

PRAC Member Comments on PRAC Rapporteur's Reports

Note

- Free text comments or short comments can be sent to CHMP/CAT/PRAC using secure e-mail.
- Use this template only if you wish to provide additional, more extensive comments.

This Document is Sent By

Name of Committee Member
Names of Assessors
Date of comments

19/08/2020

This report concerns

Product name
Procedure Number
Title of Report

Fluoroquinolones
EPITT Ref. 19522
Signal fluoroquinolone use and the risk of heart valve regurgitation

We fully endorse the PRAC rapporteur assessment, and have no further comments

We do not fully endorse the PRAC Rapporteur assessment, and have the following comments:

General comments

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Specific comments (including comments to draft questions)

Periodic Safety Update Report

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Risk Management Plan/ Post-authorisation Safety Studies/ Conditions

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Benefit-Risk Assessment

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Summary of Product Characteristics, Package Leaflet and Labelling

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Other Aspects

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