

Dr Harald Enzmann
CHMP Chairman
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: **Withdrawal of Zemdri (Plazomicin) 500mg/10ml injection**
Procedure no: EMEA/H/C/004457
Applicant: Cipla Europe NV

Dear Dr Enzmann,

Further to our letter dated May 5, 2020, Cipla Europe NV would like to inform you that, despite its best efforts thus far, at this point in time, Cipla finds itself unable to proceed with seeking the approval of the Marketing Authorization for Zemdri (plazomicin) 500mg/10ml injection which was intended to be used for Complicated urinary tract infection: infections due to carbapenem-resistant or aminoglycoside-resistant Enterobacteriaceae susceptible to plazomicin in patients with limited treatment options, for the reasons stated below and has therefore taken this difficult decision to withdraw the Application for Marketing Authorization.

This withdrawal is based on pharmacoeconomic considerations concerning the company's marketing strategy. The conditions and work and cost expected to be required for approval and post-approval, including the PIP and terminal sterilization processing, were evaluated and assessed to result in the product being financially and commercially unviable with the limited indication that was to be accepted.

On a scientifically grounded and standardized basis, investment of these development expenses does not indicate an optimal allocation of Cipla's healthcare resources.

We reserve the right to make further submissions for a Marketing Authorization in this or other therapeutic indication(s) at a future date, in the event we forecast some commercial viability on account of, including if there are exemptions of requirements or commitments.

We agree for this letter to be published on the EMEA website.
Please do the necessary in confirming our withdrawal of the MA application.

Yours Sincerely,

