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Committee on Civil Liberties, Justice and Home Affairs

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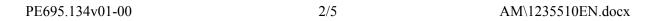
AMENDMENTS 248 - 250

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\1235510EN.docx PE695.134v01-00



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		 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
015-		

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]

Amendment

Sector	Subsecto	Type of entity
5. Health		 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

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]

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

- 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]

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 – **DNS service providers** infrastructure – **TLD name registries**

Amendment

8. Digital – *deleted* infrastructure – *deleted*

Or. en

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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]

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
 regions listed in Annex I of Regulation (EC) No
 1059/2003

Amendment

deleted – deleted

deleted

deleted

Or. en

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).