AGENȚIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE

MINISTERUL SĂNĂTĂȚII
AL REPUBLICII MOLDOVA

14.07.17 Nr 07.1501.Rg02-2972

To whom it may concern,

Hereby, the Medicines and Medical Devices Agency (MMDA), Republic of Moldova confirms that had performed a GMP inspection on the following site:

The Manufacturer: *Agio Pharmaceuticals Ltd.*

Site address: *T-81, 82 MIDC, Bhosari, Pune-411 026, Maharashtra State, India*

Period of inspection: *10/09/2014 – 17/09/2014*

Authorized activities: *sterile product aseptically prepared, small volume liquids;*
sterile product terminaly sterilised, small volume liquids;
non-sterile products: capsules, hard shell; capsules soft shell; tablets

As the result of the inspection of facilities/site and further coordination and elimination of identified deficiencies, it has been established the conformity with requirements of Good Manufacturing Practice of Medicines (GMP) for human use, approved[1] within the Republic of Moldova. This letter reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of that inspection (till 16/09/2019). However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

The inspection has been performed based on the request of the Medicines Committee of the Medicines and Medical Devices Agency of the Republic of Moldova. The results of GMP inspection have been presented to the Department of medicines avaluation and registration, MMDA, where decisions concerning authorization process.

Sincerely,

Vladislav Zara
General Director
Medicines and Medical Devices Agency

[1] *Rules developed under EU Directives and guidelines, and harmonized with WHO guidelines.*

Agenția Medicamentului și Dispozitivelor Medicale
Medicines and Medical Devices Agency
Str. Korolenko 2/1, MD-2028, Chișinău, Republica Moldova
Tel: +373 22 884301; e-mail: office@amed.md; web: www.amed.md