



Council of the
European Union

Brussels, 12 November 2014
(OR. en)

15090/14

SAN 418
PHARM 84

NOTE

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

Subject: **Employment, Social Policy, Health and Consumer Affairs Council**
meeting on 1 December 2014
Draft Council conclusions on vaccinations as an effective tool in public
health
- *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 for adoption by the Council (EPSCO) at its meeting on 1 December 2014.
3. The Council is invited to adopt the draft conclusions and forward them for publication in the Official Journal.

Draft Council conclusions on vaccinations as an effective tool in public health

The Council of the European Union

1. RECALLS that under Article 168 of the Treaty on the Functioning of the European Union (TFEU), Union action, which shall complement national policies, shall cover the fight against the major health scourges by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health. The Union shall encourage cooperation between the Member States and, if necessary, lend support to their action. Union action shall 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.
2. RECALLS Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for Disease Prevention and Control (ECDC). The ECDC supports activities for the prevention and control of communicable diseases: epidemiological surveillance, risk assessment training programmes and rapid alert and response mechanisms, and should undertake activities to ensure that Member States regularly exchange good practices and experiences on vaccination programmes.
3. RECALLS Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013, on serious cross-border threats to health and repealing Decision No 2119/98/CE, which provides that Member States shall consult each other in liaison with the Commission through the Health Security Committee with a view to coordinating their response to serious cross-border threats to health, including communicable diseases. It also provides for a possibility to engage in the joint procurement of medical countermeasures on a voluntary basis.

4. RECALLS the third Programme for the Union action in the field of health (2014-2020) established by Regulation (EU) No 282/2014, aiming to support capacity-building against major cross-border health threats and, to develop preparedness and response planning, taking into account complementarity with the work programme of the ECDC in the fight against communicable diseases.
5. RECALLS Council Recommendation on seasonal influenza vaccination (2009/1019/EU) which encourages the Member States to adopt and implement national, regional or local action plans or policies aimed at improving seasonal influenza vaccination coverage, with the aim of achieving 75% coverage in the risk groups by 2015.
6. RECALLS the Council conclusions on childhood immunisation (2011/C 202/02), in which the Member States and the Commission are invited, inter alia, to share experiences and best practices to improve the vaccination coverage of children against vaccine-preventable diseases;
7. POINTS OUT that vaccines are medicinal products subject to the rules and procedures adopted at Union level, authorised by national authorities or by the Commission on the basis of an assessment carried out by the European Medicines Agency and subject to post-marketing monitoring.
8. RECALLS the European Region Vaccine Action Plan 2015 to 2020 of the World Health Organisation (WHO), which was approved in response to the Decade of Vaccines, setting a course through a regional vision and goals for immunisation and control of vaccine-preventable diseases from 2015 to 2020 and beyond, by defining priority action areas, indicators and targets, while taking into account the specific needs and challenges of countries in the European region.¹

¹ WHO European Region Vaccine Action Plan 2015 to 2020 ([WHO EURO document EUR/RC64/15 Rev.1](#)) was adopted at the 64th session of the Regional Committee for Europe (Copenhagen, Denmark, 15–18 September 2014), see resolution [EUR/RC64/R5](#)

