

# 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 .....

29/04/2020

## 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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