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Annual report of the Good Manufacturing and Distribution Practice Inspectors Working Group 2024

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Introduction

This document is the annual report of the GMP/GDP Inspectors Working Group (GMP/GDP IWG) for the year 2024. This group was established at EMA in 1996.

There was no annual report from 2018 to 2020 as a result of the EMA Business Continuity Plan (BCP) due to the effects of the UK withdrawal from the European Union. The BCP was extended in 2020 due to the public health emergency due to COVID-19. The EMA BCP has ceased during 2022 and the GMDP IWG has gradually resumed most of the suspended activities. The meetings of the GMDP IWG have also resumed alternating in person and remote attendance.

The GMP/GDP IWG provides input and recommendations on all matters relating directly or indirectly to Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP).

The GMP/GDP IWG focuses on harmonisation and co-ordination of GMP and GDP related activities at EU level and maintains close co-operation with international partner authorities. The group's role and activities are described in more detail in its mandate available here; Good Manufacturing Practice (GMP)/Distribution Practice Practice (GDP) Inspectors Working Group | European Medicines Agency (EMA) (europa.eu) which was revised in 2024.

This annual report is set out in line with the format and objectives of the 3-year work plan.

Meetings

The GMP/GDP IWG meetings took place on:

- 05-07 March 2024 (Meeting with Interested Parties on 07 March (WebEx meeting);
- 11 - 13 June 2024 (In Person Meeting);
- 17 - 19 September 2024 (WebEx meeting);
- 25 - 27 November 2024 (In Person Meeting).

The Compliance Group, managing the Joint Audit Programme (JAP) on behalf of HMA, also met on four occasions in 2024 in the margins of the above-mentioned plenary meetings. The GMDP IWG met with the QWP and the BWP on 25th September 2024 for a joint trilateral meeting (WebEx meeting).

Drafting group meetings for ongoing topics were held by teleconference or through other virtual meeting technology.

GMP and GDP inspections in 2024

Although the end of the COVID-19 public health emergency was declared by WHO in May 2023, the restrictions applied during the pandemic continued to have some impact on the work of GMP and GDP inspectors. On site inspections had resumed since 2023, progress from the EU inspectorates was made in 2024 to largely close the existing backlog (especially for sites located in 3rd countries) by the end of the year.

The automatic extension of validity dates of EU GMP Certificates, entered into EudraGMDP database, until end of 2024 and was not longer extended, the IWG did not considered this necessary as the backlog was expected to be resolved by the end of 2024.

Mutual recognition agreements (MRAs) and other agreements on GMP

MRA General

MRA related work was maintained in 2024.

MRA with USA

Work continued on the inclusion of veterinary medicines in the operational scope of the EU – US Mutual Recognition Agreement whereby the EU and US agreed in July 2024 to extend the timeline for the completion of all assessments of veterinary inspectorates.. The current list of recognised authorities for the veterinary scope is published by the European Commission.

The GMP/GDP IWG continued to provide the forum to discuss and clarify the technical and practical aspects for the implementation of the MRA. The projects concerned amongst other, work towards expansion of the MRA to vaccines and plasma derived products and reliance on FDA's inspections conducted in third countries.

A representative from US FDA attended all GMDP IWG meetings throughout 2024.

MRA with Japan

There were no changes to the existing MRA with Japan throughout 2024.

A representative from PMDA attended all GMDP IWG meetings throughout 2024.

MRA with Canada (CETA)

No changes were made to the agreement with Canada during 2024.

A representative from Health Canada attended all GMDP IWG meetings in 2024.

MRA with Switzerland

No changes were made to the MRA with Switzerland during 2024.

A representative from Swissmedic attended all GMDP IWG meetings throughout 2024.

MRA with Australia

There were no changes made to the existing MRA with Australia throughout 2024.
Representatives from Australia attended all GMDP IWG meetings throughout 2024.

MRA with New Zealand

There were no changes to the existing MRA with New Zealand throughout 2024.

ACAA with Israel

There were no changes to the existing ACAA co-operation with Israel in 2024.

