II

(Non-legislative acts)

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2020/414

of 19 March 2020

amending Implementing Decision (EU) 2019/570 as regards medical stockpiling rescEU capacities

(notified under document C(2020) 1827)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism ([1]), and in particular point (g) of Article 32(1) thereof,

Whereas:

(1) Decision No 1313/2013/EU sets out the legal framework of rescEU. rescEU is a reserve of capacities at Union level aiming to provide assistance in overwhelming situations where overall existing capacities at national level and those committed by Member States to the European Civil Protection Pool are not able to ensure an effective response to natural and man-made disasters.

(2) Commission Implementing Decision (EU) 2019/570 ([2]) sets out the initial composition of rescEU in terms of capacities and quality requirements. The rescEU reserve so far consists of aerial forest firefighting capacities, medical aerial evacuation capacities, and emergency medical team capacities.

(3) In accordance with Article 12(2) of Decision No 1313/2013/EU, the capacities rescEU will consist of are to be determined by taking into account identified and emerging risks, overall capacities and gaps at Union level.

(4) Over the last decades, major outbreaks of serious cross-border threats to health capable of human-to-human transmission, such as Ebola, the Severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS), have put to the test the international community, calling for a coordinated response to limit the diffusion of those infectious diseases.

(5) In July 2019, the World Health Organization (WHO) declared the Ebola virus disease outbreak in the Democratic Republic of the Congo (DRC) a Public Health Emergency of International Concern and the virus is still considered a high-risk disease. The Ebola virus can be unintentionally transmitted into the Union, as already witnessed during the 2013 West Africa outbreak.

([1]) OJ L 347, 20.12.2013, p. 924.

([2]) Commission Implementing Decision (EU) 2019/570 of 8 April 2019 laying down rules for the implementation of Decision No 1313/2013/EU of the European Parliament and of the Council as regards rescEU capacities and amending Commission Implementing Decision 2014/762/EU (OJ L 99, 10.4.2019, p. 41).

(6) In the context of extremely limited availability of both investigational vaccines and therapeutics, the stockpiling of Ebola countermeasures is an important preparedness measure in case of a transmission of the disease into the Union.

(7) The global spread of this kind of highly infectious diseases, as also demonstrated by the novel coronavirus 2019-nCoV and the related coronavirus disease COVID-19 outbreak requires a coordinated action from Member States in order to avoid an escalation of the emergency across the Union, which has already been severely hit by these outbreaks.

(8) The risk of transmission of COVID-19, as well as the transmission of other diseases, can be reduced if appropriate measures are taken, including the use of personal protective equipment and other relevant medical equipment.

(9) Based on a technical report by the European Centre for Disease Prevention and Control (ECDC) ([3]), public health authorities in the Union are encouraged to plan for sufficient personal protection equipment supplies, particularly for their health professionals caring for patients infected with COVID-19.

(10) In order to be prepared for the further spread of COVID-19 and to minimise potential shortages, the Council, in its conclusions on COVID-19 of 13 February 2020 ([4]) has called upon the Commission to continue examining all available possibilities to facilitate access to personal protective equipment needed by Member States.

(11) In response to the Council conclusions, the stockpiling of medical countermeasures, intensive care medical equipment, and personal protective equipment aimed at combating serious cross-border threats to health should be included in the capacities of rescEU.

(12) For reasons of consistency with other Union acts, the definition of 'serious cross-border threats to health' in this Decision should be the definition in Decision No 1082/2013/EU of the European Parliament and of the Council ([5]).

(13) In accordance with Article 12(4) of Decision No 1313/2013/EU, quality requirements for medical countermeasures, intensive care medical equipment, and personal protective equipment capacities under rescEU should be based on established international standards, where such standards already exist.

(14) The quality requirements for medical countermeasures such as investigational vaccines and therapeutics should therefore be based on minimum standards and requirements provided by the European Medical Agency (EMA) and the WHO. The quality requirements for intensive care medical equipment should be based on minimum standards provided by the WHO and the quality requirements for personal protective equipment should be based on minimum standards provided by the WHO and ECDC.

(15) In order to provide Union financial assistance for establishing, managing and maintaining such capacities in accordance with Article 21(3) of Decision No 1313/2013/EU, the total estimated costs necessary to ensure availability and deployability thereof should be defined. Total estimated costs should be calculated taking into account the categories of eligible costs laid down in Annex IA to Decision No 1313/2013/EU.

(16) Implementing Decision (EU) 2019/570 should therefore be amended accordingly.

(17) The measures provided for in this Decision are in accordance with the opinion of the committee referred to in Article 33(1) of Decision No 1313/2013/EU,

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([3]) ECDC Technical Report, 'Personal protective equipment (PPE) needs in healthcare settings for the care of patients with suspected or confirmed novel coronavirus', February 2020.

([4]) Council conclusions on COVID-19, 2020/C 57/04ST/6038/2020/INIT (OJ C 57, 20.2.2020, p. 4).

([5]) 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).

