



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

26 March 2026  
EMADOC-1700519818-2842112  
Committee for Medicinal Products for Human Use (CHMP)

## Assessment report

### Taltz

International non-proprietary name: Ixekizumab

Procedure No. EMA/VR/0000323136

### Note

Variation assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.



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# 1. Background information on the procedure

Pursuant to Article 16 of Commission Regulation (EC) No 1234/2008, Eli Lilly and Co (Ireland) Limited submitted to the European Medicines Agency on 09 January 2026 an application for a variation.

The following changes were proposed:

Variation(s) requested		Type
C.I.3.b	C.I.3.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH	Variation type II

Update of sections 4.8 and 5.1 of the SmPC in order to update clinical information, following the outcome of the Article 46 procedure EMA/PAM/0000293431, based on the final study data for ixekizumab paediatric psoriasis study I1F-MC-RHCD (IXORA-PEDS). In addition, the MAH took the opportunity to update excipient information in the Labelling section according to the excipient guideline.

The requested variation(s) proposed amendments to the Summary of Product Characteristics and Labelling.

## **Information on paediatric requirements**

The application included an EMA Decision P/0087/2020 on the agreement of a paediatric investigation plan (PIP).

At the time of submission of the application, the PIP P/0087/2020 was completed .

The PDCO issued an opinion on compliance for the P/0087/2020.

# 2. Overall conclusion and impact on the benefit/risk balance

With this procedure, the MAH poposes to update the the Taltz SmPC to implement the revisions requested by CHMP on 13 November 2025, following the review of the Article 46 procedure number EMA/PAM/0000293431, submitted to provide the final study results for ixekizumab paediatric psoriasis Study I1F-MC-RHCD (IXORA-PEDS or RHCD). This study investigated the effects of ixekizumab versus placebo in participants from 6 to less than 18 years of age with moderate-to-severe plaque psoriasis.

In compliance with this recommendation, the MAH agrees to update the SmPC with the requested information from Study RHCD and proposes the following changes:

- **Section 4.8** is aupdated with the paediatric years of exposure in line with the data reflected in Section 8.1.1 of the abbreviated CSR, s requested within the P46 Procedure EMA/PAM/0000293431.

### 4.8 Undesirable effects

*A total of 8 956 patients have been treated with Taltz in blinded and open-label clinical studies in plaque psoriasis, psoriatic arthritis, axial spondyloarthritis, and other autoimmune conditions. Of these, 6 385 patients were exposed to Taltz for at least one year, cumulatively representing 19 833 adult patient years of exposure and 196 children cumulatively representing ~~207~~ **343** patient years of exposure.*

- **Section 5.1** is updated with a brief description of the study design for the additional treatment periods, and the information on the sustained efficacy in the parameters Psoriasis Area and Severity Index (PASI) 75 and static Physician Global Assessment (sPGA) (0,1) observed over 108 weeks.

#### 5.1 Pharmacodynamic properties

*Paediatric plaque psoriasis*

(...)

**After the initial 12 week double-blind induction period, patients were eligible to enter a 48 week open-label maintenance period (from week 12 to week 60), with ixekizumab at the weight appropriate dose, followed by an extension period for up to 108 weeks.**

#### **Clinical response at week 12**

(...)

#### **Maintenance of response at week 60 and up to 108 weeks**

**In patients continuously treated with ixekizumab, clinically meaningful improvements in efficacy endpoints were sustained through week 108:**

- **PASI 75: 83.0% at week 60; 76.6% at week 108 (NRI)**
- **sPGA (0,1): 74.5% at week 60; 68.1% at week 108 (NRI)**

In addition to the changes related to the Study RHCD final results, the MAH is taking the opportunity to implement the following EMA labelling comment in Annex III (EMA/H/C/003943/X/0051) and has implemented the following update in the "List of excipients" section for ALL outer cartons:

### **3. LIST OF EXCIPIENTS**

Excipients: sucrose; polysorbate 80; water for injections **and sodium hydroxide**. In addition, sodium hydroxide may have been added for pH adjustment. See leaflet for further information.

The proposed updates are in line with the procedures referenced above and are considered acceptable.

