Unitary supplementary certificate for medicinal products

2023/0127(COD) - 31/01/2024 - Committee report tabled for plenary, 1st reading/single reading

The Committee on Legal Affairs adopted the report by Tiemo WÖLKEN (S&D, DE) on the proposal for a regulation of the European Parliament and of the Council on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013.

As a reminder, the proposal lays down rules on the unitary supplementary protection certificate for medicinal products protected by a European patent with unitary effect and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure.

The committee responsible recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the proposal as follows:

Application for a unitary certificate

The application for a unitary certificate should be lodged **electronically**, using the formats made available by the Office.

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. The notification should contain information on any direct public financial support received for research related to the development of the product for which the SPC is requested.

The application for a unitary certificate and, where applicable, the application for an extension of the duration of a unitary certificate, should be lodged in electronic form with the Office. The Office should put the necessary arrangements in place in order to ensure that exchanges of data and information are done electronically and that the commercially confidential nature of the information exchanged is protected.

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 an application for a unitary certificate, any person may file with the Office a notice of opposition to that opinion. The notice of opposition should include **any evidence** the opponent relies on in support of the opposition.

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 respect of all oppositions filed.

Full transparency should be ensured throughout the whole opposition proceeding, which shall be open, whenever possible, to public participation.

Examination panels

The assessments should be conducted by an examination panel including one member of the Office as well as two examiners from two different participating competent national 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.

Appeals

Any reply to the statement of grounds of appeal should be submitted in writing no later than three months from the date of the filing of the statement of **grounds** of appeal. The Office should, where applicable, fix a date for oral proceedings within three months of the filing of the reply or within six months following the filing of the statement of grounds of appeal, whichever is earlier. The Office should issue a written decision within three months of the date 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 concerning applications for unitary certificates, due consideration should be given to their previous experience in matters concerning supplementary protection certificates or patent law.

Register

Public authorities should not use information in the Register for practices of patent linkage. No regulatory or administrative decisions related to **generics or biosimilars** should be based on information in the Register. Information in the Register should not be used for refusal, suspension, delay, withdrawal or revocation of marketing authorisations, pricing and reimbursement decisions or tender bids.

Taking of evidence

If the Office or the relevant panel considers it necessary for a party, witness or expert to give evidence orally, it should issue a summons to the person concerned to appear before it. Where an expert is summonsed, the Office or the relevant panel, as the case may be, should verify that that expert is free of any conflict of interest.

Evaluation

By five years after the date of application, and every five years thereafter, the Commission should present a report on the main findings. Special emphasis should be given to the effects of opposition and whether the possibility of opposition leads to significant delays in granting unitary certificates and to the effects of this Regulation on the recovery of research and development investments.