ANVISA
Agência Nacional de Vigilância Sanitária

Warning Letter nº 035/2017–CETER/GESEF/GGMED/ANVISA-MS

Brasília, June 21st 2017.

Subject: **Clarifications on Zydus Research Centre certification cancellation**

Reference: **International Inspection Report nº 007/2017 – CETER/GESEF/GGMED/ANVISA**

To whom it may concern:

1. The Brazilian Health Regulatory Agency – Anvisa – has identified critical non-conformities during an inspection performed in Zydus Research Centre (Ahmedabad, India). Such non-conformities resulted in the cancellation of the certification granted by Anvisa so that the Center could perform relative bioavailability / bioequivalence studies with the purpose of registering medicines in Brazil (Resolution RE. Nº 1.605/2017). Additionally, the studies performed by this company from 2014 until the current days were turned down and they will not be accepted as proof of efficacy and safety for the medications tested.

2. Among the non-conformities there were flaws in the traceability of the actions practiced during the study (selective registration of the activities performed and partial description of the actions in the respective report) and the use of subjects' samples for verifying the suitability of the bioanalytical methodology.

3. The Therapeutic Equivalence Coordination (CETER/GESEF/GGMED/ANVISA) understands that data integrity is a responsibility of the Center with the purpose of assuring safety, efficacy and quality of the medicines tested, so that Anvisa by its turn, can protect the public health. In the case being discussed, the deviations observed show Zydus Research Center incapacity to assure data integrity during the performance of the studies and, therefore, the certification was cancelled together with the studies performed from the year 2014 on.

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