



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Rivaroxaban Viatris

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 |
|--------------------|---|--|--|---|---------|
| IB/0011/G          | This was an application for a group of variations.<br><br>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes | 10/06/2024                                   |  | SmPC, Labelling and PL                    |         |

<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).



|             |  |            |     |      |  |
|-------------|--|------------|-----|------|--|
|             | <p>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes</p> <p>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes</p> <p>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes</p> <p>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes</p> <p>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes</p> |            |     |      |  |
| IAIN/0010/G | <p>This was an application for a group of variations.</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p>  | 27/02/2024 | n/a |      |  |
| IB/0009     | B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale  | 11/01/2024 |     | SmPC |  |

|             |   |            |     |             |  |
|-------------|---|------------|-----|-------------|--|
|             | (supported by real time data)   |            |     |             |  |
| IB/0007     | 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  | 12/12/2023 |     | SmPC and PL |  |
| IAIN/0008/G | <p>This was an application for a group of variations.</p> <p>B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place</p> <p>A.7 - Administrative change - Deletion of manufacturing sites</p> <p>B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site</p> <p>B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place</p> <p>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</p> <p>B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place</p> | 09/10/2023 | n/a |             |  |

|           |  |            |            |                              |  |
|-----------|--|------------|------------|------------------------------|--|
|           | B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site   |            |            |                              |  |
| T/0006    | Transfer of Marketing Authorisation  | 24/07/2023 | 11/08/2023 | SmPC,<br>Labelling and<br>PL |  |
| IAIN/0005 | A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs  | 22/06/2023 | 11/08/2023 | SmPC,<br>Labelling and<br>PL |  |
| 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>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a</p> | 23/05/2023 | 11/08/2023 | SmPC,<br>Labelling and<br>PL |  |

|           |   |            |            |                              |  |
|-----------|---|------------|------------|------------------------------|--|
|           | 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<br>B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s) |            |            |                              |  |
| IAIN/0003 | B.II.a.3.a.1 - Changes in the composition (excipients) of the finished product - Changes in components of the flavouring or colouring system - Addition , deletion or replacement   | 21/04/2023 | 11/08/2023 | SmPC,<br>Labelling and<br>PL |  |
| N/0001    | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)  | 06/02/2023 | 11/08/2023 | Labelling and<br>PL          |  |
| IAIN/0002 | 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   | 03/02/2023 | n/a        |                              |  |