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MEDICAL COUNTERMEASURES THAT COULD BE PROCURED IN COMMON UNDER THE JOINT PROCUREMENT AGREEMENT

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1. INTRODUCTION

The purpose of this document is to outline the scope of the Joint Procurement Agreement on medical countermeasures. In particular, the document describes what should be understood under "medical countermeasures" and "serious cross-border threat to health", and it provides examples of medical countermeasures that could be procured in common under the Joint Procurement Agreement.

The document goes back to the first request by Ministers of Health to "develop a mechanism for the joint procurement of vaccines and anti-virals" and details how this has been implemented through Decision 1082/2013/EU on serious cross-border threats to health[1].

It will be for Member States participating in the Joint Procurement Agreement to decide, on a voluntary basis, and as deemed appropriate by each of them, for which medical countermeasures they would like the Commission to analyse the feasibility of a specific procurement procedure.

The minimum number of the Contracting Parties to launch a specific procurement procedure has been set by the Joint Procurement Agreement at 5, including the Commission (Article 13(1)), which means that any specific procurement procedure could be launched once 4 Member States agree to do so.

2. FROM VACCINES AND ANTIVIRALS TO MEDICAL COUNTERMEASURES

The 2010 *'Assessment Report on EU-wide Pandemic Vaccine Strategies'*[2] and the Belgian Presidency 'Conference on lessons learnt from the A(H1N1) pandemic' identified a number of weaknesses in the procurement of pandemic influenza vaccines and antivirals by Member States during the influenza AH1N1 pandemic in relation to price, liability, confidentiality and flexibility to adjust the quantities ordered to actual needs.

In its conclusions of 13 September 2010[3], the Council invited the Commission to report on and develop a mechanism for the joint procurement of vaccines and antiviral medication which would allow Member States, on a voluntary basis, "to adopt common approaches to the negotiation of contracts with the industry, that would clearly address issues such as liability, availability and the price of medicinal products as well as confidentiality".

With regard to pandemic vaccines, in the context of the limited production capacities at global level, such a procedure would have to be undertaken with the aim of enabling more equitable access to vaccines for the Member States involved and to help them to better meet the vaccination needs of their citizens in line with their vaccination policies.

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[1] 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/EC; OJ L 293, 5.11.2013, p. 1–15

[2] http://ec.europa.eu/health/communicable_diseases/docs/assessment_vaccine_en.pdf

[3] Conclusions from the 3032nd General Affairs Council meeting, available at:

http://ec.europa.eu/health/preparedness_response/docs/council_lessonsh1n1_en.pdf

The Council of 7 December 2010[4] approved the "Technical document on a mechanism for joint procurement of pandemic influenza vaccines and antivirals" allowing Member States, on a voluntary basis, to acquire these products in common or to adopt common approaches to contract negotiations with the industry.

The need to create a mechanism for joint procurement was also supported by the European Parliament in its resolution of 8 March 2011.

The legal basis for a joint procurement of medical countermeasures has been laid down in Article 5 of Decision 1082/2013/EU.

Article 5 1) of Decision 1082/2013/EU provides that: "The institutions of the Union and any Member States which so desire may engage in a joint procurement procedure (…) with a view to **the advance purchase of medical countermeasures for serious cross-border threats to health".**

Recital 13 of the Decision invokes pandemic vaccines merely **as an example** of a product that could be procured through a joint procurement agreement.

Therefore, Decision 1082/2013/EU provides grounds for organising a **joint procurement with regard to any serious cross-border threat to health and any medical countermeasure to combat such threat.**

3. THE JOINT PROCUREMENT AGREEMENT ON MEDICAL COUNTERMEASURES

Article 5(3) of Decision 1082/2013/EU provides that "the joint procurement procedure is to be preceded by a Joint Procurement Agreement between the Parties determining the practical arrangements governing that procedure, and the decision-making process with regard to the choice of the procedure, the assessment of the tenders and the award of the contract".

