



Luxembourg, 15th of November 2016

Final flash report from the Plenary Meeting of the Health Security Committee
November 2016, Senningen/Luxembourg

The agenda included key priorities of EU agenda in health and beyond, antimicrobial resistance, preparedness and response under the EU health security framework, current health threats, joint procurement of medical countermeasures, vaccine shortages and action on migrants' health.

22 EU Member States, Norway and Serbia attended the meeting as well as the European Centre for Disease Prevention and Control (ECDC), and the Regional Office for Europe of the World Health Organisation (WHO/Europe).

1. WELCOME AND ADOPTION OF AGENDA

The Chair, John F. Ryan, Director for Public health, country knowledge, crisis management, in the Directorate-General Health and Food Safety of the European Commission, welcomed the members of the Health Security Committee (HSC). He especially thanked the Director General for Health and Food Safety of the European Commission, Xavier Prats Monné, to attend for the first time the Plenary Meeting of the Health Security Committee.

The agenda and the minutes of the meeting were adopted.

2. KEY PRIORITIES OF EU AGENDA IN HEALTH AND BEYOND

Xavier Prats Monné, Director General for Health and Food Safety of the European Commission, thanked the HSC for the important role played in averting and managing crisis situations, exchanging information, and coordinating preparedness and response planning. He emphasized the increasing prominence of global health security on the political agenda and referred to the appointment of Julian King as the new Commissioner for security union. He outlined three strategic priorities of EU agenda in health: i) country knowledge; ii) effective, accessible and resilient health systems; and iii) crisis management and preparedness in health.

Regarding the first priority, country knowledge is being developed to provide the necessary evidence base for cost-effective health promotion and disease prevention policies. A report, "The Health at a Glance: Europe," is scheduled to be published in November focusing on the whole political agenda. 28 country reports are developed in collaboration with the OECD to provide a comprehensive picture of the EU's health situation and the performance of health systems, and a horizontal analysis on key issues.

The second priority follows a clear political agenda, respecting boundaries of the EU competence. The EU supports Member States for example through the Commission proposal on health technology assessment by next year.

The third priority encompasses actions addressing health threats, such as antimicrobial resistance (AMR), where a new One-Health action plan focusing both on veterinary and human health perspective will be launched next year to support Member States in the fight against AMR.

Decision 1082/2013/EU on serious cross-border threats to health gives to the European Commission a clear mandate to coordinate preparedness and management of threats. The forthcoming report of the Court of Auditors will serve as a basis for a strategic roadmap for the Health Security Committee with concrete measures and a potential to give more visibility to the work of the HSC.

The sustainability of results of joint actions funded under the health programme should be ensured in the health security area. Joint planning should be reinforced, taking better account of the limitations of resources at national level and monitoring the impact of actions.

It is recognised by the Court of Auditors that the system of early warning and response is functioning well, but there is a need for improvement an opportunity to focus on a number of issues such as improving preparedness structures, developing standard operating procedures and strengthening coordination within the HSC.

Member States thanked the Director General and welcomed his conclusions. Points raised in the discussion included the role of EU to provide best practice in the WHO European Region with regards to the full implementation of the IHR and the need for the HSC to be prepared for an increasing threats level.

WHO/Europe underlined that the EU priorities are closely linked with those of WHO and welcomed EU commitment to support the implementation of the International Health Regulations (IHR). WHO/Europe referred to the good cooperation with the Commission. ECDC recalled that there is a clear contribution of ECDC to Commission and WHO priorities, in order to achieve better results for preparedness of communicable diseases and to learn from the past crises such as the Ebola crisis.

Xavier Prats Monné, Director General, concluded that health should be in the centre of the policy agenda for security. Within the global landscape, the EU agenda on security is advancing rapidly, amidst rising concerns about the vulnerability of the EU's population and infrastructure. The HSC is a key actor in this area, responsible for the health dimension of all kinds of health threats, and delivering under pressure to protect the health of EU citizens.

3. ANTIMICROBIAL RESISTANCE

EU Action on AMR

Xavier Prats Monné, Director General, provided an overview of the EU Action on AMR. He congratulated the HSC and the Member States for the work on this crucial issue. AMR is a key priority for the Commission for several reasons: firstly, the scale and nature of the problem; secondly, the added value that the EU can bring, notably by helping the EU

Member States to produce national plans; and thirdly, because there is a growing consensus that the time for action is now.

He recalled the 2011 Action Plan of the Commission against the rising threat from antimicrobial resistance addressing appropriate use, prevention of infection and surveillance in both human and veterinary medicine – and cross cutting actions on international cooperation, research and innovation and communication. As the Action Plan draws to an end in 2016, further and stronger initiatives are needed in the future.

