



PO Box 30016
6803 AA Arnhem
The Netherlands

T +31 (0)26 38 90 680
F +31 (0)26 38 90 674

eau@uroweb.org
www.uroweb.org

EAU Board

Executive Committee

Prof. C. Chapple
Secretary General

Prof. H. Van Poppel
Adjunct Secretary General - Education

Prof. J. Sønksen
Adjunct Secretary General - Clinical Practice

Prof. A. Stenzl
Adjunct Secretary General - Science

Prof. M. Wirth
Treasurer

Chairmen Offices

Prof. B. Malavaud
Membership Office

Prof. V. Mirone
EUSP Office

Prof. J. N'Dow
Guidelines Office

Prof. R. Nijman
EU-ACME Office

Prof. J. Palou
Education Office

Prof. D. Pushkar
Vice-Chair Membership Office

Prof. J. Rassweiler
Section Office

Dr. M. Sedelaar
Young Urologists Office

Prof. A. Stenzl
Scientific Congress Office
Ad interim

Prof. P. Van Kerrebroeck
History Office

EAU Research Foundation

Prof. A. Bjartell
Chairman

Executive Management

Jacqueline Roelofswaard
Executive Manager Operational Affairs

Maurice Schlieff, MSc
Executive Manager Business Affairs

Date: 3rd June 2019

Re: European Commission ruling on the indications for use of fluoroquinolones

To whom it may concern,

On the 11th March 2019 the European commission (EC) implemented stringent regulatory conditions regarding the use of fluoroquinolones (e.g. Ciprofloxacin, Levofloxacin, Moxifloxacin, Norfloxacin, Ofloxacin) in urology. This legally binding decision is applicable in all EU countries and is based on a review of the serious disabling and potentially permanent side effects associated with the administration of quinolone and fluoroquinolone antibiotics by mouth, injection or inhalation.

National authorities have been urged to enforce this ruling and to take all appropriate measures to promote the correct use of this class of antibiotics. It is vitally important that urologists are fully informed of the impact of this decision on their daily clinical practice.

Fluoroquinolones should not be used for the:

1. Prevention of recurrent urinary tract infections.
2. Prevention of infection after surgeries or interventions in the urogenital system, including transurethral surgery or transrectal prostate biopsy
3. Treatment of sepsis

Other indications have been maintained e.g. treatment of complicated UTI and bacterial prostatitis; restricted; or reworded according to the current medical knowledge.

The recommendations made by the EC are, for the most part, in line with the current recommendations of the EAU Urological Infections Guidelines. However, Table 12 of the 2019 EAU Urological Infections Guidelines will be amended to remove fluoroquinolones from the list of suggested prophylactic agents for transrectal prostate biopsy. Possible alternatives are a targeted therapy approach based on rectal swab cultures as well as the change to transperineal prostate biopsy. The 2020 EAU Urological Infections Guidelines will assess the evidence of alternative interventions.

Guidelines for the correct use of antibiotics must be followed and urologists are obligated to consider the serious side effects associated with fluoroquinolones and

participate in shared medical decision making with patients who have an elevated risk of complication. More information on this topic can be accessed via the European Medicines Agency website:

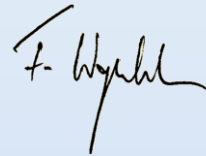
<https://www.ema.europa.eu/en/medicines/human/referrals/quinolone-fluoroquinolone-containing-medicinal-products>

On behalf of the EAU Urological Infections Guidelines Panel and the EAU Section of Infections in Urology.

Yours sincerely,



Prof. Dr. G. Bonkat
Chair EAU Urological Infections Guidelines



Prof. Dr. F. Wagenlehner
Chair ESIU



Prof. Dr. J N'Dow
Chair EAU Guidelines Office



Prof. Dr. H. Van Poppel
Adjunct Secretary General
Executive Member Education