PHARMACEUTICAL INSPECTION CONVENTION

PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

Improving the role of International Organisations through more transparent, inclusive and evidence-based international rulemaking

OECD High Level Webinar: International Organisations and their Members facing the Global Crisis Together (3 September 2020)

Intervention by Ms. Anne Hayes, Chairperson,
Pharmaceutical Inspection Co-operation Scheme (PIC/S)

Honourable Minister,
Honourable Secretary-General,
Ladies and Gentlemen,

Thank you for giving me the opportunity to explain how the COVID pandemic has impacted our organisation and activities and our response to date.

Let me present to you very briefly who we are: the Pharmaceutical Inspection Co-operation Scheme (PIC/S) is a non-binding co-operative arrangement between 53 medicines regulatory authorities working in the field of Good Manufacturing Practice by developing guidance, harmonisation of standards and training of inspectors who inspect manufacturers of medicinal products, for human and veterinary use.

Application of Good Manufacturing Practice (GMP) during the manufacture of medicinal products ensures that they meet the required quality standards and are safe for patients. This is a very important aspect of public health, as unsafe medicines can have a devastating effect on patients' wellbeing and health.

The 2,000 inspectors of PIC/S members, inspect domestic and foreign companies producing finished dosage forms and Active Pharmaceutical Ingredients. Where inspection outcomes are satisfactory, GMP certificates may be issued to the manufacturers, which facilitates export of their products to other countries.

As you can imagine, the COVID pandemic has had a very significant impact on inspections:

- Domestic on-site inspections were suspended and only carried out in very exceptional circumstances;
- Foreign inspections completely stopped worldwide due to travel restrictions.

OECD countries import most of their medicinal products[1] and we are extremely dependent on effective supply chains, as shown during the early days of the pandemic where many countries faced shortages in some products.

The initial response of PIC/S members was uncoordinated and each medicines regulatory authority took the action that it deemed appropriate. However, the actions taken were consistent with others and comprised of:

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1 In particular, Active Pharmaceutical Ingredients from India and China

1. Introducing regulatory flexibilities where appropriate, for example by extending the validity of all GMP certificates up to the end of 2021;
2. Identifying alternative processes to on-site inspections.

Such alternatives consist of

(i) remote assessments;
(ii) reliance on GMP inspections of other Medicines Regulatory Authorities, and
(iii) remote inspections, which are carried out virtually 'at a distance' using video technology.

Faced with these unprecedented developments, PIC/S has decided to take the lead and is organising a virtual seminar on the 'Remote Assessment of GMP Compliance' which will be hosted by the Finnish medicines agency. As for all PIC/S events, this seminar is open to both PIC/S members and non-members.

The purpose of the seminar is to harmonise current practices on the remote GMP assessment of manufacturers of medicines and address the challenges of virtual, real-time inspections. Following this seminar, we will develop common terminology and best practice, which may become worldwide standards. In line with our procedures, we will undertake public consultations before adopting these rules, allowing stakeholders, who consist mainly of industry and patient organisations, to give their views.

This year's seminar on the 'Remote Assessment of GMP Compliance' will be the first virtual seminar in our 50-year long history. Due to the pandemic, our regular meetings and training activities, will be held virtually. On-line training is not a new concept to PIC/S as we have, in the past few years, established a PIC/S Inspectorates' Academy (PIA), which is delivering on-line training to inspectors. Relying on virtual tools is another consequence of the COVID pandemic that you have all experienced and where the input from the OECD would be greatly appreciated.

To conclude, I would like to share with you the lessons that PIC/S, as a health organisation, has drawn from the COVID pandemic:

- A greater reliance between medicines regulatory authorities worldwide is necessary to share available information and reduce our requirement for foreign inspections, when not possible temporarily or longer term.
- Best practice and common terminology on remote inspections must be harmonised internationally to avoid differences, which will make it more difficult to recognise and accept their outcome.

The OECD's work to harmonise the rulemaking of international organisations is essential and must be strengthened. We all have to learn from each other.

My personal conclusion from the pandemic is that there is nothing more important than health so let me finish by wishing all of you continued good health. Thank you.