



Luxembourg, 12 December 2019

Final Flash report of the Plenary Meeting of the Health Security Committee
11 December 2019, Senningen/Luxembourg

1. OPENING

22 Member States, Norway and Serbia attended the plenary meeting of the Health Security Committee (HSC), as well as the European Centre for Disease Prevention and Control (ECDC), the Consumers, Health, Agriculture and Food Executive Agency (Chafea), the Regional Office for Europe of the World Health Organisation (WHO/Europe), and DGs ECHO, ENVIRONMNET and SANTE of the European Commission.

The agenda included topics on EU action on vaccination, antimicrobial resistance (AMR), the Nagoya protocol, developments under rescEU and in particular initiative on stockpiling on Ebola vaccines and investigational therapeutics, EU action on HIV, AIDS, hepatitis and tuberculosis, implementation of the HSC work plan, as well as updates on Joint Actions under the Health Programme, exercises, joint procurements, EWRS re-engineering, implementing acts, and on the Ebola outbreak response.

The Chair informed about the health priorities of the new Commission in view of the Political Guidelines focusing on six headline ambitions for Europe over the next five years, and of the mission letter of Stella Kyriakides, new Commissioner for Health and Food Safety. Priorities of special interest to the HSC were discussed including vaccination, AMR, security, crisis management, research, tackling climate, environmental and health related challenges under the European Green Deal¹, as well as progress with the Multiannual Financial Framework.

Information on the European Green Deal will be circulated to the HSC.

2. VACCINATION

The Chair recalled that the 2018 Commission Communication and the Council Recommendation on strengthened cooperation against vaccine preventable diseases provide the political framework for cooperation at EU level in the area of vaccination, focusing on vaccine hesitancy, strengthened

¹ <https://g8fip1kplyr33r3krz5b97d1-wpengine.netdna-ssl.com/wp-content/uploads/2019/12/The-European-Green-Deal-Communication.pdf>

sustainability of national vaccination programmes, and operational options to increase coverage at EU level. To achieve the objectives of the Recommendation, a Roadmap was published by SANTE for the implementation of actions to be taken by the Commission and its Agencies, including several deliverables of the Joint Action on Vaccination.

2.1. VACCINATION ROADMAP - PROGRESS

The Commission co-organised with the WHO a Global Vaccination Summit, on 12 September 2019, attracting 400 high-level participants. The Summit issued a “10 Actions toward vaccination for all” document, which will be further implemented².

Other key activities include a call for tender for a feasibility study for the development of a common EU vaccination card, a call for tender for a feasibility study for physical stockpiling of vaccines and the 2020 “State of Vaccine Confidence in the EU” report. DG RTD launched a call for proposals for projects to address vaccine hesitancy in July 2019 (deadline April 2020).

2.2. UPDATE ON THE COALITION FOR VACCINATION

The Standing Committee of European Doctors (CPME), the European Federation of Nurses (EFN) and the Pharmaceutical Group of the European Union (PGEU) co-chair the Coalition. There are 16 Coalition Members for the moment, and Members are planning commitments reaching out with information on vaccination to the health sector.

2.3. EUROPEAN VACCINATION INFORMATION PORTAL

The ECDC, with the support of the European Medicines Agency (EMA), establish a European Vaccination Information Portal (EVIP) aimed at providing “objective, transparent and updated evidence online on vaccination and vaccines, their benefits and safety, and the pharmacovigilance process”. Such portal is intended to become the EU online hub for information on vaccine-preventable diseases, vaccination and vaccines authorised and in use in immunisation programmes in the EU, targeting EU citizens and, in a secondary phase, healthcare professionals. It will link to and build upon existing national vaccination related websites targeting the general public, with a view to complementing and strengthening consistency across information provided to members of the public on vaccines and immunisation; as such, it is expected to be made available in all official EU languages in the future. Some Member States were critical regarding targeting the general public.

