Agência Nacional de Vigilância Sanitária

BRAZIL COMMENTS ON THE IMPLEMENTING ACT ON THE REQUIREMENTS FOR THE ASSESSMENT OF THE REGULATORY FRAMEWORK APPLICABLE TO THE MANUFACTURING OF ACTIVE SUBSTANCES OF MEDICINAL PRODUCTS FOR HUMAN USE

The Brazilian government thanks the European Commission for the opportunity to comment on its Implementing Act on the requirements for the assessment of the regulatory framework applicable to the manufacturing of active substances of medicinal products for human use.

After careful study, we would like to provide the following comments for your consideration.

GENERAL COMMENT

Each authority is responsible for regulating the products commercialized in their country, including the imported ones. We believe this responsibility can not be simply delegated to an authority from a third Country. However, in order to help each authority to play their own role in protecting and promoting the health of their population, there are options to be explored, like the signing of official agreements where the regulatory authorities recognize the capacity of each other, in order to avoid work duplication and better use of resources. Hence, if the EU authority wants to assure that the exporting company complies with the EU requirements, we believe this must be verified and certified by European Authorities. Besides evaluating the exporting company *in loco*, another way to conclude that the company complies with specific requirements, is requesting information directly to the local authority, considering there is confidence and desirably an agreement in place between the parties. Therefore, we believe that it is not feasible for the competent authority of the exporting country to issue a written confirmation that the company complies with the EU requirements. A regulatory authority can only certify the conformity according its own requirements. Besides that, it must have reciprocity. Brazil is not sure if the European Union would be ready to certify their products accordingly with any other Countries requirements.

ANNEX

Regarding items 2E, 3B and 8B of the Annex, we would like to request detailed information on how those criteria will be applied.