
Proposed suppression of the monograph on Tetrazepam (1738)
from the Ph. Eur.

Q1-4 (5404)

Please choose country:

(66725)

Type: (!/list-dropdown)

A10 - Estonia (EE)

Please choose: **(66726)**

Type: (L/list-radio)

In favour of the suppression of the monograph on *Tetrazepam (1738)* from the Ph. Eur.

A1

If you answered 'opposed', could you please justify your reply and/or provide details of any marketing authorisations for medicinal products containing substances covered by this monograph that may exist in your country.

(66727)

Type: (T/text-long)

n.a

Can you approve the accompanying note outlining the reason for suppression, as reproduced below? This note will be used for the public consultation:

Tetrazepam is a benzodiazepine derivative which was mainly used to treat painful contracture and spasticity.

The monograph on *Tetrazepam (1738)* was elaborated between 1996 and 2000 and since then, only corrections have been made. The test for related substances is not aligned with the current Ph. Eur. policy on impurities and specifications do not follow the ICH guidelines Therefore, this monograph would require a complete revision.

After a review of efficacy and safety data, marketing authorisations of products containing tetrazepam were suspended in EU member states in 2013 and no manufacturers of products or of the active substance currently active on the European market could be identified. It is therefore proposed to suppress the monograph on *Tetrazepam (1738)* from the European Pharmacopoeia.

(66729)

Type: (L/list-radio)

Yes

A1

Remarks:

(66728)

Type: (T/text-long)

n.a