2.4. JOINT ACTION ON VACCINATION, PROGRESS AND DELIVERABLES

The Joint Action (JA) on Vaccination implements a large number of key objectives of the vaccination roadmap. The JA develops sustainable mechanisms of cooperation and communication between Member States and other stakeholders to facilitate the implementation of vaccination policies.

The French Ministry of Health provided an update on the state of play of the JA on Vaccination, building concrete tools to improve vaccination coverage in Europe and strengthen national

² https://ec.europa.eu/health/vaccination/ev_20190912_en

immunization programs. Major topics covered by this JA are scientific evidence for national programs, digital immunisation information systems, the concept of data warehouse on demand and supply, vaccine research priority-setting framework and vaccine confidence.

Member States welcomed priorities and Commission actions on vaccination. The importance of avoiding overlaps in implementing activities by different stakeholders, as well as the sensitivity of providing information and messages to the public and the role of national authorities in this regard were raised. WHO/Europe updated on activities, including the review process of the European Vaccine Action Plan.

Concerning the European Vaccination Information Portal the HSC proposed to set up an editorial board focusing on the content of the Portal. DG SANTE will circulate a description of general tasks of the group and ask HSC members to nominate representatives for this board. In the future, more time will be dedicated to discuss the topic of vaccination, the HSC will be informed on the progress with implementing key actions.

3. ANTIMICROBIAL RESISTENCE

3.1. UPDATE ON THE IMPLEMENTATION OF THE EU ACTION PLAN AGAINST AMR – REPORT OF THE COURT OF AUDITORS

An update on the Joint Action on Antimicrobial Resistance and Healthcare Associated Infections was presented by France. Good progress is being made on implementation of the Joint Action in areas such as national action plans against AMR, peer review visits and infection prevention and control. A detailed sustainability plan has been developed.

DG SANTE presented AMR outcome indicators which have recently been updated by ECDC and EMA. Sales of antimicrobials for use in food producing animals fell by 32.5% between 2009 and 2017. Consumption of antimicrobials in humans fell by 6.5% between 2015-2018. Over the same period there was a 3.4% increase in the proportion of E. coli infections resistant to third generation cephalosporin and also increases in carbapenem resistance. There were decreases in methicillin resistance in Staphylococcus aureus infections (MRSA) and penicillin resistance in S. pneumoniae.

DG SANTE presented the main findings from the special report of the European Court of Auditors on AMR. The Commission accepts all the recommendations and will report back to HSC on implementation.

DG SANTE presented the main priorities on AMR for Commissioner Stella Kyriakides, namely the full implementation of the European AMR action plan and advocacy for a new global agreement on access and use of antimicrobials. Member States welcomed priorities and informed activities at national level on AMR.

The nature and scope of a potential global agreement on AMR are currently being reflected on by the Commission, the HSC will be informed about developments. There will be a meeting of the

Transatlantic Taskforce on Antimicrobial Resistance in Luxembourg 9-10 December 2020 – the HSC will be invited.

Member States were encouraged to make use of the One Health country visits, in particular the countries that have not yet developed or have not recently updated their national AMR action plans.

4. PREPAREDNESS

4.1. NAGOYA PROTOCOL

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their utilisation, adopted in 2010, is a complementary legal agreement to the Convention on Biological Diversity (CBD). Aiming to implement the objective of the CBD, namely the fair and equitable sharing of benefits arising out of the utilization of genetic resources, the Nagoya Protocol sets out core obligations for its contracting Parties to take measures in relation to access to genetic resources, benefit sharing and compliance.

The EU has been a party of the Protocol since 2014. The EU adopted Regulation No 511/2014 on compliance measures for users of the Nagoya Protocol in the Union. In 2016, the Commission issued a Guidance on the scope of application and core obligations of the EU Regulation 511/2014/EU. DG ENVIRONMENT together with Member States expert has been working on an additional guidance document addressing specific sectoral issues, as well as on additional clarifications to be placed in the current Horizontal guidance document.