The Commission has just published a road map for a Communication on a One-Health Action Plan to support Member States in the fight against AMR. This new Action plan, to be adopted in 2017, will focus on the added value the EU can bring to the fight against AMR. EU action is proposed in 3 main areas. Firstly, EU support to Member States in their efforts to address AMR – including through the development of national ‘one health’ action plans making the EU a ‘global best practice region’ for action on AMR. Secondly, EU funding for further development of new antimicrobials, alternatives such as vaccines and diagnostics to combat AMR. And thirdly, actions in the international arena – both bilaterally with partners such as China and India, and multilaterally through WHO and other international organisations, and via cooperation mechanisms such as the G7 and G20 and the Transatlantic Taskforce on Antimicrobial Resistance.

Member States discussed the need for stronger collaboration between Member States bringing together expertise with both human and animal health perspectives following a ‘One Health’ approach, and supported the idea of creating a working group on AMR. ECDC recalled the joint reports between ECDC and EFSA on AMR in zoonoses as good example of the one health working arrangements and the initiative of the European Antibiotic Awareness Day, which gives a global visibility to the actions on AMR.

Joint Action on Antimicrobial Resistance and Healthcare-Associated Infection

Professor Benoit Vallet, France, presented the Joint Action on Antimicrobial Resistance and Healthcare-Associate Infection. The work, based on a strong commitment, is coordinated by France (Inserm is coordinator and Ministry of Health provides support) and involves partners from 22 EU Member States plus Norway and Serbia, and collaborating stakeholders from a further 6 EU Member States plus Moldova. It envisages collaboration with ECDC, WHO and OECD and a number of stakeholder organisations as collaborative partners in a stakeholder forum. The main objective is to join forces to build a European programme and to define common approaches to fight AMR and to control healthcare-associated infections (HCAI) in line with ongoing EU and international policies. The Joint Action aims to draw on the best programmes in each country, while taking into account the specificities of each country. The expected outcomes are: support Member States in the development and implementation of national strategies; ensure a common approach at European level on the implementation of the Global Action Plan; produce guidance documents and tools; enhance the implementation of organisational change and/or other methods; strengthen the "One health" approach; promote awareness and commitment by governments and stakeholders and have a coordinated European response in regards to prioritizing and

assisting in the implementation of research and innovation to help achieve public health-related AMR and HCAI goals and objectives.

Member States and WHO/Europe welcomed the Joint Action and thanked France for leading the initiative.

Follow up:

- France asked Member States to ensure high-level involvement in the Joint Action Steering Committee in order to provide a strategic view on Joint Action deliverables, as well as to connect the Joint Action with national strategies on AMR and HCAI.

Draft EU guidelines on prudent use of antimicrobials in human medicine

In the context of ongoing work against the rising threats from antimicrobial resistance and given the role of antimicrobial misuse and overuse in the emergence and spread of resistance, the European Commission asked ECDC to develop draft EU guidelines on the prudent use of antimicrobials in human medicine, including generic principles of good practice on the appropriate use of antimicrobials agents in human medical practice in the EU. On 17 June 2016, the Council of the European Union adopted conclusions on the "One Health" approach to combat antimicrobial resistance, calling on Member States and the EC to develop EU guidelines on the prudent use of antimicrobials in human medicine to support national guidelines and recommendations.

ECDC provided a technical presentation on the draft EU guidelines on prudent use of antimicrobials in humans. The purpose was to provide generic elements of good practice on prudent and appropriate use of antimicrobials for all the main aspects of human medicine. The target audience was all actors who are responsible for or play a role in antimicrobial use and whose contribution is necessary to ensure that antimicrobials are used appropriately. ECDC recalled the scope of the guidelines, which are divided into two parts: resources, systems and processes that EU health systems should provide, and clinical practice. The guidelines focused on antibacterial agents and did not cover specific medical conditions or specific antimicrobials.

Member States welcomed the proposals for EU guidelines on the prudent use of antimicrobials in humans, the widespread stakeholder engagement during the development process and its potential to support the development of national action plans.

Follow-up:

- The Chair invited members to send any further comments in writing with a deadline of 10 December. SANTE will come back to the HSC with a revised version of the guidelines together with proposals on implementation and will keep the HSC regularly updated on the development of the new Action Plan on AMR and of the progress of the Joint Action on AMR and HCAI.

