

Ms. Kristin Michaels
Chief Executive
Society of Hospital Pharmacists of Australia

Boehringer Ingelheim Pty Limited
ABN 52 000 452 308

16th August 2023

Subject: Supply update for Metalyse (tenecteplase) and Actilyse (alteplase) in Australia

REF:
Dr. Alberto de la Hoz
Head of Medicine

Dear Ms Michaels,

We wanted to update you on the current supply situation for thrombolytic treatments Actilyse® (alteplase) and Metalyse® (tenecteplase). In 2022, we advised supply shortages for Metalyse were anticipated until the end of 2023.

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As we continue to build our global supply capacity for these medicines, **the limited availability and supply constraints for Metalyse will continue throughout 2024.**

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When the supply constraint for Metalyse became clear in 2022, we anticipated that it would consequently place pressure on Actilyse supply, with that thrombolytic being used as an alternative to Metalyse in some clinical situations. With the current measures remaining in place, Actilyse supply will continue to meet the additional demand we have seen in 2023.

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In collaboration with the TGA Medicines Shortage Section and States and Territories, we will continue the current allocation approach for Metalyse and Actilyse. The allocation in 2024 will be based on the volumes made available throughout 2023. We are committed to providing timely and transparent information regarding any changes in production capacity and will keep you informed of any updates or developments.

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We understand that the current supply constraints have been a challenge for healthcare providers. Given how important it is to ensure a stable supply of these treatments, we continue to work closely with the Therapeutic Goods Administration (TGA) and other stakeholders to implement strategies to manage the situation:

In 2022 the following actions were taken:

1. Joint Statement

In August, the TGA and its panel of expert advisers released a [Joint Statement: Shortage of tenecteplase \(Metalyse\)](#). This guidance was designed to preserve stock and optimise use of available supplies of Metalyse for settings where there are no alternatives.

2. Shelf-life Extension

We also worked collaboratively with the TGA to extend the shelf-life of specific batches of Metalyse by 12 months to reduce wastage and maximise access to stock held by pharmacies and ambulances.

3. Supply allocation strategy

We engaged with the TGA and State and Territory procurement teams to develop a supply strategy aligned to the clinical needs of patients and physicians. Allocations were agreed with each State and Territory team on the basis of demand forecast by each team and in accordance with recommendations from the Joint Statement.

We sincerely appreciate the cooperation the healthcare community has shown in supporting these measures over the past 12 months. As a result, the patient impact of the supply shortage has been minimised, and ongoing supply has been maintained for both Metalyse and Actilyse. We extend our deep thanks for your commitment to patient care.

We want to assure you that we are actively working to address these supply issues. Biologics like, both Metalyse and Actilyse are complex and time consuming to produce. We have more than doubled our production capacity at our facility in Biberach, Germany, over the last 10 years, however demand has continued to increase. In the medium term we are optimistic that supply volumes will increase as we work on new and improved production processes. We will also be opening our new production centre in Vienna. We are working on the required regulatory approvals and expect the opening of new production site will contribute to addressing the supply constraints and support a more stable supply of Metalyse and Actilyse.

We would like again to express our appreciation for your patience and understanding as we navigate these supply challenges. If you have any questions regarding supply allocations please contact your relevant procurement team. For thrombolytic advice or training resources, please contact Boehringer Ingelheim Medical Information on 1800 226 315 or medinfo.syd@boehringer-ingelheim.com

Thank you for your continued support.

Dr. Alberto de la Hoz

Head of Medicine, Australia & New Zealand