EMA/594722/2024
Human Medicines Division

# Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): levofloxacin (Inhalation use)

Procedure No. EMEA/H/C/PSR/S/0046

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## Scientific conclusions

Taking into account the PRAC Assessment Report for the non-interventional imposed PASS final study report for the medicinal product mentioned above, the scientific conclusions of CHMP are as follows:

Annex II of the product information is updated to remove the PASS, as the study has been completed. Information about additional monitoring, including the black triangle, should also be removed from the SmPC and the package leaflet. In addition, the information in section 4.8 of the SmPC for haemoptysis has been updated. A revised RMP version 3.2 has been adopted.

The CHMP agrees with the scientific conclusions made by the PRAC.

## Grounds for the variation to the terms of the marketing authorisation

On the basis of the scientific conclusions for the results of the study for the medicinal product mentioned above, the CHMP is of the opinion that the benefit-risk balance of the medicinal product is unchanged, subject to the proposed changes to the product information.

The CHMP is of the opinion that the terms of the marketing authorisation of the medicinal product mentioned above should be varied.