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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Directive 2011/24/EU on the application of patients' rights in cross-border healthcare

1. Introduction

Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare[1] provides rules for facilitating access to safe and high quality cross-border healthcare in the European Union. To this end, patients are reimbursed for healthcare in accordance with the principles established by the European Court of Justice of the European Union and codified by the Directive. At the same time, Member States remain responsible for providing adequate healthcare in their territory. The Directive applies to cross-border healthcare without affecting the framework provided by the Social Security Coordination Regulations[2].

2. Legal basis

With this report, the Commission meets the reporting requirements established in Article 17 of Directive 2011/24/EU. Pursuant to that provision, the Commission is empowered to adopt delegated acts, as referred to in Article 17(1), with a view to:

- adopting measures to exclude specific categories of medicinal products or medical devices from the recognition of prescriptions, where necessary to safeguard public health, as provided for in Article 11(5);
- adopting specific criteria and conditions that the European Reference Networks (ERNs) must fulfil, and the conditions and criteria required from healthcare providers wishing to join such networks, including criteria for evaluating ERNs and for the exchange of information, as envisaged in Article 12(5).

Pursuant to Article 17(1) of Directive 2011/24/EU, the power to adopt delegated acts concerning the matters listed in Articles 11(5) and 12(5) is conferred on the Commission for a period of five years. This power can be automatically extended unless the European Parliament or the Council revokes it in accordance with Article 18.

3. Exercise of the delegation

Since the last report[3], the Commission has not exercised the delegated powers conferred to it under Articles 11(5) and 12(5) of Directive 2011/24/EU.

4. Conclusion

The Commission sees the need for an automatic five-year extension of the delegations of power provided for in Article 17(1) of Directive 2011/24/EU. The rationale for the delegations of power has not changed.

It is important to keep the possibility to:

- maintain the necessary flexibility in the legal framework;
- exclude specific categories of medicinal products or medical devices from the recognition of prescriptions, where necessary to safeguard public health; and

[1] OJ L 88, 4.4.2011, ELI: http://data.europa.eu/eli/dir/2011/24/oj.
[2] OJ L 166, 30.4.2004, ELI: http://data.europa.eu/eli/reg/2004/883/oj and OJ L 284, 30.10.2009, ELI: http://data.europa.eu/eli/reg/2009/987/oj.
[3] EUR-Lex - 52018DC0651 - EN - EUR-Lex.

- amend the list of the specific criteria and conditions that the ERNs must fulfil, and the conditions and criteria required from healthcare providers wishing to join such networks, as envisaged in Article 12(4)(a).

With this report, the Commission complies with the reporting requirements established in Article 17(1) of Directive 2011/24/EU.

The Commission invites the European Parliament and the Council to take note of this report.