9. POINTS out that post-marketing studies including those carried out by marketing authorisation holders are important for the evaluation of vaccine products and should be carried out in a transparent way. Studies on the impact of vaccination programmes, carried out independently from commercial interests are equally important. Both kinds of studies can contribute to increasing public trust in immunisation. Member States are encouraged to fund independent studies.
10. RECOGNISES that communicable diseases, including some re-emerging ones, such as Tuberculosis, measles, pertussis and rubella, still present a public health challenge and can cause a high number of infections and deaths, and that the recent emergence and outbreaks of communicable diseases, such as polio, avian influenza H5N1 and H7N9, Middle East respiratory syndrome caused by a coronavirus (MERS) and Ebola virus disease have confirmed that vigilance must remain high also with respect to diseases that are not currently present in the territory of the Union.
11. RECOGNISES that while vaccination programmes are the responsibility of individual Member States and that various vaccination schemes exist in the EU, efforts to improve vaccination coverage may also benefit from cooperation within the EU and from improved synergies with other EU policy areas, having special regard to the most vulnerable populations identified in the different regions and individual Member States of the Union and to increasing mobility.
12. OBSERVES that many vaccines used in community vaccination programmes have been able to prevent disease in individuals and at the same time interrupt the circulation of pathogens through the so called “herd immunity” phenomenon, contributing to a healthier global society. Community immunity could thus be considered an objective in national vaccination plans.;
13. CONSIDERS that an evidence-based, cost-effective, safe and efficient immunisation system is an integral part of a well-functioning health system.
14. POINTS OUT that, given the changes in the demographic structure of the European population, there must be a greater focus on preventing infectious diseases by means of vaccination of all age groups where this improves the epidemiological control of the disease.

15. RECOGNISES that immunisation programmes require sustainable access to long-term funding and quality supply.
16. RECOGNISES the importance of the general public understanding the value of vaccinations and NOTES that the occasional lack of awareness of the benefits of some vaccines and the increasing refusal of vaccination in some Member States may lead to under-vaccination in some populations, resulting in public health problems and costly outbreaks.
17. RECOGNISES that the public should be aware of the value of vaccination and UNDERLINES the crucial role of health care professionals in informing and educating the population about the benefits of vaccination.
18. RECOGNISES that effective vaccination campaigns are useful in preventing the spread of communicable diseases that may cause permanent health damage or even death, particularly in vulnerable age-groups of the population.
19. RECOGNISES the positive effect that a reinforced vaccination policy at national level may have on the development of and research in new vaccines in the EU.
20. POINTS OUT that Member States should, if relevant, inform their citizens travelling abroad about the risk of communicable diseases which are not present in the Union, but may be contracted on international trips outside the Union.
21. POINTS OUT that some viral agents may also cause chronic pathologies, some of a neoplastic nature, such as cervical cancer, and that vaccinations could contribute to addressing these diseases.
22. CONSIDERS IT NECESSARY that an analysis and evaluation of the safety, effectiveness and impact of vaccines to prevent distinct communicable diseases, of the risks related to communicable diseases and of the usefulness of vaccinations is periodically carried out in the European Union on the basis of developments in scientific knowledge.

23. CONSIDERS IT USEFUL that Member States collaborate and exchange best practices concerning the prevention of communicable diseases through vaccination given the fact that communicable diseases cannot be confined to one country either within or outside the European Union, and to do so with the support of the ECDC and the WHO.
24. CONSIDERS IT NECESSARY that policies to encourage research, including clinical and, post-authorisation studies in the field of vaccination, be supported within the Union, taking into account also the financial constraints, in order to make safer and more effective-vaccines available.
25. OBSERVES that as a result of the success in reducing the spread of a number of serious communicable diseases due to the widespread use of vaccinations, the population may believe that these diseases no longer represent a threat to public health.
26. CONSIDERS IT APPROPRIATE, especially in order to react to inaccurate information regarding vaccinations in some Member States, that communication campaigns continue to be carried out to educate the public about the risks related to communicable diseases preventable by vaccination.
27. CONSIDERS IT USEFUL to consult stakeholders including health professionals' organisations, academia, industry and civil society to give them the opportunity to express their positions which could be of use Member States' authorities.
28. Invites MEMBER STATES to:
 - a) continue to improve epidemiological surveillance and evaluation of the situation concerning communicable diseases in their territories, including diseases preventable by vaccination;
 - b) continue to improve national vaccination programmes and to strengthen national capacity for carrying out evidence-based, cost-effective vaccination, including the introduction of new vaccines where considered appropriate;