The Joint Procurement Agreement is intended to implement Article 5 of Decision 1082/2013/EU. It is a framework agreement laying down common rules for practical organisation of joint procurement procedures with a view to the advance purchase of medical countermeasures for serious cross-border threats to health.

The Joint Procurement Agreement was signed by the Commission on 20 June 2014. Until 1 December 2014 the Agreement was signed by the majority of the Member States[5].

4. MEDICAL COUNTERMEASURES

The term "medical countermeasures" is not defined in Decision 1082/2013/EU.

Article 2 of the Joint Procurement Agreement provides that medical countermeasures are "any medicines, medical devices, other goods or services that are aimed at combating serious cross-border threats to health, as referred to in Decision 1082/2013/EU".

[4] http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/118254.pdf

[5] The list of the member States that signed the Joint procurement Agreement can be found under the following address: http://wcmcom-ec-europa-eu-wip.wcm3vue.cec.eu.int:8080/health/preparedness_response/joint_procurement/jpa_signature_en.htm

The term should be interpreted in the light of the aim of the Decision 1082/2013/EU, which, in accordance with its Article 1(2), is "to support cooperation and coordination between the Member States in order to improve the prevention and control of the spread of severe human diseases across the borders of the Member States, and to combat other serious cross-border threats to health in order to contribute to a high level of public health protection in the Union".

Where medicines, medical products or other goods or services can prove necessary to prevent or to control the spread of severe human diseases across the borders of the Member States, or to combat other serious cross-border threats to health, they should be covered by the term "medical countermeasure".

Therefore, all potential medicines, medical devices, other services and goods that could be used to mitigate/treat a life threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin which spreads, or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection, can be procured in common under the Joint Procurement Agreement.

In terms of products and services, the Joint Procurement Agreement may cover for example laboratory tests, diagnostic tools/kits for seasonal or pandemic influenza, influenza vaccines, antivirals, decontamination products, masks and personal protective equipment or other goods and services depending on the need triggered by a serious cross border threat to health.

5. SERIOUS CROSS BORDER THREATS TO HEALTH

Article 3(g) of Decision 1082/2013/EU defines a **serious cross border threat to health as** "a life threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection".

Article 2 of Decision 1082/2013/EU specifies the following **categories of serious cross border threats to health:**

a) threats of biological origin, consisting of:

(i) communicable diseases;

(ii) antimicrobial resistance and healthcare associated infections related to communicable diseases;

(iii) biotoxins or other harmful biological agents not related to communicable diseases;

b) threats of chemical origin;

c) threats of environmental origin;

d) threats of unknown origin;

e) events which may constitute public health emergencies of international concern under the IHR, provided that they fall under one of the categories of threats set out in points (a) to (d).

5.1. Threats of biological origin

5.1.1. Communicable diseases

Article 3(b) of Decision 1082/2013/EU defines a communicable disease as "infectious disease caused by a contagious agent transmitted from person to person by direct contact with an infected individual or by indirect means such as exposure to a vector, animal, fomite, product or environment, or exchange of fluid, which is contaminated with the contagious agent".

The scope of Decision 1082/2013/EU as set out in Article 2 and the definition provided for in Article 3 (g) are considered to be decisive in setting the scope of the Joint Procurement Agreement[6].

The list included in point 2 of Annex I to Commission Decision 2000/96/EC[7] may be used as an indication of the diseases, which could fall into this category but it is of indicative value only.

Joint Procurement Agreement allows to jointly procure any medical countermeasures aimed to prevent or control the spread of the communicable diseases that can be considered as serious cross-border threats to health.

The products that could be procured in common under the Agreement are the following: diagnostic tools/kits, laboratory tests and services, vaccines, anti-virals, medicines, ancillary products and protective equipment for health care workers.

5.1.2. Antimicrobial resistance and healthcare associated infections[8]

The emergence and spread of microbes that are resistant to antibiotics (antibacterial agent), renders the drugs concerned ineffective for the treatment of an infection[9].

