

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 (Text with EEA relevance)

CHAPTER V

**EMERGENCY SITUATIONS**

*Article 12*

**Recognition of emergency situations**

- 1 The Commission may recognise a situation of public health emergency in relation to:
  - a epidemics of human influenza considered to have pandemic potential, where the Director-General of the WHO has been informed and has not yet adopted a decision declaring a situation of pandemic influenza in accordance with the applicable rules of the WHO; or
  - b cases other than that referred to in point (a) where the Director-General of the WHO has been informed and has not yet adopted a decision declaring a public health emergency of international concern in accordance with the IHR, and where:
    - (i) the serious cross-border threat to health in question endangers public health at the Union level;
    - (ii) medical needs are unmet in relation to that threat, which means that no satisfactory method of diagnosis, prevention or treatment is authorised in the Union or, despite the existence of such a method, the authorisation of a medicinal product would nonetheless be of major therapeutic advantage to those affected.

2 The Commission shall adopt the measure referred to in paragraph 1 by means of implementing acts.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

On duly justified imperative grounds of urgency related to the severity of a serious cross-border threat to health or to the rapidity of its spread among Member States, the Commission may recognise situations of public health emergency pursuant to paragraph 1 through immediately applicable implementing acts in accordance with the procedure referred to in Article 18(3).

3 The Commission shall inform the Director-General of the WHO of the adoption of the measures referred to in paragraph 1.

*Article 13*

**Legal effects of recognition**

The recognition of an emergency situation pursuant to Article 12(1) shall have the sole legal effect of enabling point 2 of Article 2 of Regulation (EC) No 507/2006 to apply or,

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*Changes to legislation: There are outstanding changes not yet made to Decision No 1082/2013/EU of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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where the recognition specifically concerns epidemics of human influenza considered as having a pandemic potential, of enabling Article 21 of Regulation (EC) No 1234/2008 to apply.

#### *Article 14*

#### **Termination of the recognition**

The Commission shall, by means of implementing acts, terminate the recognition referred to in Article 12(1) as soon as one of the applicable conditions laid down therein is no longer met.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

Termination of the recognition, as referred to in the first paragraph, shall not affect the validity of marketing authorisations granted on the basis of Regulation (EC) No 507/2006 to medicinal products referred to in point 2 of Article 2 thereof or granted in accordance with the procedure referred to in Article 21 of Regulation (EC) No 1234/2008.

**Changes to legislation:**

There are outstanding changes not yet made to Decision No 1082/2013/EU of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

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**Changes and effects yet to be applied to :**

- Decision revoked by [S.I. 2021/877 reg. 15\(b\)](#)