HAS ADOPTED THIS DECISION:

Article 1

Implementing Decision (EU) 2019/570 is amended as follows:

(1) Article 1 is amended as follows:

— point (d) is replaced by the following:

'(d) total estimated costs of emergency medical team type 3 rescEU capacities;';

— the following point (e) is added:

'(e) total estimated costs of medical stockpiling rescEU capacities.';

(2) Article 2 is amended as follows:

(a) in paragraph 1, the third indent is replaced by the following:

'— emergency medical team capacities,';

(b) in paragraph 1, the following fourth indent is added:

'— medical stockpiling capacities.';

(c) in paragraph 2, the point (e) is amended as follows:

'(e) emergency medical team type 3 capacities: Inpatient Referral Care;'

(d) paragraph 2, following point (f) is added:

'(f) stockpiling of medical countermeasures or personal protective equipment aimed at combatting serious cross-border threats to health, as referred to in Decision No 1082/2013/EU of the European Parliament and of the Council (*).

(*) 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)';

(3) the following Article 3c is inserted:

'Article 3c

Total estimated costs of medical stockpiling rescEU capacities

1. All cost categories referred to in Annex IA to Decision No 1313/2013/EU shall be taken into account when calculating the total estimated cost of medical stockpiling rescEU capacities.

2. The equipment costs of the total estimated costs of medical stockpiling rescEU capacities shall be calculated on the basis of market prices at the time when the capacities are acquired, rented or leased in accordance with Article 12 (3) of Decision No 1313/2013/EU.

Where Member States acquire, rent or lease rescEU capacities, they shall provide the Commission with documentary evidence of the actual market prices or, where there are no market prices for certain components of those capacities, with equivalent evidence.

3. The categories of the total estimated costs of medical stockpiling rescEU capacities referred to in points 2 to 8 of Annex IA to Decision No 1313/2013/EU shall be calculated at least once during the period of each multiannual financial framework, taking into account information available to the Commission, including inflation. That calculation of the total estimated costs shall be used by the Commission for the purpose of providing annual financial assistance.

4. The total estimated cost referred to in paragraphs 2 and 3 shall be calculated where at least one Member State expresses interest in acquiring, renting or leasing a medical stockpiling rescEU capacity.';

(4) the Annex is amended as set out in the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 19 March 2020.

For the Commission
Janez LENARČIČ
Member of the Commission

ANNEX

In the Annex, the following Section 6 is added:

'6. **Stockpiling of medical countermeasures and/or personal protective equipment aimed at combatting serious cross-border threats to health**

Tasks	— Stockpiling of medical countermeasures, comprising of vaccines or therapeutics, intensive care medical equipment, personal protective equipment, or laboratory supplies, for the purpose of preparedness and response to a serious cross-border threat to health ([1]).
Capacities	— Adequate number of doses of vaccines necessary for individuals considered to be at risk ([2]) linked to one or more cases of serious cross-border threats to health. — Adequate number of doses of therapeutics necessary to treat one or more cases of serious cross-border threats to health. — Vaccines and therapeutics shall fulfil one of the following requirements: — Marketing authorisation from EMA; — A positive recommendation for compassionate or emergency use from EMA or a national regulatory agency of a Member State; — A positive recommendation for expanded or emergency use from WHO and acceptance by at least one National Regulatory Agency of a Member State. — Adequate intensive care medical equipment ([3]), to provide supportive care to one or more cases of serious cross-border threats to health, in accordance with WHO standards. — Adequate number of sets of personal protective equipment ([4]) for individuals considered to be at risk ([5]) linked to one or more cases of serious cross-border threats to health, in accordance with the standards of the ECDC and the WHO. — Adequate number of laboratory supplies, including sampling material, laboratory reagents, equipment and consumables ([6]), to ensure laboratory diagnosis capacity for one or more cases of serious cross-border threats to health.
Main components	— Appropriate storage facilities in the Union ([7]) and adequate stockpiling monitoring system. — Appropriate procedures ensuring the adequate packaging, transport and delivery of the products referred to under capacities, where needed. — Appropriately trained personnel to handle, and administer the products referred to under capacities.
Deployment	— Availability for departure maximum 12 hours after the acceptance of the offer.

([1]) As defined in Decision No 1082/2013/EU.
([2]) Individuals considered at risk may comprise: high risk potential contacts, first responders, laboratory workers, health care workers, family members and other defined vulnerable groups.
([3]) This may comprise, but is not limited to, intensive care ventilators.
([4]) Covering the following categories: (i) eye protection; (ii) hand protection; (iii) respiratory protection; (iv) body protection; and (v) foot protection.
([5]) See footnote 2.
([6]) This may include, but is not limited to, RT-PCR reagents, such as enzymes, RNA extraction reagents, RNA extraction machine time, PCR machine time, primer and probe reagents, positive control reagents, PCR laboratory consumables (e.g. tubes, plates) and disinfectants.
([7]) For the purposes of the logistics of storage facilities, "in the Union" encompasses the territories of Member States and Participating States of the Union Civil Protection Mechanism.'