As stated in *the Annual epidemiological report Reporting on 2011 surveillance data and 2012 epidemic intelligence data*[10] antimicrobial resistance (AMR) is a serious threat to public health. The percentages of AMR, especially multidrug resistance, continued to increase in Europe, leading to mounting healthcare costs, failed treatments, and deaths[11].

Over the last four years, there has been a significantly increasing trend of multidrug resistance (combined resistance to multiple antibiotics) in both Escherichia coli and Klebsiella pneumonia in more than one third of the reporting EU/EEA countries.

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[6] See point 5 of the note.

[7] Commission Decision 2000/96/EC of 22 December 1999 on the communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of the European Parliament and of the Council (OJ L 28, 3.2.2000, p. 50).

[8] http://www.ecdc.europa.eu/en/publications/Publications/healthcare-associated-infections-point-prevalence-survey-long-term-care-facilities-2013.pdf

[9] http://ec.europa.eu/dgs/health_consumer/docs/communication_amr_2011_748_en.pdf

http://www.ecdc.europa.eu/en/publications/Publications/0909_TER_The_Bacterial_Challenge_Time_to_React.pdf

[10] http://www.ecdc.europa.eu/en/publications/Publications/Annual-Epidemiological-Report-2013.pdf#page=217

[11] Each year, about 25 000 patients die in the EU from an infection with the selected multidrug-resistant bacteria. Infections due to these selected multidrug-resistant bacteria in the EU result in extra healthcare costs and productivity losses of at least EUR 1.5 billion each year.

Options for treatments of patients who are infected with such multidrug-resistant bacteria are limited to only few last-line antibiotics, such as carbapenems. However, carbapenem resistance is increasing and is already high in some countries, which further limits options for the treatment of infected patients[12].

Any medical countermeasures to combat antimicrobial resistance or healthcare-associated infections related to communicable diseases that can be considered as serious cross-border threats to health may be jointly procured under the Joint Procurement Agreement.

In terms of products diagnostic tools/kits, specific antibiotics developed to combat multi-resistant bacteria and other medicines needed for specific treatment of people contaminated could be procured in common under the Joint Procurement Agreement.

5.1.3. Biotoxins and bio-agents

The term biotoxin is used as a generic term for any toxin originating from a living organism (plant, animal, bacteria, etc.). They can be classified into fungal biotoxins, or short mycotoxins, microbial biotoxins, plant biotoxins, short phytotoxins and animal biotoxins.

The examples of biotoxins can be botulism or anthrax and ricin that may cause severe morbidity and mortality for which existing treatment is not always quickly available[13].

The yearly number of cases of diseases originating in biotoxins in the Member States is low and often significantly lower than the minimum quantity necessary to start producing a batch of treatment, therefore reducing the interest for industry to produce it.

Grouping the needs of the Member States could allow reaching a volume sufficient to motivate the industry to produce the treatments and to maintain an existing production capacity.

5.1.4. Threats of chemical origin

Threats of chemical origin are i.a. threats caused by acute release of dangerous substances deliberately or during an industrial accident.

Establishments where major quantities of dangerous substances are handled or stored represent a major source of industrial accident risk for human populations and the environment. Types of industry covered in this category comprise chemical installations, chemicals manufacture, general engineering, liquefied natural gas production, storage and distribution, processing of metals, production of pharmaceuticals, etc.

Substances may be considered dangerous because of their potential hazards: health hazards (e.g. acute toxic substances), physical hazards (e.g. explosives, highly flammable substances) or environmental hazards.

[12] http://www.ecdc.europa.eu/en/publications/Publications/Annual-Epidemiological-Report-2013.pdf#page=217

[13] *Concept paper on potential shortages of vaccines and treatment for rare communicable diseases in Europe*, The report was commissioned by ECDC, February 2012.

Among the products to remedy these potential threats detection kits, protective equipment, decontamination equipment and products as well as other medical countermeasures could be procured in common.