- c) continue to develop plans and standard operating procedures in collaboration with the ECDC and the WHO to ensure a timely and effective response to vaccine-preventable diseases during outbreaks, humanitarian crises and emergencies;
- d) continue to develop comprehensive and coordinated approaches within vaccination programmes, following the Health in All Policies approach creating synergies with broader health policies and pro-actively working with other preventive sectors;
- e) ensure transparency with regard to the post-marketing evaluations of vaccines and of studies on the impact of vaccination programmes in order to provide reliable information for both governments, medicines regulators and manufacturers;
- f) actively offer appropriate vaccination to population groups considered to be at risk in terms of specific diseases and consider immunization beyond infancy and early childhood by creating vaccination programmes with life-long approach;
- g) work with health professionals on risk communication in order to maximize their role in informed decision making;
- h) further increase activities aimed at expanding, where necessary, the immunology and vaccinology components of the basic medical training curricula for students of medical and health sciences and provide health professionals with relevant in-services training opportunities;
- i) inform the population in order to raise its trust in vaccinations programmes, using appropriate tools and communication campaigns also by engaging opinion leaders, civil society and relevant stakeholders (e.g. academia).

29. Invites MEMBER STATES and the COMMISSION to:
- a) continue to exchange information and data with the ECDC and the WHO on the risks posed by communicable diseases and on national vaccination policies; in this regard, the communication toolkits developed by the ECDC and made available to the Member States (following the example of the already developed toolkit for influenza) could be taken into consideration;
 - b) continue to exchange data on vaccination coverage for all target risk groups;
 - c) convey informed and clear messages on vaccinations;
 - d) find the best ways to allow stakeholders, including industry and civil society, to express their positions;
 - e) promote activities aimed at engaging with health care professionals more directly and actively on critical vaccination issues, in particular focused on strengthening their role in advocating vaccination;
 - f) share information on cost-effectiveness studies in the EU for the implementation of new vaccines, which would assist the Member States in their national vaccination programmes;
 - g) coordinate activities aimed at advocating and encouraging the use of vaccines included in national vaccination programmes by sharing information on communication plans and campaigns for vaccine introduction;
 - h) further encourage research and innovation aimed at developing of new vaccines and demonstrating the benefits of a life course approach, the cost effectiveness of immunisation and the effectiveness of risk communication, while at all times giving priority to citizens' safety;
 - i) develop joint action programmes co-financed by the Commission and Member States to share best practices on national vaccination policies;

- j) encourage research activities and continue to exchange information in respect of the monitoring of vaccination impact on disease burden and the development of new vaccines.

30. Invites the COMMISSION to:

- a) identify and encourage synergy between the promotion of immunisation and the implementation of relevant EU legislation and policies, in particular focusing on the identification and development of integrative and coherent approaches for better preparedness and coordination in health emergencies, while fully respecting national competences;
- b) ensure that European Union funding is channeled to foster current and future vaccine research, including wide partnership between academia, industry, and public and private funders, and to address and resolve bottlenecks in vaccine development;
- c) ensure that funding provided by the European Union and other stakeholders, such as academia or public health institutions, and made available by the relevant public health bodies is channeled to support post-marketing studies, including studies on vaccine effectiveness and the impact of immunisation programs carried out by national public health institutes, academia and other partnerships;
- d) examine with the ECDC and the EMA and in close cooperation with the WHO, options to:
- identify guidance and methodologies which Member States could choose to use on a voluntary basis to strengthen the financial and programmatic consistency and sustainability of their national vaccination programmes and the cost effectiveness of vaccines;
 - facilitate the introduction of research methods which Member States could use voluntarily to assess the effectiveness of risk communication and the dynamics of social attitudes towards vaccines and devise effective strategies to promote vaccine uptake;

- e) assist Member States in making the best use of the technical and scientific expertise of the Union agencies and Commission's technical committees, in order to respond to questions;
 - f) place technological and IT tools at the disposal of Member States and improve links to existing European portals and tools to support Member States in their efforts to strengthen vaccination as an effective tool in public health.
-