A representative of DG ENVIRONMENT presented generalities on the Nagoya Protocol and Access and Benefit sharing, the implementation of the Protocol in the EU (the EU ABS Regulation on Compliance Measures (Reg 511/2014/EU) and related Commission Implementing Regulation (1866/2015/EU) and Guidance documents currently being updated) as well as health interrelations and future challenges such as Digital Sequence Information.

Finland presented implications of the Nagoya Protocol from a public health perspective stating that it is essential to public health and food security for conducting surveillance and risk assessment, development of diagnostic tools, vaccines and therapeutics, risk management and implementing of evidence-based public health strategies. Points of concern for the health sector include issues regarding sharing of microbes or samples and relevant information linked to them such as genetic sequence data. Members of the HSC were invited to work together with the environmental and agricultural sector to raise awareness and increase collaboration at national, EU and global level and to take note of ongoing discussions in different for a.

The Chair emphasized how this topic is of concern for health ministries but usually managed by the environmental and agricultural ministries. Several countries raised some specific concerns related to the sharing of pathogens and unintentional introduction, digital sequence data and specialized instruments for ABS.

The Chair suggested that a draft statement of the HSC will be prepared reflecting the discussion and the views of the Health Security Committee. The draft will be circulated for comments, and shared with DG Environment.

4.2. MEDICAL COUNTERMEASURES

The Chair recalled the importance of availability of and access to medical countermeasures (MCM) as a key priority for health security. In this regard, the different initiatives of the Commission were highlighted: the tender for a study on exploring the feasibility of and identifying options for stockpiling of vaccines and development of a concept for the exchange of vaccine supplies; the Joint Action on Vaccination which is working on vaccine supply management and virtual stockpiling; the upcoming Joint Action to strengthen health preparedness and response to biological and chemical terror attacks which may consider availability and deployment of MCMs; the work of the Joint procurement Mechanism for MCMs; and the EWRS as a functioning tool to support voluntary exchanges of MCMs.

4.2.1 UPDATE ON RESCEU - STOCKPILING FOR EBOLA VACCINES AND TREATMENTS

The rescEU instrument serves to reinforce and strengthen the Union's Civil Protection Mechanism (UCPM). DG ECHO presented the functionalities of UCPM and the background of the rescEU mechanism, which aims to improve the protection of citizens from disasters and the management of emerging risks, of which some can be categorized as low probability with high impact risks. The mechanism currently includes capacities related to aerial firefighting, emergency medical capacities (EMT-3 and medical evacuation), as well as chemical, biological, radiological and nuclear capacities. DG ECHO highlighted that the ongoing work of DG ECHO, DG SANTE and EMA, related to a stockpile of Ebola vaccines and therapeutics under rescEU would be considered as part of the medical capacities section of rescEU.

The proposal has been presented to the HSC at past audio meetings, and most recently to DG ECHO's Civil Protection Committee in October 2019. The HSC indicated that the work foreseen in the task team, comprising civil protection and health nominations, DG SANTE, DG ECHO and EMA, should include issues such as liability, speed of deployment, criteria for deployment, legal frameworks, quantities and ensure complementarity to other potential international level stockpiling initiatives. The task team will be convened in January 2020. WHO/Europe informed on general global stockpiling plans regarding Ebola vaccine.

Specific points raised by Member States will be discussed between the HSC and civil protection counterparts during the Task Team meeting organized by DG ECHO.

4.3. JOINT ACTIONS ON PREPAREDNESS, STATE OF PLAY

Finland presented on the progress of the Joint Action **Strengthened International Health Regulations and Preparedness in the EU (JA SHARP)**. The general objective of the JA SHARP is to strengthen IHR implementation and preparedness, to support capacity building and to contribute to a high level of protection of health and security in EU Member States in line with the EU health security framework.

SHARP will also collaborate with other Joint Actions, specifically with JA “Healthy Gateways” that addresses Points of Entry and the new Joint Action to strengthen health preparedness and response to biological and chemical terror attacks, coordinated by Norway.

