

Government Decree 246/2015 (IX.8.)

on the identification, designation and protection of critical systems and facilities in healthcare

The Government, acting on the basis of authorisation by section 14 a)-d) and g)-h) of Act CLXVI of 2012 on the identification, designation and protection of critical systems and facilities, acting within its functions provided for in Article 15(1) of the Fundamental Law, decrees as follows:

1. Interpretative provisions

Section 1 (1) For the purpose of this decree

1. *medium safety-level category* means a biological pathogen factor which can cause a serious human illness and may therefore pose a serious threat to persons with whom it comes in contact, and the risk of its spreading in the human community may exist, however, in general its spreading can be prevented, or the treatment of the illness is effective;

2. *high safety-level category* means a biological pathogen factor which can cause a serious human illness and therefore poses a serious threat to persons with whom it comes in contact, and the risk of its spreading in the human community is high, in general its spreading cannot be prevented, or the treatment of the illness is not effective;

3. *microbiological or other biological substance, as well as toxin* means a substance defined in, set out in Class 1 of Annex I to Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items, under control register number 1C351-1C354, which is suitable for causing illness, destroying, modifying or altering the genetic material in humans, animals or plants;

4. *technical and technological support* means activities related to research, development, production, experimentation and all other technical and technological services related to microbiological or other biological substances and toxins, which may include education, training, transfer of work experience or skills, or provision of consultancy services, including verbal forms of support.

(2) The terms not covered by paragraph (1) shall be interpreted in accordance with the provisions of Act CLIV of 1997 on Healthcare (hereinafter Healthcare Act) and Act CLXVI of 2012 on the identification, designation and protection of critical systems and facilities (hereinafter Hungarian CIP Act).

2. Advisory authorities

Section 2¹ The following bodies shall act as advisory authorities as regards critical infrastructures for the healthcare sector (hereinafter critical infrastructure) defined in the table of Annex 1 of the Hungarian CIP Act

¹ Declared by Government Decree 375/2020 (VII.30.) section 74. Effective from 31.07.2020

- a) in the case of active inpatient care and the service necessary for its operation sub-sector of the healthcare sector set out in row 14, the National Healthcare Service Center,
- b) in the case of the rescue services sub-sector of the healthcare sector set out in row 15, the National Rescue Services,
- c) in the case of
- ca) healthcare reserves sub-sector of the healthcare sector in row 16, the National Healthcare Service Center,
- cb) blood stocks sub-sector of the healthcare sector in row 16, the Hungarian National Blood Transfusion Service,
- d) in the case of the high safety-level biological laboratories sub-sector of the healthcare sector set out in row 17, the Hungarian Chief Medical Officer,
- e) in the case of the pharmaceutical wholesale sub-sector of the healthcare sector set out in row 18, the National Institute of Pharmacy and Nutrition.

3. The sectoral designating authority

Section 3 (1) When defining critical elements in the sub-sectors under section 2, the activities of the sectoral designating authority shall be performed by the minister responsible for healthcare (hereinafter minister).

(2) The minister shall be assisted in the performance of the duties under paragraph (1) above by a decision-preparatory committee (hereinafter Committee).

(3)¹ The Committee shall consist of the chairperson and 9 members in accordance with paragraphs (5) and (6), whereby a member of the Committee may only be a person who has already completed or agrees to complete the security liaison officer course within one year from the appointment or the acceptance of the invitation.

(4) The chairperson of the Committee shall be invited by the minister.

(5) The members of the Committee shall be delegated by the secretary of state responsible for management, oversight of the following areas, respectively

- a) active inpatient care,
- b) rescue services,
- c) organisation handling healthcare reserves,
- d) organisation handling blood reserves,
- e) high safety-level biological laboratories,
- f)²
- g) pharmaceutical wholesale.

(6) Three members of the Committee shall be appointed by the minister, from the government officials of the ministry lead by the minister (hereinafter ministry).

(7) Persons with at least five years of professional experience in the relevant sub-sector set out in paragraph (5) may be delegated to the Committee.

(8) The chairperson and the members of the Committee shall be mandated for three years.

(9)³ A quorum shall exist at the Committee if the chairperson or, in the event of the chairperson being prevented from attending, the alternate person, and at least 6 other

¹ Modified by Government Decree 368/2016 (XI.29.) section 13, Government Decree 375/2020 (VII.30.) section 77a)

² Repealed by Government Decree 375/2020 (VII.30.) section 78a). Ineffective from 31.07.2020

³ Modified by Government Decree 375/2020 (VII.30.) section 77b)

members are present. Decisions of the Committee shall be taken by a majority of votes, in the event of a tie, the chairperson shall have a casting vote.

(10) The Committee shall establish its rules of operation in its rules of procedure. In order to clarify the facts, the Committee may request data from the advisory authority and the operator of the critical infrastructure proposed for designation in order to formulate its proposition.

