

5 June 2024

Dear Colleagues and Friends,

We hope this letter finds you well. As part of the Thrombolysis Taskforce of the ESO Executive Committee, we would like to provide you with important updates regarding the security of supply for Metalyse[®] (tenecteplase) and Actilyse[®] (alteplase) in the context of the European launch of Metalyse[®] 25 mg for acute ischemic stroke (AIS) treatment.

The European Medicines Agency approved the use of Metalyse[®] 25 mg on January 12, 2024. Boehringer Ingelheim has adopted a stepwise approach for the Metalyse[®] 25 mg launch. Initially, it will be launched in 11 European countries in 2024, aligning with national reimbursement timelines and production volumes. The expected schedule for 2024 is as follows:

- February: Germany
- March: Austria
- April: Denmark, Iceland, Netherlands, Finland, Sweden, Norway
- May: Ireland
- September: France
- October: United Kingdom

Further expansion into other European and international markets is planned from 2025 onwards.

We would also like to make you aware that Metalyse[®] 40 mg and 50 mg are specifically intended for acute myocardial infarction and should not be used for AIS treatment. Use of these dosages are regarded as off-label use and would deprive STEMI patients of essential treatment and risks destabilizing the supply chain for Metalyse[®] 25 mg.

Boehringer Ingelheim anticipates an end of supply constraints for all Actilyse[®] presentations in the second half of 2024, after the transfer of alteplase drug substance production to an additional Boehringer Ingelheim manufacturing site in Vienna, Austria is completed.

Best wishes

Thrombolysis taskforce of the ESO Executive Committee

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