During the week of the 14th of October, the SHARP Joint Action organised a successful two-day conference on One Health Security in Helsinki.

The Joint Action to strengthen health preparedness and response to biological and chemical terror attacks is currently being prepared. The Norwegian Directorate of Health coordinates this Joint Action with 23 countries. The Joint Action aims to strengthen health preparedness and response to terror attacks across the health, security and civil protection sectors, focusing on biological and chemical agents. The final proposal is expected for February 2020.

Norway presented on the current status of the development of the Joint Action. It was highlighted that it will be complementary to other EU work related to Security Union topics.

4.4. UPDATE ON EXERCISES AND WORKSHOPS

A workshop on preparedness for mass-casualties resulting from the deliberate release of opioids will be organized on 21-22 January in Luxembourg. The workshop will attempt to identify the key clinical and public health response and generally improve health preparedness against opioid threats. Participants will be emergency responders and first receivers, public health and health care professionals, poisons centre specialists, toxicologists, emergency planners, law enforcement and policy makers.

An exercise on medical countermeasures exchange to test the procedure and the templates through EWRS is planned with Member States, as requested by the HSC. The scenario will be based on an urgent need for a specific medical countermeasure for an outbreak event.

A workshop on contact tracing with EU agencies and international organizations is also under preparation planned for 2020/Q2, with the HSC Working Group on Contact Tracing.

An exercise database is being developed to track the implementation of the recommendations provided by past exercises; the prototype of the database presented to the HSC at the last plenary meeting. The analysis of the recommendations is ongoing, involving the Joint Action SHARP.

The HSC will be updated on the developments of the exercise database, and upcoming exercises.

5. UPDATES ON FILES

5.1. IMPLEMENTATION OF THE WORK PLAN OF THE HEALTH SECURITY COMMITTEE

As part of the Work Plan of the HSC, the revised rules of procedures of the HSC and the terms of reference of the Working Group on Preparedness was discussed. In addition, at its plenary meeting of 3-4 July 2019, the HSC agreed on setting up the ad-hoc working group on contact tracing, as proposed by the Working Group on Preparedness, in collaboration with ECDC and WHO and

representatives from the transport sector. A draft terms of reference including a detailed mandate, deliverables and timeline was presented to the HSC.

The terms of reference of the working groups on preparedness and on contact tracing were adopted. The HSC Rules of Procedures will be finalized after written consultation.

5.2. IMPLEMENTING ACTS UNDER DECISION 1082/2013/EU

The Chair noted the ongoing work related to the revision of the implementing act under Decision 1082/2013/EU Article 4 on **reporting of preparedness and response planning**. This work is being undertaken by a Task Force under the Working Group of Preparedness and Response Planning comprising Estonia, Spain, Norway, Finland, Sweden, Germany, Belgium, WHO/Europe and the ECDC. The Task Force has reviewed existing tools and reporting requirements in order to ensure there is no overlap with other reporting requirements. Following this, the Task Force has been reviewing a revised Article 4 reporting questionnaire, with this process expected to finish in December 2019. Overall, the revised version now ensures alignment with the WHO, and incorporates more questions on cross-border and cross-sectoral interoperability. The Task Force's final version of the reporting questionnaire will be shared with the HSC in January 2020 for their comments.

Article 6(5)(c) of Decision 1082/2013/EU requires that the **operating procedures of the epidemiological surveillance network** as developed by the ECDC in application of Articles 5, 10 and 11 of Regulation (EC) No 851/2004 are reflected in an implementing act. Currently, all Member States use one integrated European surveillance system based on the European Surveillance System (TESSy). This surveillance system includes statutory communicable diseases, follows EU-wide reporting standards and common principles of collaboration and agreements on data exchange, access and publication. The Commission works in close cooperation with ECDC for the development of an implementing act for the necessary update of the operational procedures established by the dedicated surveillance networks. The implementing act aims to develop the legal requirement in support of the established reporting required under TESSy and planned to be adopted in Q2/2020.

The HSC will be informed on developments related to the work on implementing acts.

