

Dear Madam,  
Dear Sir,

The present e-mail contains the position of the **Pharmaceutical Inspection Co-operation Scheme (PIC/S)** on the concept paper submitted for public consultation, dated 7 December 2011, with respect to 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 (SANCO/D3/(2011)ddg1.d3. 1438409)”

PIC/S is an organisation comprising 40 National Drug Regulatory Authorities around the world competent for GMP inspections for human and/or veterinary products, whether API or finished products (for more information, see [www.picscheme.org](http://www.picscheme.org)).

PIC/S wishes first to congratulate the European Commission on this initiative which is in the PIC/S spirit of sharing information and avoiding the unnecessary duplication of inspections.

PIC/S would like to make the following comments with reference to consultation items n°4 (“other issues”) and n° 5 (“any other issue or comment you would wish to make which has not been addressed in the consultation items above”)

**Consultation item n° 4:**

- PIC/S expresses its appreciation that reference has been made to the PIC/S Assessment and Reassessment Programme (point 4.2 § 20); at the same time, PIC/S hopes that PIC/S (re-)assessment reports will not only be “taken into consideration” but that PIC/S audit results and conclusions will also be duly recognised by the Commission (the same way as PIC/S duly recognises EU audit results today);
- PIC/S is unsure on the meaning of point 4.3 § 21 (regular verification), which should be clarified with respect to the timing and frequency of verifications. It is unclear whether countries may be entered into the list without a first verification (following the equivalence assessment) inasmuch as the first verification must take place within 3 years of the country being placed on the list. Moreover, the reassessment frequency is not defined i.e. whilst the first verification must take place within 3 years of the country being placed on the list, the timeframe for verification thereafter has not been specified. With respect to the notion of “regular verification” PIC/S would like to suggest a timeframe that does not prejudice non-EEA Participating Authorities of PIC/S which may be subject to more stringent requirements than EEA Participating Authorities under the EU Joint Audit Programme (JAP). Too frequent reassessments may require a lot of human resources at a time when National Drug Regulatory Authorities have more and more responsibilities. Finally, PIC/S notes that the verification process has not been specified in the Directive or the concept paper, nor has the necessary structure related to the establishment and maintaining of the list as well as the resources in connection therewith been specified.

**Consultation item n°5:**

- PIC/S draws the Commission’s attention on the need to urgently and actively train API inspectors (basic & advanced) both in and outside the EU in order to ensure equivalence in terms of API inspections. PIC/S expresses the hope that the Commission will support the current international training programme established by the PIC/S Expert Circle on APIs.

Yours sincerely,

**Daniel Brunner**  
PIC/S Secretariat

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