4. PREPAREDNESS AND RESPONSE UNDER THE EU HEALTH SECURITY FRAMEWORK

Lessons learnt from the Brussels terrorist attacks

Belgium provided an overview of experience from the Brussels terrorist attacks. After the 13 November 2015 terrorist attacks in France, Belgium started revising its guidelines, in order to be better prepared for terrorist attacks with regards to information sharing, monitoring and vigilance, emergency medical services, multidisciplinary dispatch centres, fire brigade and hospital capacity. Workshops and exercises have been organised and a medical intervention plan was in place. Belgium recalled the scenario of the two attacks at the airport and the metro killing 32 people, and highlighted burden on the health and social system including figures of days spent in hospital, intensive care, burn units or temporary sheltering as a consequence of the attack. The importance of preparing for secondary effects, to providing psychological care for patients and relatives was emphasised. Lessons have been learned on the importance of damage control surgery, victim traceability, care of the victims, risk communication and communication to the media.

Member States complemented the Belgian presentation and found very important to reflect on experience shared also by France in the previous plenary meeting. The role of the Ministry of Health during an attack together in coordination with civil protection and military sectors was discussed. Trainings, workshops, exercises were discussed to be essential, such as the exercises done for Euro2016 in France, which proved to be very useful considering the attacks in Nice. Mobile units to treat patients directly on the field are a condition of success; also victim traceability has to be prepared in advance.

Follow-up:

- France will share the manuals under preparation after translation into English. A reflection paper will also be prepared and shared with the HSC on preparedness and response to terrorist attacks including coordination between the health and security sector and civil protection.

Plan of actions to strengthen preparedness in the EU to support the implementation of the International Health Regulations

The Chair provided an update on the state of play of the action plan to strengthen preparedness and support the implementation of the IHR in the EU. The proposed actions are building upon the lessons learnt from the Ebola outbreak, on the findings of the report on preparedness reporting under Article 4 of Decision 1082/2013/EU and on findings and recommendations from the draft report of the European Court of Auditors on dealing with serious cross-border threats to health in the EU.

The action plan will be developed in discussion with ECDC and WHO/Europe, considering the new developments under the WHO Health Emergencies Programme. The action plan also aims to inform the development of a strategic roadmap, and the working methods of the HSC and its dedicated working groups. The draft action plan was discussed within the Working Group on Preparedness and Response Planning at its

meeting on 8 November. Member States asked for clearer prioritisation and an articulation with the proposed roadmap for the HSC.

Follow-up

- The draft action plan will be further developed based on the discussion and after written consultation and discussion in the working group focusing on prioritizing actions, and then circulated to the HSC for discussion.

Medical countermeasures to respond to health threats: Standard Operating Procedures for the exchange of medical countermeasures

The Chair informed the HSC on the state of play with the proposed Standard Operating Procedure (SOP) for a voluntary mechanism for exchanging medical countermeasures. The objective of such SOP is to ensure that Member States have an option to offer rapid mutual assistance on a voluntary basis, in case of shortages or need in case of an emergency. The non-paper on SOP for a voluntary mechanism for exchanging medical countermeasures had been discussed within the Drafting Group and then within the Working Group on Preparedness and Response Planning. Several comments were received, in particular with regards to the proposed voluntary mechanism based on a virtual stockpile of medical countermeasures, which were addressed in the form of an option paper to be discussed by the HSC.

The Chair asked the HSC to decide on which of the two options should be developed in more detail such as i) SOP based on exchange mechanism through EWRS, ii) exchange mechanism based on a virtual stockpile.

Member States welcomed the development of the draft SOP and the option paper and expressed a preference for the first option. Several Member States raised concerns to share information about their stockpiles due to security considerations and resource need for regular updating. They agreed that detailed reflections on specific obstacles for exchanges, such as compensation modalities, liability and logistics will need to be integrated into the document. The shortage of mantoux test in Malta and possible exchange through EWRS was also discussed by Member States.

Follow up:

- The paper will be developed further within the Working Group on Preparedness and Response Planning, to review rules and obstacles and possibilities regarding compensation modalities, liability and logistics for further discussion by the HSC. Meanwhile the EWRS mechanism will be used for the exchange of medical countermeasures.

5. CURRENT THREATS UPDATE

Andrea Ammon, ECDC Acting Director gave a presentation on emerging health threats to the EU/EEA. The epidemiological update included information on Zika cases globally and the incidence of microcephaly/other CNS malformations and Guillain-Barré

syndrome. In Europe, 20 EU countries have reported 1 944 travel-associated Zika virus infections, and 7 EU countries 91 Zika infections among pregnant women.

