

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

[^{F1}TITLE IX

PHARMACOVIGILANCE

CHAPTER 4

Supervision of post-authorisation safety studies

[^{F1}Article 107n

1 Before a study is conducted, the marketing authorisation holder shall submit a draft protocol to the Pharmacovigilance Risk Assessment Committee, except for studies to be conducted in only one Member State that requests the study according to Article 22a. For such studies, the marketing authorisation holder shall submit a draft protocol to the national competent authority of the Member State in which the study is conducted.

2 Within 60 days of the submission of the draft protocol the national competent authority or the Pharmacovigilance Risk Assessment Committee, as appropriate, shall issue:

- a a letter endorsing the draft protocol;
- b a letter of objection, which shall set out in detail the grounds for the objection, in any of the following cases:
 - (i) it considers that the conduct of the study promotes the use of a medicinal product;
 - (ii) it considers that the design of the study does not fulfil the study objectives; or
- c a letter notifying the marketing authorisation holder that the study is a clinical trial falling under the scope of Directive 2001/20/EC.

3 The study may commence only when the written endorsement from the national competent authority or the Pharmacovigilance Risk Assessment Committee, as appropriate, has been issued.

Where a letter of endorsement as referred to in paragraph 2(a) has been issued, the marketing authorisation holder shall forward the protocol to the competent authorities of the Member States in which the study is to be conducted and may thereafter commence the study according to the endorsed protocol.]

Textual Amendments

- F1** Substituted by [Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use \(Text with EEA relevance\)](#).