



MINISTRY OF HEALTH
NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES OF ROMANIA
48, Av. Sanatescu St, sector 1, 011478 Bucharest
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

ANTIBIOTICE S.A.
Nr. 111 A
ZI 05 Luna 01 An 2022

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI ȘI
A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
INTRARE Nr. 21/2022
IEȘIRE
Ziua Luna 12 Anul 2022

To

ANTIBIOTICE SA

Regarding your letter number 2482P/20.12.2021 and registered under number 67912/20.12.2021 at the National Agency for Medicines and Medical Devices of Romania (NAMMDR) on the status of conformity with Good Manufacturing Practice (GMP) for the manufacturing site of ANTIBIOTICE SA from Str. Valea Lupului nr. 1, Iași, jud. Iași, cod 707410, Romania (Certificates no.040/2017/RO, no.041/2017/RO and no. 023/2018/RO), please be inform as follows:

- the validity of the GMP Certificates issued by NAMMDR for the company ANTIBIOTICE SA, Romania is automatically extended until the end of 2022 as also specified in the EudraGMDP database, according to the "Notice to stakeholders-Questions and answers on regulatory expectations for medicinal products for human use during the COVID-19 pandemic" issued by European Commission on 30 September 2021;
- the Certificates of conformity with Good Manufacturing Practice no.040/2017/RO, no.041/2017/RO and no.023/2018/RO are available in the EudraGMDP database.

Yours,
Sincerely,

for PRESIDENT
Ioana ȚENE
VICEPRESIDENT

