

29 November 2023

Dear Colleagues and Friends,

We would like to keep you updated with this 5th letter on the current shortage of alteplase and tenecteplase.

We can identify a growing interest in gradually shifting from alteplase towards tenecteplase, which means availability of tenecteplase for Stroke is awaited. Boehringer Ingelheim has applied to official authorities for approval of a specific presentation of tenecteplase for the indication of AIS and is expecting a decision during Q1/2024 in Europe. After this approval, pending regulatory review, it is expected that at least eleven European countries (Austria, Denmark, Finland, France, Germany, Iceland, Ireland, Netherlands, Norway, Sweden, and the United Kingdom) will be able to introduce tenecteplase for use in AIS in 2024, with multiple further countries following in 2025.

In order to facilitate coming back to a normalized supply situation, Boehringer Ingelheim has built a second factory for alteplase production in Vienna. Start of production is expected to take place in Q2/2024, also pending final regulatory approval. The level of market supply for alteplase will be about the same in 2024 as in 2023, whereas the production of tenecteplase is expected to be considerably higher in 2024 compared to 2023. Overall, this translates into drug availability for a potential 9% more AIS patients from one year to the other, considering both alteplase and tenecteplase (when approved).

ESO is very pleased that an end to the shortage of alteplase is in sight. Part of the solution of the shortage is the increase of tenecteplase use after regulatory approval. This is in line with the ESO recommendation on tenecteplase for AIS which was published early this year.^[1] Therefore, ESO supports measures to encourage the use of tenecteplase in cooperation with national societies.

Best wishes

Thrombolysis taskforce of the ESO Executive Committee

European Stroke Organisation (ESO)

1. Alamowitch S, Turc G, Palaiodimou L, et al. European Stroke Organisation (ESO) expedited recommendation on tenecteplase for acute ischaemic stroke. *European Stroke Journal* 2023;8:8-54

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