PHARMACEUTICAL INSPECTION CONVENTION
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By registered mail & e-mail
(xavier.prats-monne@ec.europa.eu)

Mr
Xavier Prats Monné
Director General
Health and Food Security (DG SANTE)
European Commission
B-1049 Brussels
Belgium

Dear Mr Prats Monné,

Subject: Guidelines on Good Manufacturing Practice for Advanced Therapy Medicinal Products

With reference to our previous exchange of communication, in particular our letter dated 7 October 2016 and your reply dated 21 November 2016, we would like to revert to the European Commission's proposal to lower GMP requirements for Advanced Therapy Medicinal Products (ATMPs), as contained in the above-mentioned, stand-alone GMP Guidelines.

The PIC/S Committee, which comprises representatives of PIC/S' 49 Participating Authorities as well as representatives from Partner Organisations such as EMA, EDQM and WHO, has discussed the matter at its last meeting in Geneva on 9-10 February. As you know, PIC/S is a purely technical experts' organisation active in the field of GMP since 1971. PIC/S' expertise in the field of GMP is undisputed.

The PIC/S Committee is unanimously concerned about the impact on public health and for the safety of patients that the ATMP GMP Guideline will cause. By lowering the GMP requirements for ATMPs, the European Commission is not only exposing patients to an increased risk to their health; it is also engaging its individual and collective responsibility for any health incident (and related court action) that lower ATMP standards may occasion. We would like you to duly ponder this aspect.

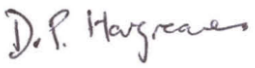
The PIC/S Committee is also concerned that due to the European Commission's initiative in the field of ATMP, the PIC/S GMP Guide and the EU GMP Guide will no longer be equivalent. Since 1989, both Guides have been developed in parallel and systematically kept aligned on the basis of a harmonised consultation procedure, which PIC/S and the EMA have duly and respectfully implemented. Your decision to amend Annex 2 and repeal Annex 13 of the EU GMP Guide is a serious setback in terms of co-operation between the EU and PIC/S. It is very unfortunate that under your leadership the process of GMP harmonisation between the EU and PIC/S GMP Guides has resulted in a divergence that may be difficult to reconcile in the future. We deeply regret the lack of consultation in this matter.

With regard to allegations that some PIC/S Participating Authorities have enacted lower GMP requirements for ATMP, as mentioned in your letter, we believe that there may have been a misunderstanding on the European Commission's part. Some Participating Authorities may have introduced non-binding guidelines regarding ATMPs. However, these guidelines do not overrule GMP requirements, as enshrined in the national GMP Guide. Moreover, where ever there is a slight difference in terms of requirements for ATMPs, PIC/S Participating Authorities have expressed their will to align and harmonise their requirements with those of PIC/S. The international harmonisation of GMP standards is a never-ending process, which PIC/S aims to facilitate. PIC/S Participating Authorities are disappointed in the decision made by the European Commission to enact its standalone Guidelines on ATMPs, which will add barriers in the field of GMP and make harmonisation efforts more difficult.

We have tried our best to draw your attention to the risks that lower ATMP standards may have on the patients' health. Patient health risks aside, PIC/S would like to remind the European Commission of liabilities to which it may be exposed.

For the sake of transparency and the rights of patients, this letter will be published on the PIC/S website.

Yours sincerely,



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