Medicinal products for human use: Community code. Codification

1999/0134(COD) - 30/03/2015 - Follow-up document

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.

The Medicinal Product Directive, as amended by Directive 2010/84/EU and Directive 2011/62/EU, empowers the Commission to adopt delegated acts on:

- post-authorisation efficacy studies (Article 22b),
- the principles of good manufacturing practice for active substances (Article 47),
- criteria to assess the potential falsified character of medicinal products transiting through the EU (Article 52b) and
- safety features for medicinal products (Article 54a).

Exercise delegated powers: to date the Commission has exercised the delegated powers provided for by Regulation (EC) No 726/2004 and in two of the four instances provided for by Directive 2001/83/EC.

Post-authorisation efficacy study: under Article 22b of the Medicinal Product Directive, the Commission is empowered to specify the situations in which post-authorisation efficacy studies may be required.

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.

Good manufacturing practice for active substances: as a result of the amendment to the Directive on medicinal use of products for human use introduced by Directive 2011/62/EU, since 2 January 2013, the manufacturing of active substances has been subject to good manufacturing practice for active substances regardless of whether the substances are manufactured in the Union or imported.

In this context, it is necessary to set EU-wide standards for the manufacturing of active substances and to harmonise the implementation and enforcement of these standards throughout the EU. To this end, the Commission is empowered to adopt, by means of delegated acts, measures supplementing the provisions of that Directive on good manufacturing practice for active substances.

The Commission adopted the Delegated Regulation (EU) No 1252/2014 and notified the European Parliament and the Council of it on 17 July 2014. The European Parliament decided to extend the deadline

for objections until 17 November 2014, but neither it nor the Council issued any objections. The Delegated Regulation was published in the Official Journal and entered into force on 15 December 2014.

Other delegations:

Safety measures for medicinal products (Article 54a): the Commission intends, **before the end of 2015** , to adopt a delegated regulation supplementing the Directive with regard to the detailed rules for the safety features appearing on the packaging of medicinal products for human use.

To prepare this delegated regulation, the Commission carried out extensive consultations with interested parties. An Expert Group on the delegated act on safety features for medicinal products for human use was set up.

Evaluation criteria of the potential falsified character of medicinal products introduced into the EU (Article 52b): the public consultation carried out by the Commission showed that Member States' and stakeholders' interest in the proposed measures was limited. Consequently, **the Commission does not intend to initiate work** on a delegated act at this stage

In conclusion, **the Commission is of the view that the delegated powers** conferred by Articles 22b, 47, 52b and 54a of Directive 2001/83/EC, as amended by Directive 2010/84/EU and Directive 2011/62/EU, **should remain in force**.