(11) The chairperson and members of the Committee may not be instructed in the course of performance of their duties or in connection therewith.

4. Healthcare sub-sector criteria for national critical infrastructures

Section 4 The active inpatient care provider and its premises (hereinafter together hospital) shall be declared a national critical infrastructure, if

a) it has at least 400 active beds or the number of persons subject to its territorial care obligation reaches or exceeds 1.5 million, and

b) in the event of an outage, the nearest hospital cannot be reached by road within 45 minutes by the patients, or there is a health policy interest in the continued operation of the hospital.

Section 5 The rescue service centres from which the rescue service activity pursuant to section 94 (1), (2), (4) and (5) of the Healthcare Act is controlled with respect to at least one county or the capital.

Section 6 As regards the State Healthcare Reserve (hereinafter SHR), the following shall be declared as national critical infrastructure

a) the record system the failure of which renders normal operation impossible for at least 24 hours or the restoration of which takes at least 48 hours,

b) any storage facility or storage capacity where at least 10% of the total value of the SHR is located; and

c) warehouses containing more than 50% of the quantity of stocks of certain items of medical device- and pharmaceutical standards specified in the decree on the rules of the management of the State Healthcare Reserve.

Section 7 As regards blood stocks the following shall be declared as national critical infrastructure

a) the system for recording national blood and transfusion stocks; and

b) the infrastructure elements necessary for storage and blood donation, if their injury would disrupt the national blood supply system for 3 days or more.

Section 8 The following shall be declared as national critical infrastructures

a) laboratories that regularly store, process or test microbiological or other biological substances of medium or high safety-level and toxin, or provide technical and technological support for this activity, and

b) reference laboratories designated in accordance with the decree on the minimum professional conditions for the provision of healthcare services.

Section 9¹

¹ Repealed by Government Decree No. 375/2020 (VII.30.) section 78b). Ineffective from 31.07.2020

Section 10 An economic entity engaged in pharmaceutical wholesale shall be declared as national critical infrastructure, if

a) its market share for the distribution of pharmaceuticals in Hungary exceeds, on the basis of its annual sales revenue

aa) 15% in the case of pharmacy deliveries, or

ab) 15% in the case of an inpatient care performing hospitals,

b) has nationwide logistics; and

c) in accordance with the needs of users it markets the full range of pharmaceutical products in its area of distribution.

5. Healthcare sub-sector criteria for European critical infrastructures

Section 11 (1) The following may be proposed for designation as a European critical infrastructure

a) the hospital

aa) that has at least 1,500 active beds or the number of persons subject to its territorial care obligation reaches or exceeds 3 million, and

ab) in the event of an outage, the nearest hospital cannot be reached by road within 90 minutes by the patients, or there is a health policy interest in the continued operation of the hospital;

b) the rescue service centre from which the rescue service activity pursuant to section 94 (1), (2), (4) and (5) of the Healthcare Act is controlled with respect to at least three counties and the capital.

c) as regards the State Healthcare Reserve, the stock items for the treatment of cross border health threats;

d) the system for recording national blood and transfusion stocks if its injury would disrupt the national provision of services for at least 7 days;

e) as regards blood stocks, the infrastructure element necessary for storage and blood donation, if the injury of the element would disrupt the national blood supply system for 5 days or more;

f) laboratories that regularly store, process or test microbiological or other biological substances of high safety-level and toxin, or provide technical and technological support for this activity, and

g)¹

(2) An economic entity engaged in pharmaceutical wholesale may be proposed to be designated as a European critical infrastructure, if

a) its market share for the distribution of pharmaceuticals in Hungary exceeds, on the basis of its annual sales revenue

aa) 30% in the case of pharmacy deliveries, or

ab) 30% in the case of an inpatient care performing hospitals,

b) has nationwide logistics; and

c) in accordance with the needs of users it markets the full range of pharmaceutical products in its area of distribution.

¹ Repealed by Government Decree 375/2020 (VII.30.) section 78c). Ineffective from 31.07.2020

6. Identification test of critical infrastructures¹

Section 12 (1)² In the course of the identification test of critical infrastructures for the healthcare sector, the provision of Government Decree 65/2013 (III.8.) on the implementation of Act CLXVI of 2012 on the identification, designation and protection of critical systems and facilities (hereinafter implementation decree of the Hungarian CIP Act) shall be applied with the additions specified in paragraphs (2)-(7).

(2)³ Section 2 of the implementation decree of the Hungarian CIP Act shall apply with the addition that the following are required to prepare an identification report:

a) hospitals,

b) the rescue services organisation,

c) the manager of the SHR,

d) public blood stocks manager,

e) the laboratory obliged to prepare reports pursuant to section 3 of Government Decree 21/2013 (I.30.)² on the implementation of declaration obligations and control procedures under the convention on the prohibition of the development, production and stockpiling of bacteriological (biological) and toxin weapons and on the destruction of such weapons (hereinafter laboratory)

f)⁴

g) the entity carrying out pharmaceutical wholesale activities that meets the requirements specified in section 10.