A representative from the Ministry of Health attended the September 2024 GMP/GDP IWG meeting.

Support for EU Accession Countries

Observers from Albania, Bosnia and Herzegovina, Georgia, Kosovo, Moldova, Montenegro, North Macedonia, Serbia, Turkiye and Ukraine attended GMDP IWG meetings throughout 2024 under a programme of support of EU candidate countries including through a new cycle of the Instrument for Pre-Accession Assistance.

Other international collaborations on GMP

EDQM attended all four GMP/GDP IWG meetings in 2024 as an observer and informed the GMDP IWG during the year on a number of topics of common interest including the progress of sampling and testing programmes, the proceedings of the annual OMCL meeting, the EDQM reinspection programme and the CEP Steering Committee.

WHO and PIC/S observers also attended the GMDP IWG meetings throughout 2024.

The United Kingdom attended all four GMP/GDP IWG meetings in 2024 as an observer.

A delegation of the African Medicines Regulatory Harmonisation Initiative GMP Technical Committee (AMRH GMP TC) observed part of the June 2024 plenary meeting.

Harmonisation topics

Joint Audit Programme (JAP)

During 2024 the Compliance Group (CG), a Sub-group of the GMDP IWG responsible for coordination of the JAP, met on four occasions. The GMDP IWG confirmed the appointment of a new Chair of the Compliance Group and confirmed the renewal of the membership of several members. Throughout 2024 the Compliance Group monitored the implementation of open corrective and preventive actions (CAPAs), adopted reports and closed some of the JAP audits.

The Compliance Group worked also closely with the EU4Health Joint Action 11 in the review of JAP procedures and supported the organisation of a JAP auditor face-to-face training in October 2024. During 2024 15 JAP on-site audits were conducted.

Compilation of Union Procedures on Inspections and Exchange of Information

In August 2024, the Compilation of Union Procedures on Inspections and Exchange of Information (CoUP) was restructured from one document into separate documents for every procedure/template. The Compilation was restructured in order to facilitate access as well as review of the individual documents. In the future, updates for every procedure/template will be recorded in the individual documents, which have been published starting with version 1.0. As reference, the last version of the combined Compilation before the restructure was 19.1.

The Community procedure "Co-ordinating GMP inspections for centrally authorised products" was updated during 2024.

Manufacture of Veterinary Medicinal Products Other Than Immunological Veterinary Medicinal Products (Annex 4).

Work has continued on the drafting of an updated Annex 4 during 2024.

Manufacture Of Immunological Veterinary Medicinal Products (Annex 5)

Work has continued on the drafting of an updated Annex 5 during 2024.

Chapter 4 of the guidelines on good manufacturing practice – documentation

A drafting group has been formed to work on the update of Chapter 4. The group are working in partnership with the drafting group on Annex 11.

Annex 11 – validation of computerised systems

Work has continued on the drafting of an updated Annex 11 during 2024.

Annex 19 – Reference and Retention Samples

The IWG agreed for a revision to Annex 19 to reflect additional details on retention and reference samples for Parallel Distribution/Trade and adopted a revision of the text.

The GMDP IWG undertook a targeted stakeholder consultation with relevant industry stakeholders as part of the update.

Questions & Answers (Q&As)

Work was carried out on a number of Q&As, guidance documents and templates with a view to harmonising interpretation and expectations on various GMP topics. The following were published in 2024.

- Q&A on Annex 1
- Q&A on Suspicious offers for Wholesalers and Brokers**.**
- Q&A on Annex 14 concerning APIs derived from human plasma
- Q&A on Annex 16 concerning traceability of the supply chain for QP batch release.
- Wholesale Distribution Authorisation Template **–** Published in Compilation of Union Procedures.
- Distant Assessment Guidance.

Work is continuing on the following supplementary guidance;

- Q&A on the QP Declaration **–** Targeted stakeholder consultation.
- Q&A on Decentralised Manufacturing – Drafting ongoing

Good Distribution Practice

The GMDP IWG agreed to the formation of a working group devoted to Good Distribution Practice. The GDP working group had its first meeting on 1st October 2024.

