



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Tacforius

Procedural steps taken and scientific information after the authorisation

| Application number | Scope                                                                                                                                                                                                                                                 | Opinion/ Notification <sup>1</sup> issued on | Commission Decision Issued <sup>2</sup> / amended on | Product Information affected <sup>3</sup> | Summary |
|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|------------------------------------------------------|-------------------------------------------|---------|
| IA/0014/G          | This was an application for a group of variations.<br><br>B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer | 23/05/2023                                   | n/a                                                  |                                           |         |

<sup>1</sup> Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.

<sup>2</sup> A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



|           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |            |            |                     |                                                                                                                                                                               |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|------------|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|           | A.7 - Administrative change - Deletion of manufacturing sites                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |            |            |                     |                                                                                                                                                                               |
| IB/0013/G | <p>This was an application for a group of variations.</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH</p> | 10/01/2023 | 19/12/2023 | SmPC and PL         |                                                                                                                                                                               |
| IA/0012   | B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 06/09/2022 | n/a        |                     |                                                                                                                                                                               |
| R/0010    | Renewal of the marketing authorisation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 23/06/2022 | 05/08/2022 | SmPC, Labelling and | Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Tacforius in the approved indication remains favourable and |

|           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |            |            |                                  |                                                                                           |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|------------|----------------------------------|-------------------------------------------------------------------------------------------|
|           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |            |            | PL                               | therefore recommended the renewal of the marketing authorisation with unlimited validity. |
| IB/0011/G | <p>This was an application for a group of variations.</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH</p> <p>C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH</p> | 08/06/2022 | 05/08/2022 | SmPC, Annex II, Labelling and PL |                                                                                           |
| IA/0009   | A.7 - Administrative change - Deletion of manufacturing sites                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 25/10/2021 | n/a        |                                  |                                                                                           |
| N/0007    | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 09/07/2021 | 05/08/2022 | PL                               |                                                                                           |

|           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |            |            |                                  |  |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|------------|----------------------------------|--|
| IA/0008   | B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer                                                                                                                                                                                                                                                                                                                                                                                                       | 17/06/2021 | n/a        |                                  |  |
| IB/0006   | B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 08/10/2020 | n/a        |                                  |  |
| IAIN/0005 | B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer                                                                                                                                                                                                                                                                                                                                                                                                           | 18/09/2020 | n/a        |                                  |  |
| IB/0004/G | <p>This was an application for a group of variations.</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH</p> | 16/04/2020 | 26/03/2021 | SmPC and PL                      |  |
| IB/0003/G | <p>This was an application for a group of variations.</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following</p>                                                                                                                                                                                                                                                                                                                                                                                                                                   | 02/10/2019 | 17/02/2020 | SmPC, Annex II, Labelling and PL |  |

|           |                                                                                                                                                                                                                                                                                                                                                                 |            |            |      |  |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|------------|------|--|
|           | assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH<br>C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation |            |            |      |  |
| IAIN/0002 | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation                                                                                                                                                                                                                                                                  | 28/02/2019 | 17/02/2020 | SmPC |  |
| IA/0001   | B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure                                                                                                                                                                                                                                                    | 06/02/2019 | n/a        |      |  |