(3) The minister shall keep the identification report for 10 years from the date of receipt.

(4) The risk analysis in the identification report shall include – in addition to those set out in the implementation decree of the Hungarian CIP Act – an analysis on the current level of security and the consequences of any possible outage.

(5) In the case of laboratories, in the identification report – in addition to those set out in the implementation decree of the Hungarian CIP Act – the name, quantity, location of the substances on which the notification obligation is based, as well as the related technical and technological support service, the size of the laboratory, the number of employees and their qualifications shall be presented.

(6)⁵ In the event of a change in the activity on which the designation is based, the operator of the designated critical infrastructure set out in paragraph 2 a) and g) shall conduct an identification test and submit the identification report to the advisory authority within 90 days from the decision on ordering the modification of the operating license becoming final.

(7)⁶ The operator of an organisation referred to in paragraph (2) above does not need to prepare a new identification report, if the minister has waived the preparation of the report during the previous identification test and there has been no material change in the organisation's activities, unless the minister calls on the organisation to submit the identification report by setting a deadline.

¹ Modified by Government Decree 375/2020 (VII.30.) section 77c)

² Modified by Government Decree 375/2020 (VII.30.) section 77c)

³ Declared by Government Decree 64/2016 (III.31.) section 3. Effective from: 01.04.2016

⁴ Repealed by Government Decree 375/2020 (VII.30.) section 78d). Ineffective from 31.07.2020

⁵ Modified by Government Decree 64/2016 (III.31.) section 5a), Government Decree 375/2020 (VII.30.) section 77d)

⁶ Modified by Government Decree 375/2020 (VII.30.) section 77e)

6/A.¹ Extent and thresholds for significant disruptive effect related to essential services in the healthcare sector

Section 12/A² (1) As regards essential services for the healthcare sector as set out in Annex 3 of the implementation decree of the Hungarian CIP Act, the following shall qualify as significant disruptive effect: any security incident which results in a reduction or loss of a health service, and which

- a) adversely affects the health of a significant number of patients,
- b) causes permanent damage to the health of at least one person, or
- c) leads to the otherwise avoidable death of at least one person.

(2) The significant disruptive effect referred to in paragraph (1) above shall mean in particular:

a) in the case of a rescue services activity, the security incident during which the rescue services or the healthcare provided in connection with the rescue services suffers such a loss of time which:

- aa) adversely affects the health of a significant number of patients,
- ab) causes permanent damage to the health of at least one person, or
- ac) leads to the otherwise avoidable death of at least one person,

b) in the case of blood stocks and state healthcare reserves, any security incident which, due to the obstruction or impossibility of using the stocks and reserves, causes disruptions in patient care and jeopardises the quality of emergency patient care,

c) as regards active inpatient care, any security incident that jeopardises or obstructs emergency patient care in such a way that it is not possible to prepare in advance for the replacement of the service.

Section 12/B³ As regards essential services for the healthcare sector as set out in Annex 3 of the implementation decree of the Hungarian CIP Act, the operator meeting any of the criteria set out sections 4-7 and 10 above, may be identified as an operator of essential services.

7. Rules related to the security liaison officer

Section 13⁴ (1) The relevant specialised qualification in the healthcare sector for the purposes of section 6(1) of the implementation decree of the Hungarian CIP Act shall mean the medical degree.

(2) In the case of employment in a laboratory, in addition to the provisions of paragraph (1) above

- a) the degree in biology, or
- b) the degree in microbiology

shall mean the relevant specialised qualification in the healthcare sector for the purposes of section 6(1) of the implementation decree of the Hungarian CIP Act.

¹ Added by Government Decree 375/2020 (VII.30.) section 75. Effective from: 31.07.2020

² Added by Government Decree 375/2020 (VII.30.) section 75. Effective from: 31.07.2020

³ Added by Government Decree 375/2020 (VII.30.) section 75. Effective from: 31.07.2020

⁴ Declared by Government Decree 375/2020 (VII.30.) section 75. Effective from: 31.07.2020

(3) In the case of employment in the pharmaceutical wholesale trade, instead of the provisions of paragraph (1) above

a) a qualification meeting the conditions laid down in the ministerial decree on the conditions of qualification of persons authorized to assure the quality of medicinal products, or

b) any higher education degree in a technical field, engineering, logistics, mechanical engineering, pharmacy, chemistry or computer science

qualifies as relevant specialised qualification in the healthcare sector for the purposes of section 6(1) of the implementation decree of the Hungarian CIP Act, whereby in the case of point b) only if the person having the qualification defined therein was employed or engaged as an agent obtaining at least 3 years of experience carrying out an activity requiring the relevant qualification at a company, entity or authority or other organisation working in the field of pharmaceutical trade or other pharmaceutical activity.