Inspections, Non-compliance, Quality Defects and Referrals

Nitrosamine contamination and Sartans Lessons Learnt

Work continued the implementation of the GMP related recommendations arising from the Sartans Lessons Learned exercise. The IWG continued to be informed of the latest developments concerning nitrosamines as discussed by the Nitrosamines Implementation Oversight Group (NIOG).

1. EudraGMDP database

Several minor changes have been implemented in EudraGMDP modules in order to reflect network needs. The GMP/GDP IWG was consulted / informed on all proposed changes to the database and provided technical input and direction as needed, ensuring national systems were updated accordingly and that there was appropriate communication to stakeholders.

2. Collaboration with the European Commission

New legislative developments were monitored to assess and advise on the potential impact on GMP, GDP, inspections or inspection-related activities. In particular, attention was paid to developments related to the Revision of the Pharmaceutical Legislation for human and veterinary medicinal products.

Liaison with other groups

The GMP/GDP IWG maintained dialogue and monitored developments involving external groups in areas of common interest. The aim was to communicate the work of the Group and to assess the impact of other groups' activities on GMP/GDP guidance, the Compilation of Union Procedures and other inspection-related activities.

Pharmaceutical Inspection Co-operation Scheme (PIC/s)

The GMP/GDP IWG continued the close collaboration with PIC/s on the harmonisation of guidance and procedures, training events and the (re) assessment of inspectorates as topics of strategic importance. The IWG and PIC/s liaisons have attended each other's meetings and working groups.

International Conference on Harmonisation for Registration Of Pharmaceuticals For Human Use (ICH)

The GMP/GDP IWG continued to be consulted on a number of topics in connection with the revisions and implementation of specific chapters and annexes and developing specific training material for ICH guidelines including Q9R1 (Quality Risk Management), ICH Q2(R2) (Validation of analytical procedures), ICH Q12 (Lifecycle management), ICH Q13 (Continuous Manufacturing), Q14 (Analytical Procedure Development).

International Conference on Harmonisation for Registration Of Veterinary Products (VICH)

The GMP/GDP IWG were consulted on the development of a GMP for veterinary active pharmaceutical ingredients.

Interested Parties

A Formal interested parties meeting was held in March 2024.

The following organisations participated in the meeting with Interested Parties in 2023: AESGP (Association of the European Self-Medication Industry), APIC (Active Pharmaceutical Ingredients Committee), EFPIA (European Federation of Pharmaceutical Industries and Associations), Medicines for Europe, EIPG (European Industrial Pharmacists Group), EQPA (European QP Association), Animal Health Europe (formerly IFAH-Europe), ISPE (International Society for Pharmaceutical Engineering), PDA (Parenteral Drug Association), GIRP (European Healthcare Distribution Association, EAEPC (European Association of Euro-Pharmaceutical Companies representing Europe's licensed parallel distribution industry),, *Vaccines Europe (VE), Plasma Protein Therapeutics Association (PPTA)*, *European Association for Logistics and Transportation in Healthcare (Ealth)*, *International Plasma and Fractionation Association (IPFA) (invited) and International Pharmaceutical Excipients Council – Europe (IPEC).*

Quality Working Party and Biologicals Working Party

There were regular exchanges on matters of joint interest with both groups during the year. In addition, the first joint trilateral meeting with IWG, BWP and QWP was held in September 2024.

Innovation Task Force (ITF)

The GMDP IWG agreed to take part in relevant ITF meetings in order to provide a platform for early interactions with companies in relation to new technologies and they reviewed a small number of case studies on innovative manufacturing technologies during 2024.

Quality Innovation Group

The GMDP IWG has been closely informed and consulted where necessary on the work of the Quality Innovation Group. The QIG representatives reported on the work of the group in 2024, including Listen and Learn Focus Group meetings, as well as the requests for scientific advice received from applicants as well as 1:1 meetings between the QIG and applicants. The IWG was also consulted by QIG in specific topics concerning inspections and GMP expectations.