4.1.5. Threats of environmental origin

Threats of environmental origin include hazards related to climate change and can be, for example, extreme weather conditions such as heat and cold waves.

Severe weather phenomena such as storms, snowfall and heavy precipitation are clearly associated to an increased risk of floods or with landslides.

Following the impact assessments conducted in a number of European countries and research funded by the EU and WHO-EURO, climate change is expected to have impacts on the epidemiology of many diseases and health conditions[14].

Climate change may alter the distribution and transmission of communicable diseases principally through impacting disease pathogens directly; through impacting the distribution of vectors which may carry diseases; or through impacting human behaviours leading to changing patterns of exposure to infectious diseases[15] (for ex. food-borne diseases like salmonellosis have been observed to be highly temperature sensitive, meaning that increased annual average temperatures could have important effects on food safety).

Climate change may also influence water quality and availability (both drinking and bathing) while leading as well to increased risks of flooding in some regions[16].

The nature and scale of the final impacts will depend on the adaptive capacity and actions of health systems and the access of different populations to these services.

The products that could be procured in common under the Joint Procurement Agreement with regard to threats of environmental origin could be diagnostic tools, laboratory tests and services, medicines, protective equipment for health care worker, specific equipment needed to take care of people requiring health care in extreme conditions.

5.1.5. Events which may constitute public health emergencies of international concern under the IHR, provided that they fall under one of the categories of threats set out in points (a) to (d) of Article 2 of the Decision

According to the International Health Regulations (2005)[17], a **public health emergency of international concern** (PHEIC) refers to an extraordinary public health event which is determined,

[14] Commission Staff Working Document *Accompanying document to the* White Paper Adapting to climate change: Towards a European framework for action *Human, Animal and Plant Health Impacts of Climate Change* {COM(2009) 147 final}.

[15] http://www.ecdc.europa.eu/en/healthtopics/climate_change/Pages/index.aspx

[16] As above.

[17] The International Health Regulations (2005) (the IHR) are "an international agreement that is legally binding on 194 countries (States Parties), including all WHO Member States. The IHR define their "purpose and scope" as: "to prevent,

under specific procedures, to constitute a public health risk to other States through the international spread of disease, and to potentially require a coordinated international response.

The parameters for notification to WHO of all events which may constitute a public health emergency of international concern are based on the following criteria[18]:

- seriousness of the public health impact of the event;
- unusual or unexpected nature of the event;
- potential for the event to spread internationally; and/or
- the risk that restrictions to travel or trade may result because of the event.

The most recent example of the health threat falling into this category is Ebola outbreak in West Africa. Namely, following the meeting of the Emergency Committee on the Ebola outbreak 2014 held on 6 August it was unanimously agreed that the conditions for a Public Health Emergency of International Concern (PHEIC) have been met. Therefore on 8 August 2014 the Ebola outbreak in West Africa was declared to be considered as a PHEIC.

The joint procurement in this case could be organised to commonly procure diagnostic tools/kits, laboratory tests and services, medicines, and personal protective equipment (PPE).

6. CONCLUSIONS

The Joint Procurement Agreement enables Member States to purchase medical countermeasures for different categories of threats, provided that they can be considered as a cross-border threat in the meaning of Article 3 (g) and in line with the objectives of Decision 1082/2013/EU.

Therefore, all potential medicines, medical devices, services and goods that could be used to mitigate/treat a life threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin which spreads, or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection, can be procured in common under the Joint Procurement Agreement.

The aim of the joint procurement mechanism is to enable more equitable access to medical countermeasures for the Member States involved, to help them to better meet their citizen's needs and to obtain more balanced contractual conditions.

protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade". Since their entry into force on 15 June 2007, the IHR directs and governs particular WHO and States Parties activities aiming that protect the global community from public health risks and emergencies that cross international borders." See more: http://www.who.int/ihr/about/10things/en/

[18] Annex 2 of the IHR.