Overall, the benefit-risk profile of ixekizumab remains positive for the current authorised indications.

## **3. Recommendations**

Based on the review of the submitted data, this application regarding the following change:

<b>Variation(s) requested</b>		<b>Type</b>
C.I.3.b	C.I.3.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH	Variation type II

Update of sections 4.8 and 5.1 of the SmPC in order to update clinical information, following the outcome of the Article 46 procedure EMA/PAM/0000293431, based on the final study data for

ixekizumab paediatric psoriasis study I1F-MC-RHCD (IXORA-PEDS) which was performed in compliance with a paediatric investigation plan (PIP). In addition, the MAH took the opportunity to update excipient information in the Labelling section according to the excipient guideline.

The requested variation(s) proposed amendments to the Summary of Product Characteristics and Labelling.

is recommended for approval.

### ***Paediatric data***

The CHMP reviewed the available paediatric data of studies subject to the agreed Paediatric Investigation Plan PIP P/0087/2020 and the results of these studies are reflected in the Summary of Product Characteristics (SmPC) and, as appropriate, the Package Leaflet.

## **4. EPAR changes**

The table in the 'Steps after' module of the EPAR will be updated as follows:

### ***Scope***

Please refer to the Recommendations section above

### ***Summary***

Please refer to Scientific Discussion 'Taltz – EMA/PAM/0000293431'

**Annex: CHMP assessment comments on the type II variation**

## **5. Introduction**

Ixekizumab is a humanised monoclonal antibody designed and engineered to selectively inhibit IL-17A, a proinflammatory cytokine. Elevated levels of IL-17A have been implicated in the pathogenesis of a variety of autoimmune diseases. Ixekizumab is indicated for the treatment of moderate-to-severe plaque Ps, PsA, and axSpA (including both radiographic axSpA and non-radiographic axSpA) in adults and moderate-to-severe plaque Ps in paediatric patients aged 6 years and older. Ixekizumab was first approved on 22 March 2016 in the US and on 25 April 2016 in the EU, and as of 31 May 2024, has been granted marketing authorisation in 75 countries.

This Type II variation is submitted to implement the SmPC revisions requested by the CHMP, following the review of the Article 46 procedure number EMA/PAM/0000293431 submitted on 25 August 2025 to provide the final study results for ixekizumab paediatric psoriasis Study I1F-MC-RHCD (IXORA-PEDS or RHCD). This study investigated the effects of ixekizumab versus placebo in participants from 6 to less than 18 years of age with moderate-to-severe plaque psoriasis.

## **6. Clinical Efficacy aspects**

### ***6.1. Results and discussion***

The 12-week primary endpoint data from study I1F-MC-RHCD was provided with variation EMEA/H/C/003943/II/0031 (extension of indication with addition of paediatric psoriasis) and assessment of data resulted in approval of the indication "Paediatric plaque psoriasis (age 6 years and above)". The final study results from study I1F-MC-RHCD were provided in the Article 46 procedure number EMA/PAM/0000293431 including results from period 3 (48-week open-label maintenance period), period 4 (extension period including withdrawal phase) and period 5 (safety follow-up period) and an update of the SmPC was requested including a brief description of the study design for the additional treatment periods, along with information on the sustained efficacy in the parameters PASI 75 and sPGA (0,1) observed over 108 weeks.

In compliance with this recommendation, the MAH agrees to update the SmPC with the requested information. The proposed SmPC updates, as discussed in section 2, are considered acceptable.

For more information about the background of this variation and the assessment of the final study results for ixekizumab paediatric psoriasis Study I1F-MC-RHCD (IXORA-PEDS or RHCD), please refer to procedure EMA/PAM/0000293431.

## **7. Changes to the Product Information**

As a result of this variation, section(s) 4.8, and 5.1 of the SmPC are being updated to update clinical information, following the outcome of the Article 46 procedure EMA/PAM/0000293431, based on the final study data for ixekizumab paediatric psoriasis study I1F-MC-RHCD (IXORA-PEDS).

In addition, Labelling section is updated with excipient information according to the excipient guideline.

Please refer to Attachment 1 which includes all agreed changes to the Product Information.