Introduction

The Compilation of Union Procedures on Inspections and Exchange of Information (hereafter referred to as 'Compilation'), formerly known as the Compilation of Community Procedures on Administrative Collaboration and Harmonisation of Inspections, is a tool for facilitating co-operation between the GMP and GDP inspectorates of the Member States and a means of achieving harmonisation. The procedures within it provide the basis for national procedures that form part of the national GMP inspectorates' quality systems. These quality systems are based on a framework laid down in one of the documents of the Compilation. In July 2010 documents connected with Good Distribution Practice (GDP) inspections started to be added to the Compilation.

The contents of the Compilation are constantly updated, developed and agreed, under the co- ordination of the European Medicines Agency, by representatives of the GMP Inspectorates of each Member State, including those supervising the manufacture and import of veterinary medicinal products only.

The Compilation has two parts; procedures within the Part I and other documents (e.g. interpretation documents and forms used by regulators) within the Part II. Once agreed by the GMDP Inspectors' Working Group, documents are reviewed by the European Commission and then published on its behalf by the European Medicines Agency.

To facilitate harmonisation in inspections of GMP for investigational medicinal products for human use and, where required by national legislation in accordance with Directive 91/412/EEC, for investigational veterinary medicinal products, many of the procedures on GMP also apply to investigational medicinal products and, where relevant, with modifications set out in the procedures.

Guidelines on inspections of pharmacovigilance of medicinal products are part of the Good Vigilance Practice guidelines adopted by the European Medicines Agency. Guidelines on GCP inspections are part of EudraLex, Volume 10.

The Heads of Medicines Agencies have agreed to the setting up of a joint audit programme of GMP inspectorates to verify the implementation and equivalence of EEA GMP inspectorates with relevant provisions of European Directives into national laws and consequently maintain mutual confidence in the GMP inspection systems of each member state by the other Member States, Level of compliance with the Compilation of procedures provides criteria on which the audits may be based.

Member States are obliged to take account of the Compilation by virtue of Article 3(1) of Directive (EU) 2017/1572, Article 17.1 of Regulation (EU) 2017/1569, recital (69) and article 123 of regulation 2019/6.

Some procedures within the compilation details tasks and provide guidance for the supervisory authority. For human medicinal product this is defined in the article 18 of regulation 726/2004, for the veterinary medicines the EU/EEA authorities have agreed that the supervisory authority term shall be understood as following:

In the case of medicinal products manufactured within the Union, the supervisory authorities for manufacturing shall be the competent authorities of the Member State or Member States which granted the manufacturing authorisation provided for in Article 40(1) of Directive 2001/83/EC and Article 88 (1) (a) and (b) of Regulation 2019/6 in respect of the medicinal product concerned.

In the case of medicinal products imported from third countries, the supervisory authorities for imports shall be the competent authorities of the Member State or Member States that granted the authorisation provided for in Article 40(3) of Directive 2001/83/EC and Article 88 (1) (c) of Regulation 2019/6 to the importer, unless appropriate agreements have been made between the Union and the exporting country to ensure that those controls are carried out in the exporting country and that the manufacturer applies standards of good manufacturing practice at least equivalent to those laid down by the Union."

Similarly for active substances for human and veterinary use, the national competent authorities have agreed:

Supervisory authority for active substance manufacturing sites located in the EEA is the competent authority of the country where the site is located.

For active substance manufacturing sites located in countries outside the EEA, the competent authority of the Member State which is the supervisory authority for a medicinal product has also the responsibility for supervision and inspection of the active substance manufacturers associated with the medicinal product.