

FDA will obtain full PIC/S membership in 2010



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During the upcoming PIC/S Conference in November 2010 in Kuala Lumpur (Malaysia), the PIC/S delegation will recommend to the PIC/S Committee Meeting to accept the FDA as a full member. This is according to a statement by Benda Holman (Executive Director, ORA Strategic Initiatives, ORA, FDA) during the PDA/FDA Joint Regulatory Conference on 14 September 2010 in Washington. This could mean that in future the number of foreign FDA inspections will be significantly reduced to only include countries that are not yet members of the PIC/S inspection community.

Goals of the PIC/S

The PIC/S (Pharmaceutical Inspection Cooperation Scheme) has the declared goal of developing and disseminating harmonised GMP standards and guidelines. Collaboration between participating agencies with regard to inspections will be encouraged with the aim of maintaining mutual trust and promoting quality assurance inspections. This means that, as a rule, inspections by the national agencies in all other PIC/S member states (see figure 1) will be recognised. The membership of non-European countries such as Australia, Canada, Israel and a number of Asian countries (Singapore, Malaysia) will raise the standing of the PIC/S.

Current PIC/S Member States

- | | |
|------------------|-------------------|
| – Argentina | – Latvia |
| – Australia | – Liechtenstein |
| – Austria | – Lithuania |
| – Belgium | – Malaysia |
| – Canada | – Malta |
| – Cyprus | – Netherlands |
| – Czech Republic | – Norway |
| – Denmark | – Poland |
| – Estonia | – Portugal |
| – Finland | – Romania |
| – France | – Singapore |
| – Germany | – Slovak Republic |
| – Greece | – South Africa |
| – Hungary | – Spain |
| – Iceland | – Sweden |
| – Ireland | – Switzerland |
| – Israel | – United Kingdom |
| – Italy | |

Partners

- European Directorate for the Quality of Medicines & HealthCare (EDQM)
- European Medicines Agency (EMA)
- United Nations International Children’s Emergency Fund (UNICEF)
- World Health Organization (WHO)

The application process

It was reminiscent of a detective novel when Brenda Holman talked about the long journey to this important step at the PDA/FDA Joint Regulatory Conference 2010, which had begun as early as 2005. That was when the FDA applied to join this association of inspection agencies. One could sense that it was initially considered sobering that the FDA was not given PIC/S membership too easily. Currently, 10 new supervisory agencies are applying for PIC/S membership and all of them have to undergo an appropriate admission process, including the FDA.

The written evaluation process came first and in 2009, a PIC/S delegation visited Washington, DC, to check compliance with PIC/S standards.

The FDA was rather surprised that the report of the first evaluation inspection in August 2009 revealed 5 criteria that were not met and 15 that were partially met out of a total of 89 criteria. On this basis, the FDA could not be admitted to join the PIC/S. If it had not done so before, the FDA now came to realise that it would have to take the evaluation process more seriously. For according to the admission statutes of the PIC/S, the application process has to start again if no decision regarding admission has been arrived at within 6 years. This would be the case if the decision regarding the FDA's membership in PIC/S has not been made by the end of 2010.

Once the FDA as applicant had made an effort to understand the details of the PIC/S requirements, and had taken part in meetings and training courses, a new evaluation meeting was scheduled for August 2010. The FDA tried its best to prepare the meeting such that all PIC/S requirements (see figure 2) were met. Between 9 and 13 August, the second evaluation inspection took place. There are still criteria that are not fully met (no details have been published), but according to Brenda Holman, the delegation gave the green light and will recommend to the PIC/S at the next Committee Meeting on 12 November 2010 in Kuala Lumpur, Malaysia, to accept the FDA as a full member.

The implications of this step

It is expected that the PIC/S will grant the application by the FDA. Especially since, as Brenda Holman emphasised, the agency is planning to do justice to the responsibility and the duties of a full PIC/S

PIC/S admission criteria

This Scheme is open for participation by competent authorities (hereinafter referred to as "Participating Authorities") having the arrangements necessary to apply an inspection system comparable to that referred to in this Scheme and whose requirements and procedures could ensure the proper implementation of the Scheme and contribute to its effective operation.

5. The Participating Authorities should in particular ensure that:

- (a) the inspectors in their service have appropriate qualifications and experience for the tasks to be undertaken by them,
- (b) the inspectors and/or the control laboratories have the power to call for the submission of quality control records and, where appropriate, samples relating to any batch of any medicinal products,
- (c) the inspectorate utilises the PIC/S GMP Guide (or equivalent) as well as other current guides, guidelines, explanatory notes and recommendations, adopted under the Scheme and available at <http://www.picscheme.org>, as the basis for inspections and authorisation of manufacturers,
- (d) the operation of the inspectorate is subject to a system of quality management aimed at ensuring the maintenance of necessary standards (see PI 002).

member. This also means that the FDA is planning to review its guidelines in view of the existing PIC/S guidelines. This would represent a clear step towards harmonising the western GMPs.

It is no doubt the case that the PIC/S will significantly gain in standing as a result of FDA becoming a member. Given the attractive American pharma market, the FDA has gained a somewhat superior position. Until now, every company that wanted to supply the US American market had to undergo an FDA inspection to ensure compliance with the US GMP regulations. The FDA may now have recognised that

this approach is no longer in keeping with the times, and that it makes more sense to contribute towards harmonising GMP regulations. It remains to be seen what effect the FDA and the PIC/S will have on the development of new GMP standards.

For industry, this may result in fewer agency inspections in the medium term.

Outlook

This important conference has shown that the convergence between the US and Europe has accelerated significantly, not just in this regard. Many statements made by FDA representatives indicate that opinions have changed considerably and now favour closer cooperation. Perhaps one day this conference will be seen as the turning point towards a global GMP alliance.

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Thomas Peither

Sources of information:

- www.picscheme.org
- [GMP-BERATER](#) (includes the most important PIC/S guidelines – including German translation and index)
- [GMP-MANUAL](#) (English originals with index)

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