5.3. JOINT PROCUREMENT OF MEDICAL COUNTERMEASURES - PROGRESS

The joint procurement agreement under the Cross Border Health Threats Decision provides for a voluntary mechanism enabling participating Member States and the Commission to purchase jointly MCMs for different categories of cross-border health threats and ensure equitable access to specific MCMs and, ideally, more balanced prices.

The joint procurement of pandemic influenza vaccines led to concluding a framework contract signed by the Commission and 14 Member States with Seqirus for the production and supply of pandemic influenza vaccines. Negotiations with the second company have not been concluded yet.

Member States have expressed interest for additional joint procurement procedures, which are currently in preparatory phase and Member States can still express their interest to join them. The next meeting of the overall Joint Procurement Agreement Steering Committee is scheduled back to back with a Workshop on Lessons Learnt from the Joint Procurement of MCMs and will be held in the first quarter of 2020 in Luxembourg. Member States are invited to provide input on the topics of their interest to be discussed at these meetings.

6.2. EWRS REMODELLING, STATE OF PLAY AND NEXT STEPS

Since June 2017, the EWRS was updated, to be made compatible with the newest IT technologies, and to integrate features to allow using the system more efficiently for notification and crisis management. **The updated EWRS went live on 15 October 2018 and has been completed in November 2019.**

The new EWRS includes all the functionalities that were available in the previous platform, as well as new characteristics and functionalities, including a structured notification template, a search function, and a new tool to notify and monitor public health measures in response to serious cross border health threats.

Over the course of the year, more modules and functionalities have been gradually added to the updated platform, including Risk Communication, Preparedness, Training and simulation exercises modules, as well as interlinking with other EU alert systems - currently with the Rapid Alert System for Blood/Tissue and Cells (RAB/RATC, DG SANTE) and the European Warning System on New Psychoactive Substances (EWS-NPS, EMCDDA). The 'Situational Awareness' module provides contextual information directly linked to a specific alert notification when activated, and 'Line Listing' allows Member States to share the number of cases and relevant related information.

On 11th and 13th of November, SANTE and ECDC organized training for Member States users of the EWRS, on the recent updates and new modules implemented on the platform.

The EWRS re-engineering project has been finalized. The HSC will continue to receive updates on the further development of the EWRS, in particular on the interlinking with other EU alert systems.

6. EBOLA OUTBREAK, STATE OF PLAY AND PREPAREDNESS

The ongoing Ebola outbreak in DRC, provinces of North Kivu and Ituri has been a prominent threat in the recent period. As of 7 December, there have been 3320 Ebola virus disease cases, of which 3202 confirmed and 118 probable, including 2209 deaths since the beginning of the outbreak. The case fatality is 67%. Overall, the outbreak transmission trends in DRC have been declining in the recent weeks.

ECDC updated the Rapid Risk Assessment on August, 9th 2019. Since the last HSC Plenary, 2 audio conference of the HSC were held in the months of July and October to discuss preparedness, response and vaccine issues. The epidemic occurs in the context of prolonged humanitarian crises and an unstable security situation. The violence, widespread civil unrest, and targeted attacks in

eastern DRC have continued in the past week, restricting the access of Ebola response teams to the affected communities and activities such as contact tracing. The epidemic is a public health emergency of international concern (PHEIC).

The European Commission is in contact with the national authorities working on the frontline, the WHO and partners on the ground to channel support. The EU support for Ebola response include ensuring access to health care and diagnosis, supporting community screening facilities, infection prevention and control measures, community engagement, and providing humanitarian assistance to survivors. The response to the Ebola outbreak entails the activation of the Civil Protection Mechanism, launch of ECHO flight humanitarian air service for transfer of medical teams, equipment and supplied to the affected areas.

