

Authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

2001/0252(COD) - 30/03/2015

The Commission presented a report on the exercise of the delegation of powers conferred on the Commission pursuant to:

- [Directive 2001/83/EC](#) of the European Parliament and of the Council on the Community code relating to medicinal products for human use;
- **Regulation (EC) No 726/2004** of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

Delegation of power: pursuant to the aforementioned texts, the power to adopt delegated acts is conferred on the Commission for five years from January 2011. The Commission is required to report on its exercise of those powers at the latest six months before the end of this period.

Regulation (EC) No 726/2004, as amended by [Regulation \(EU\) No 1235/2010](#), empowered the Commission to adopt delegated acts on post-authorisation efficacy studies (Article 10b).

Exercise delegated powers: to date, the Commission has exercised the delegated powers provided for by Regulation (EC) No 726/2004.

Under this Regulation, it may be necessary in specific situations to complement the data available at the time a medicinal product was granted marketing authorisation with additional information on its efficacy, to address concerns that could not be resolved before the authorisation was granted.

Under Article 10b of the Regulation, the Commission is empowered to specify the situations in which post-authorisation efficacy studies may be required.

Following the consultation with the Expert Group formed by the Pharmaceutical Committee, the Commission adopted the [Delegated Regulation \(EU\) No 357/2014](#) and notified the European Parliament and the Council of it. Neither institution objected to the delegated act. The Commission Delegated Regulation was published in the Official Journal and entered into force on 30 April 2014.

In conclusion, **the Commission considered that the delegated powers** conferred by Article 10b of Regulation (EC) No 726/2004, as amended by Regulation (EU) No 1235/2010, **should remain in force**.