The ninth update of ECDC's Zika risk assessment and scientific developments were introduced in relation to transmission and detection of the virus and associated risks. New criteria for travel-related risks need to be developed, considering climatic determinants, vector presence and abundance and spatial and temporal suitability. An epidemiological update was provided on XDR TB cluster in Romania; on MERS Corona virus with most cases reported from Saudi Arabia, and no local transmission in the EU/EEA since 2013; and on S. Enteritidis multi-country outbreak which requires effective coordination of investigation by ECDC/EFSA/EC/Member States and implementing control measures.

6. STATE OF PLAY OF THE IMPLEMENTING ACTS UNDER THE DECISION 1082/2013/EU ON SERIOUS CROSS-BORDER HEALTH THREATS

The Chair informed that the Draft Commission Implementing Decision on the procedures for the notification of alerts in the EWRS and for the information exchange, consultation and coordination of responses pursuant to Articles 8 and 11 of Decision 1082/2013 was discussed with the Committee on serious cross-border threats to health on 23 September. Member States' comments focused on the EWRS contact points and the deliberations of the HSC. A revised draft has been prepared taking into consideration the outcome of Member States comments and will be sent to the Committee for opinion in the coming days.

The Chair also informed that work on the implementing act under Article 6 regarding the list of communicable diseases to be covered by the epidemiological surveillance network and the case definitions of those diseases as well as the procedures for the operation of the network is ongoing in close cooperation with ECDC. The implementing act is planned to be adopted in 2017.

Regarding the update of the Early Warning and Response System, which will be taken forward by ECDC, the Commission would want to ensure that system users are fully part of the revision process. HSC members were invited to nominate, on a voluntary basis, members for a users group to contribute to the process. The EWRS Focal Points have already been informed and the ECDC will further involve other stakeholders.

Follow up:

- Member States were invited to reflect whether they would like to withdraw or add any disease on the list.
- Regarding the update of the EWRS, the HSC Secretariat will circulate an email to the HSC members to explain the process and the proposed structure for the updated system by ECDC, and will request nominations.

7. IMPLEMENTATION OF THE JOINT PROCUREMENT OF MEDICAL COUNTERMEASURES

SANTE updated on the implementation of the Joint Procurement of medical countermeasures. SANTE will re-launch the call for tenders for personal protective equipment and is preparing a procedure with Member States for the joint procurement of BCG vaccine against TB, tuberculin (diagnostic), diphtheria - and botulism anti-toxins. SANTE has accelerated the preparation of the joint procurement for pandemic vaccines, the call is intended to be launched in 2017.

8. VACCINE SHORTAGES – STATE OF PLAY

The Chair recalled that on request of the HSC an ad hoc expert group discussed and agreed a reflection paper on vaccine shortages at a last audio meeting on 24 October 2016. The objective of the paper was to identify possible measures to address vaccine shortages in a more generic way. The document together with a cover note was distributed to the HSC last week. Accordingly involved experts suggest to the HSC common actions in the areas of i) mutual assistance; ii) vaccine forecasting; iii) vaccine implementation research; and iv) stakeholder dialogue. Member States welcomed the document.

Follow up:

- The Chair invited HSC Members to submit final written comments to the findings and suggestions in the reflection paper before finalisation.

9. ACTION ON MIGRANT HEALTH

The Chair recalled the European Agenda on Migration sets out the European response to the crisis and that improving the situation of refugees and migrants is a major priority for the European Commission. He mentioned that substantial financial and technical support has been provided to help authorities of the Member States most affected to manage the refugee/migrant crisis. He recalled the Action Plan on Better Integrating non-EU Migrants, including several proposals on health, linked to the Work Programme 2016 of the Health Programme, and a proposal to reform the Blue Card Directive to allow applications from refugees, including healthcare professionals. To support Member States facing high levels of migration to address the health challenges EUR 7.2 million were provided in 2015 through the Health Programme and EUR 7.5 million in 2016. In addition direct grants were provided to the World Health Organization and the International Organization for Migration to work on the health of refugees. Through the Emergency Support Instrument (ESI) funds were awarded to international humanitarian organisations to support the Greek authorities in addressing the most acute humanitarian needs. The EC has also provided funds in emergency assistance under the EU Asylum, Migration and Integration Fund (AMIF).

The Chair further recalled that the HSC had an information meeting on migrant health on 28 September. The purpose of the meeting was to provide an overview of the health challenges and needs of migrants and refugees, and to map the existing activities and future action at EU level.

Member States focused on several issues related to migrant health and communicable diseases. Particular reference was made to problems related to tuberculosis among asylum seekers, difficulties to vaccinate, and health professionals' mobility.

*
* *

The next Plenary meetings of the HSC are scheduled for 29-30 June 2017 and 8 November 2017.