Ebola 'ring' vaccination (i.e. vaccination of contacts of suspected cases and contacts of the contacts) has been a pillar in the response activities. Since the start of vaccination on 8 August 2018, 255 852 people have been vaccinated with the rVSV-ZEBOV vaccine (Merck). As of 4 December 2019, 1 161 people had been vaccinated with the second Ad26.ZEBOV /MVA-BN-Filo vaccine (Johnson & Johnson) in the two health zones of Karisimbi in Goma.

ECDC provided support to ECHO, deploying 3 senior expert to the DRC, supporting the Ebola Operation Centre Goma analytical cell working on a comprehensive risk analysis, looking at the epidemiological patterns and dynamics by health zone. WHO/Europe updated on activities to respond to the Ebola outbreak.

Medical evacuation

Information on the capacities for medical evacuation (Medevac) in the European Member States was collected with the HSC. In 2018, eight countries confirmed arrangements are in place for emergency deployment if needed for evacuation of nationals from affected countries. Since the last HSC, SANTE asked Member States to update their replies on Medevac capacities. On the 13 Member States who updated their replies, 3 new countries have confirmed arrangements are in place, totalling 11 Member States.

Jointly, DG SANTE, DG ECHO, and WHO HQ Geneva developed Standard Operating Procedures for requesting medical evacuation in humanitarian contexts for Viral Haemorrhagic Fevers. This includes illnesses like the Ebola Virus Disease, Marburg, Riff Valley fever, etc. Given their coordination role, the evacuation system is managed by the WHO and DG SANTE and DG ECHO provide support to identify a treatment facility in one of the EU Member States for an international health or humanitarian aid workers requiring a medical evacuation.

Countries reported involvement in the management of the outbreak. Additionally, France highlighted that on the 3rd of December a declaration of intent for the provision of care in French hospitals for WHO staff who contract or were exposed to highly pathogenic infectious diseases, was signed.

6. EU ACTION ON HIV/AIDS, TUBERCULOSIS AND HEPATITIS

Policy dialogue on EU action on HIV/AIDS, tuberculosis and hepatitis has been transferred to the Health Security Committee following the recent closure of the EU HIV/AIDS, Viral Hepatitis and Tuberculosis Think Tank.

The Commission continues helping Member States in their national efforts to reach the Sustainable Development Goals' Health targets, including ending HIV and tuberculosis, and reducing hepatitis, as committed in 2016 in the "Communication on Next Steps for a Sustainable European Future". Furthermore, the Commission President-elect has specifically requested the new College of the Commissioners to jointly deliver on the Sustainable Agenda.

People who inject drugs are a high-risk group for infectious diseases, in particular HIV and/or viral hepatitis. The 2013-2020 EU drugs strategy and its two consecutive action plans, which advocate an integrated, balanced and evidence-based approach to drugs policy, guide efforts at EU level. The strategy also aims at ensuring a high level of human health protection and one of its objectives is to help reduce the demand for drugs, drug dependence and drug-related health and social risks and harms. All stakeholders are invited to participate in an **online public consultation** as part of the **evaluation of the current EU drugs strategy**, which is **open until 4 February 2020** and available in all EU languages.

The Commission's staff working document on "Combatting HIV/AIDS, viral hepatitis B and C and tuberculosis in the European Union and neighbouring countries"³ of July 2018 gives an overview of EU policy initiatives and activities to help Member States and beyond to tackle these epidemics. These efforts must continue with a focus on scaling-up the good practices at national level. In addition to the EU Health Programme, other funding instruments could be sought for such upscaling. Several Member States expressed concerns about the closure of the Think Tank and Civil Society forum.

An HSC audio meeting will be organized to inform on financial instruments available for Member States to support activities on HIV/AIDS, tuberculosis and hepatitis, as well as on the governance of related expert groups.

9. AOB

The Netherlands provided an update on activities in response to the Lassa fever event. Germany informed about finalizing the Joint External Evaluation.

The next plenary meetings of the HSC is tentatively scheduled for 30 June-1 July 2020.

³ SWD(2018) 387 final (https://ec.europa.eu/health/sites/health/files/communicable_diseases/docs/swd_2018_387_en.pdf).