(4) With the exception of employment in the pharmaceutical wholesale trade, in addition to the provisions of paragraphs (1) and (2), any other higher education qualification other than that provided for in paragraphs (1) and (2) shall qualify as relevant specialised qualification in the healthcare sector for the purposes of section 6(1) of the implementation decree of the Hungarian CIP Act, if the person was employed or engaged as an agent obtaining at least 3 years of experience in the field of health administration.

Section 13/A¹ The joint maintainer of the critical infrastructures belonging to the active inpatient care sub-sector may also ensure compliance with the obligation prescribed in section 6 (7) of the CIP Act by employing one or more common security liaison officers in relation to the infrastructures in its maintenance.

8. Special rules on the Operator security plans for critical infrastructures

Section 14 (1) The Operator security plans for the critical infrastructures for the healthcare sector (hereinafter OSP) shall be created in accordance with the requirements specified in the CIP Act and the implementation decree of the Hungarian CIP Act - with the additions specified in paragraphs (2)-(4) below.

(2) In the case of a hospital, the OSP shall include the following sub-plans, taking into account the obligations of the healthcare provider in relation to the sub-plans of its contingency plan listed in the annex to the ministerial decree on the content requirements of health care contingency plans of healthcare institutions and amending certain ministerial decrees on healthcare:

a) plan for the replacement and alternative operation of public utilities,

b) plan for the provision of the necessary, indispensable services,

c) the meal plan,

d) a substitution plan for medicinal products, medical consumables, blood and blood products, and

e) the communication plan.

(3) In the case of the laboratory, the OSP shall include the following sub-plans:

¹ Added by Government Decree 368/2016 (XI.29.) section 11. Effective from: 01.01.2017

a) contingency plan for the escape of the microbiological or other biological substance and toxin; and

b) plan for the registration of entry and the prevention of entry of unauthorized persons.

(4) In the case of a pharmaceutical wholesaler, the OSP shall include the following sub-plans:

a) plan for the replacement and alternative operation of public utilities,

b) plan to ensure the necessary, indispensable deliveries,

c) the alternative logistics plan (vehicles available),

d) plan for the replenishment of medicinal products, and

e) the communication plan.

9. Monitoring of critical infrastructures

Section 15 The body conducting the on-site monitoring shall be

a)¹ as regards the critical infrastructures pursuant to section 12(2)a) and e) above, the capital city and county government office acting in its capacity for public health,

b)² as regards the critical infrastructures pursuant to section 12(2)b)-d) and g), the minister, who shall perform the task with the assistance of the organisational unit designated thereby of the ministry which carries out monitoring tasks.

9/A.³ Extraordinary occurrences

Section 15/A⁴ The following shall be considered extraordinary occurrences in the healthcare sector

a) in the case of a facility or institution, a public utility outage expected to last more than 2 hours,

b) any event affecting the infrastructure, as defined in separate legislation, which leads to the cessation of the conditions necessary for its operation or to the transformation of its core activities,

c) any extraordinary occurrence affecting the infrastructure, as defined in separate legislation, which leads to the cessation of the conditions necessary for its operation or to the transformation of its core activities,

d) if the competent authority imposes a health quarantine at the designated critical infrastructure,

e) critical shortage of human resources to such an extent that it may lead to the cessation or suspension of the activity.

10. Final provisions

Section 16 This decree shall enter into force on the 8th day following its promulgation.

Section 17 The hospital and laboratory which receives an operating license after this decree's entry into force, shall submit its identification report – by way of derogation from

¹ Modified by Government Decree 64/2016 (III.31.) section 5b)

² Modified by Government Decree 64/2016 (III.31.) section 5c), Government Decree 375/2020 (VII.30.) section 77f)

³ Added by Government Decree 375/2020 (VII.30.) section 76. Effective from: 31.07.2020

⁴ Added by Government Decree 375/2020 (VII.30.) section 76. Effective from: 31.07.2020

section 15 of the implementing decree of the Hungarian CIP Act– for the first time within 180 days following its operating license becoming final, to the competent advisory authority.

Section 17/A¹

Section 17/B²

Section 18 This decree serves the purpose of compliance with the Council Directive (EU) 2008/114/EC of 8 December 2008 on the identification and designation of European critical infrastructures and the assessment of the need to improve their protection.

Section 19³ This decree serves the purpose of compliance with the Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union.

¹ Repealed by Government Decree 375/2020 (VII.30.) section 78e). Ineffective from 31.07.2020

² Repealed by Government Decree 375/2020 (VII.30.) section 78e). Ineffective from 31.07.2020

³ Added by Government Decree 394/2017 (XII.13.) section 8. Effective from 10.05.2018