
Proposed suppression of the monograph on Pivampicillin (0852) from the Ph.
Eur.

Q1-4 (4257)

NPA: (54023)

Type: (l/list-dropdown)

A10 - Estonia (EE)

Please choose: (54024)

Type: (L/list-radio)

In favour of the suppression of the monograph on Pivampicillin (0852) from the European Pharmacopoeia

A1

If your answer is "opposed", could you please justify your reply and/or provide details of marketing authorisations of medicines containing substance covered by this monograph that may exist in your country?

(54025)

Type: (T/text-long)

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Can you approve the accompanying note outlining the reasons for suppression as reproduced here below? This note will be published on Knowledge Database :

This monograph is published in Pharmeuropa to inform all stakeholders that the text is proposed for suppression from the Ph. Eur.

Any stakeholders wishing either to share any important information or concerns directly related to this suppression process are requested to submit a detailed comment.

Pivampicillin is a semi-synthetic antibiotic derived from ampicillin and belonging to the class of penicillins.

The monograph on *Pivampicillin (0852)* was published in the Ph. Eur. in 1993 for the first time. Since that date, the related substances method was not revised, although experience has shown that it lacked specificity. Moreover, the test in question contains only a limit of maximum 3 per cent for the total of impurities; no impurity is specified, which is not in accordance with current guidelines. Therefore, this monograph would require a complete revision.

However, no drug product containing pivampicillin and no manufacturers of the drug substance could be identified on the European market.

It is therefore proposed to suppress the monograph on *Pivampicillin (0852)* from the European Pharmacopoeia.

(54027)

Type: (L/list-radio)

Yes

A1

Remarks: (54026)

Type: (T/text-long)

No medicinal products containing pivampicillin are authorised, and no manufacturers of pivampicillin are approved in Estonia.