



2020/0359(COD)

30.6.2021

AMENDMENTS

248 - 250

Draft opinion

Lukas Mandl

(PE693.822v01-00)

Measures for a high common level of cybersecurity across the Union, repealing Directive (EU) 2016/1148

Proposal for a directive

(COM(2020)0823 – C9-0422/2020 – 2020/0359(COD))

AM_Com_LegOpinion

Amendment 248
Lukas Mandl

Proposal for a directive
Annex I – Point 5 (Health) – indent 6 (new)

Text proposed by the Commission

Sector	Subsector	Type of entity
5. Health		<ul style="list-style-type: none">– Healthcare providers referred to in point (g) of Article 3 of Directive 2011/24/EU (90)– EU reference laboratories referred to in Article 15 of Regulation XXXX/XXXX on serious cross-border threats to health⁹¹– Entities carrying out research and development activities of medicinal products referred to in Article 1 point 2 of Directive 2001/83/EC (⁹²)– Entities manufacturing basic pharmaceutical products and pharmaceutical preparations referred to in section C division 21 of NACE Rev. 2– Entities manufacturing medical devices considered as critical during a public health emergency (‘the public health emergency critical devices list’) referred to in Article 20 of Regulation XXXX⁹³

⁹¹ [Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU, reference to be updated once the proposal COM (2020)727 final is adopted]

⁹² Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p.67).

⁹³ [Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal produces and medical devices, reference to be updated once the proposal COM(2020)725 final is adopted]

Amendment

Sector	Subsecto	Type of entity
5. Health		<ul style="list-style-type: none">– Healthcare providers referred to in point (g) of Article 3 of Directive 2011/24/EU (90)– EU reference laboratories referred to in Article 15 of Regulation XXXX/XXXX on serious cross-border threats to health⁹¹– Entities carrying out research and development activities of medicinal products referred

to in Article 1 point 2 of Directive 2001/83/EC ⁽⁹²⁾)

– Entities manufacturing basic pharmaceutical products and pharmaceutical preparations referred to in section C division 21 of NACE Rev. 2

– Entities manufacturing medical devices considered as critical during a public health emergency ('the public health emergency critical devices list') referred to in Article 20 of Regulation XXXX⁹³

– ***Entities holding a distribution authorisation referred to in Article 79 of Directive 2001/83/EC***

⁹¹ [Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU, reference to be updated once the proposal COM(2020)727 final is adopted]

⁹² Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p.67).

⁹³ [Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, reference to be updated once the proposal COM(2020)725 final is adopted]

Or. en

Amendment 249

Patrick Breyer

Proposal for a directive

Annex I – Point 8 (Digital infrastructure) – indent 2 and 3

Text proposed by the Commission

8. Digital
infrastructure

- ***DNS service providers***
- ***TLD name registries***

Amendment

8. Digital
infrastructure

- ***deleted***
- ***deleted***

Or. en

Amendment 250

Patryk Jaki

Proposal for a directive

Annex I – Point 9 (Public administration)

Text proposed by the Commission

**9. Public
administration**

- **DNS service providers**
- **Public administration entities of NUTS level 1 regions listed in Annex I of Regulation (EC) No 1059/2003 ⁽⁹⁸⁾**
- **Public administration entities of NUTS level 2 regions listed in Annex I of Regulation (EC) No 1059/2003**

⁹⁸ **Regulation (EC) No 1059/2003 of the European Parliament and of the Council of 26 May 2003 on the establishment of a common classification of territorial units for statistics (NUTS) (OJ L 154, 21.6.2003, p. 1).**

Amendment

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Or. en