing secondary use and analysis of data on a larger scale in compliance with data protection legislation, while fully respecting Member States competences;
31. ENCOURAGE early dialogue and provision of parallel scientific advice between innovators, regulators and HTA bodies, taking into account, as appropriate, input from patients, healthcare professionals and payers, to support evidence generation and regulatory authorisation, while fully respecting Member States competences;
32. ENCOURAGE dialogue with Member States' authorities and stakeholders to facilitate step-by-step implementation of the public health genomics approach both at European Union and national level on the basis of past European Union initiatives, such as the European Best Practice Guidelines for Quality Assurance, Provision and Use of Genome-based Information and Technologies – Public Health Genomics European Network¹⁴, and facilitate ongoing European Union initiatives such as the position paper on Public Health Genomics in Cancer, to be developed under the Joint Action on Comprehensive Cancer Control with the support of the Commission expert groups on cancer control and on rare diseases;
33. TAKE personalised medicine into account in the broader context of the future framework for sustainable European Union collaboration on patient safety and quality of care, requested in the Council conclusions on patient safety and quality of care of 1 December 2014;

¹⁴ http://www.phgen.eu/typo3/fileadmin/downloads/QA_Report.pdf.

34. CONTINUE the work of the Expert Group on Safe and Timely Access to Medicines for Patients (STAMP), which analyses issues related to the implementation of European Union pharmaceutical legislation with the aim of identifying ways to maximise effective use of existing European Union regulatory tools and further improve safe and timely access of medicines for patients, including innovative medicinal products; continue, within the STAMP expert group, to monitor progress on the adaptive pathway pilot project undertaken by the European Medicines Agency and its potential to allow early authorisation of a medicine for use in a well-defined patient population with a high level of medical need.

INVITES THE COMMISSION TO:

35. EXAMINE, based on a study under the Third Health Programme (2014-2020), how to realise the potential of Big Data, which is used in personalised medicine, in contributing to innovative, efficient and sustainable health systems, respecting the right to protection of personal data. This study should also consider ethical, legal and social aspects;
36. FACILITATE cooperation and PROMOTE exchange of best practices on education training and continuing professional development of health professionals in the field of personalised medicine;
37. PROMOTE the possibilities offered by the European Reference Networks within the framework of the Directive on patients' rights in cross-border healthcare, to help facilitate the implementation of translational cross-sectorial research, including, where appropriate, into personalised medicine for patients suffering from rare or low-prevalence diseases or complex diseases;
38. CONTINUE to promote the important contributions to personalised medicine from research carried out under the Framework Programme for Research and Innovation, Horizon 2020, including through actions carried out under the Innovative Medicines Initiative (IMI), in order to speed up the development of more effective preventive and diagnostic tools as well as better and safer medicines for patients.