PRAC Member Comments on Rapporteurs' 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.....	22-09-2016

This report concerns

Product name/No.	Fluoroquinolones
Procedure Number	Not applicable
Title of Report	EPITT 18651

General comments

We fully share the assessment and conclusion of the Rapporteur on the particular limitations of the two studies (several biases, no collection of relevant risk factors notably smoking) precluding any formal conclusion on causality, and that a warning could only be considered as a precautionary measure in view of the life threatening conditions, the biological plausibility (collagen) and the comparable results in both studies.
As a matter of fact performing an additional study minimizing the biases and collecting relevant risk factors would have been important to better substantiate the association.

However, given the critical impact on the therapeutic management (will particularly challenge the resort to quinolones in any old patient notably and in patient with hypertension) an interaction with the FDA (*especially since the FDA has recently (November 2015) performed a benefit/risk assessment of quinolones in so called benign indications*) would be very important since physicians might question a potential different approach between institutional bodies on such an issue.

Specific comments (including comments to draft questions)

Quality Aspects

Non-clinical Aspects

Clinical Pharmacology

Clinical Efficacy

Clinical Safety

Periodic Safety Update Report

Risk Management Plan/ Post-authorisation Safety Studies/ Conditions

Benefit-Risk Assessment

Summary of Product Characteristics, Package Leaflet and Labelling

Other Aspects