Supplementary protection certificate for medicinal products. Recast

2023/0130(COD) - 28/02/2024 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 518 votes to 29, with 70 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast).

As a reminder, this proposal for a recast of Regulation (EC) No 1610/96 lays down the rules on the supplementary protection certificate for medicinal products protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a plant protection product, to an administrative authorisation procedure.

According to the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission, the Commission proposal does not include any substantive amendments other than those identified as such in the proposal and whereas, as regards the codification of the unchanged provisions of the earlier acts together with those amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amends the Commission's proposal as follows:

Content of the application for a certificate

The application for a certificate should contain if applicable, the consent of the third party as well as information on any direct public financial support received for research related to the development of the product. The authority should publish, without undue delay, notification of the fact that a certificate has been granted.

Publication of the centralised application

If the centralised application complies, or if an application for an extension of the duration of certificates complies with the provisions laid down in the Regulation, the Office should publish the application, in the Register without undue delay and no later than five working days after.

Examination of the centralised application

The Office should adopt an examination opinion within 6 months after publication of the centralised application in the Register. Whenever duly justified for reasons of urgency, the applicant may submit a request for an expedited procedure. Where the request for an expedited examination procedure is deemed justified, the Office should adopt an examination opinion within 4 months from the publication of the application for a unitary certificate. Whenever the expedited procedure applies, observations should be submitted within six weeks after publication of the application in the Register.

Opposition

Within a period of 2 months following the publication of the examination opinion in respect of a centralised application, any person may file with the Office a notice of opposition to that opinion. The notice of opposition should contain any evidence the opponent relies on in support of the opposition. The

Office should issue a decision on the opposition including a detailed reasoning for that decision within 6 months, unless the complexity of the case requires a longer period.

In cases where several oppositions have been filed against an examination opinion, the Office should deal with the oppositions jointly and issue one single decision in regards to all oppositions filed. Full transparency should be ensured throughout the whole opposition proceeding, which shall be open, whenever possible, to public participation.

Competent national authorities

On a request made to the Office, any competent national authority may be appointed by the Office as a participating office in the examination procedure. Once a competent national authority is appointed, that authority should designate one or more examiners to be involved in the examination of one or more centralised applications, on the basis of their relevant expertise and of their experience in the field.

Examination panels

The assessments should be carried out by an examination panel consisting of one member of the Office and two examiners from two different participating national competent authorities. When setting up an examination panel, the Office should ensure the following:

- **relevant expertise and sufficient experience** in the examination of patents and supplementary protection certificates, ensuring, in particular, that at least one examiner has a minimum of five years of experience in the examination of patents and supplementary protection certificates;

- where possible, **geographical balance** amongst the participating offices.

Appeal

Any reply to statement of the grounds of appeal should be submitted in writing within three months from the date of the notification of the statement of the grounds of appeal. Where applicable, the Office should set a date for an oral hearing within three months after the filing of the reply to the grounds of appeal or within six months of the filing of grounds of appeal, whichever is earlier. The Office should issue a written decision within three months of the oral hearing or of the filing of the reply to the statement of grounds of appeal, as applicable.

When appointing members of the Boards of Appeal in matters regarding centralised applications for certificates, their prior experience in supplementary protection certificate or patent matters should be taken into account.

Implementation of an examination of a centralised application at national level

After the completion of the examination of a centralised application, and after the time limits for appeal and opposition have expired, or, the case being, after a final decision on the merits has been issued, the opinion should be transmitted to the respective national patent offices of the designated Member States. The Office should ensure the transmission takes place within a timeframe allowing national patent offices to grant the certificate or reject the application, as applicable, before the expiry of the basic patent.

Register

The information provided in the register should not be used in regards to practices of patent linkage and no regulatory or administrative decisions related to **generics or biosimilars**, such as marketing authorisations, pricing and reimbursement decisions or tender bids to the existence of the SPC, should be based on information provided for in the register.