

Patentstyret
Styret for det industrielle rettsvern
Postboks 4863 Nydalen
0422 Oslo

Oslo, 4 March 2025

Your ref.:

Our ref.: 147212NO/IMO/IMO

New SPC application in Norway

AEGIS THERAPEUTICS, LLC & ARS PHARMACEUTICALS OPERATIONS, INC.

EURneffy - Combination of epinephrine or a salt thereof, and dodecylmaltoside

Please find enclosed three documents hereby submitted for the SPC application with Application number: 2025010, filed on 14 February 2025.

We request that the enclosures herein are included as the basis documents for the assessment of the SPC application as filed. Please assess the documentation provided herein in full, rather than the arguments provided in the cover letter dated 14 February 2025.

The SPC application with Application number: 2025010 is based on the Basic Patent EP3678649 validated in Norway, granted on 26 October 2022, with an expiry date of 6 February 2039. The relevant documents were filed on 14 February 2025.

Marketing Authorisation:

The Norwegian Medical Products Agency granted Marketing Authorisation in Norway for EURneffy, adrenaline (epinephrine), in its letter of 27 August 2024.

The EU Marketing Authorisation document and associated Summary of Product Characteristics (SmPC) confirm that the active ingredient of EURneffy is epinephrine (adrenaline). The SmPC further confirms the presence of dodecylmaltoside (DDM) in EURneffy.

The relevant documents were filed on 14 February 2025.

Supplementary Submissions

Please refer to the document titled "Attorney Letter Accompanying new SPC Application documents – EURneffy" for supplemental information relevant for this application. Further to this an accompanying document "Press Release from the EMA re EURneffy" is submitted.

The product EURneffy (epinephrine and dodecylmaltoside) is covered by the basic patent:

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Please refer to the document titled “How the Patent Protects the Product – EURneffy (epinephrine + dodecylmaltoside)” for our reasoning.

Conclusion:

On basis of the information provided in the SPC application with Application number: 2025010, filed on 14 February 2025, and the two documents submitted to form part of the basis documents for this case, we believe the requirements for supplementary protection are fulfilled. We look forward to hearing from you.

The applicant further requests an opportunity to submit further arguments before a final decision is made for this SPC application.

We look forward to hearing from you.

Yours sincerely,
Bryn Aarflot AS



Ida Monshaugen

Enclosure

Attorney Letter Accompanying new SPC Application documents – EURneffy
How the Patent Protects the Product – EURneffy (epinephrine + dodecylmaltoside)
Press Release from the EMA re EURneffy