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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The issue and update of GDP certificates

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Title	The issue and update of GDP certificates
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Reason for revision	Modifications were introduced as a result of the entry into application of Regulation (EU) 2019/6 on veterinary medicinal products and repealing Directive 2001/82/EC and Regulation (EU) 2019/5 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
Notes	Not applicable

The issue and update of GDP certificates

1. Introduction

Article 111(5) of Directive 2001/83/EC requires a certificate of Good Distribution Practice to be issued to the wholesale distributor of medicinal products for human use within 90 days of carrying out an inspection if the outcome of the inspection shows that the wholesale distributor complies with the principles and guidelines of Good Distribution Practice as provided for by Union legislation. The GDP certificates issued or the information indicating that a wholesale distributor does not comply with GDP, shall be entered into the Union database as required under Article 111(6) of Directive 2001/83 EC.

Regulation 2019/6 does not explicitly require to issue a certificate of Good Distribution to the wholesale distributor of veterinary medicinal product within 90 days of carrying out an inspection if the outcome of the inspection shows that the wholesale distributor complies with the principles and guidelines of Good Distribution Practice. However, wholesale distributor shall verify that the supplier complies with good distribution practice for veterinary medicinal products through information obtained from the national competent authorities or the Union database on manufacturing, import and wholesale distribution referred to in Article 91(1) of Regulation (EU) 2019/6. In this context, Competent Authority willing to issuing GDP certificates may follow this procedure.

The requirement applies regardless as to whether the inspections are unannounced or routine.

This document is intended to give interpretation on aspects of responsibilities of the issue, renewal and update of GDP certificates.

2. Use of certificates

GDP certificates are for the purpose of confirming to a wholesale distributor the overall conclusion of an inspection with respect to compliance with GDP. Within the EEA they do not replace confirmation of the holding of a wholesale authorisation.

3. When GDP certificates should be issued and union database entry

3.1 Responsibility for issue of GDP Certificates

Responsibility for issuing GDP certificates and placing entries into Union database rests with the competent authority.

Following each relevant inspection, a report in accordance with the Union format should be produced by the responsible inspector, which should contain a clear statement as to whether or not the wholesale distributor complies with the principles and guidelines of GDP as provided for in Union legislation.

Where this is the case, within 90 days of the last day of the inspection concerned, the competent authority should issue a GDP certificate in accordance with the Union format to the wholesale distributor that underwent the inspection.

In the case of non-compliance see the relevant Union procedure.

Each certificate should include a reference that enables traceability within the inspectorate that issued it so that the inspectorate can respond promptly to enquiries regarding authenticity.

Duplicates of valid GDP certificates may be issued in response to a request from the wholesale distributor.

3.2 Circumstances where the issue of a certificate to a wholesale distributor may not be applicable (other than in cases of failure to comply with GDP)

If the aim of any particular visit to a site is not primarily to assess compliance with GDP and the issue of a certificate is therefore not foreseen, then this should be made clear to the concerned wholesale distributor at the outset.

It may not be appropriate to issue a GDP certificate following an inspection in response to an application for, or variation to a wholesale authorisation, even if the outcome of the inspection is positive with respect to the application, particularly where approval is based upon plans and commitments rather than a direct inspection of facilities and operations.

Normally, an inspection is conducted in a single visit over a consecutive period of days but it may be split into a number of separate visits. Provided the subsequent visits occur within a reasonable period of time of the first visit, as decided by national procedures, the individual visits may collectively be considered as one inspection for which a single certificate will be issued within 90 days of the last day of the last visit. The wholesale distributor should be informed of this beforehand.

3.3 Scope of individual certificates

The certificate should include all operations deemed to be GDP compliant as a result of the inspection.

For ease of database entry and to reduce the use of free text, the Union database contains standard phrases to cover the most common situations.

3.4 Responsibility for Union database entry

The competent authority may enter the details of the certificate into the Union database before or at the time the certificate itself is issued to the wholesale distributor, or as soon as possible thereafter. Database entries will have a status of draft, current or withdrawn.

4. Non-compliance with GDP

A separate Union procedure deals with the handling of non-compliance.

5. Renewal and update of GDP certificates

- 5.1 A **certificate** itself is not renewed, as it is a declaration of the status of GDP compliance at a particular point in time connected with a satisfactory inspection outcome. A new certificate will be issued following the next inspection, if appropriate. Entries in Union database however require a different approach.

Union database requires the Member State inputting new information to decide whether the new certificate replaces an existing entry for the site in question, in which case they must take action to withdraw the superseded information, or, whether the information is in addition to the existing information, in which case the information being supplemented should remain in the database.

However, sometimes it will be necessary to retain some of the existing information if it is not superseded following a new inspection. This would happen, for example, when the most recent inspection does not cover everything covered by the previous inspection. In this case the following action is appropriate:

Withdraw the existing certificate (or have the original issuing authority withdraw it) and re-issue it having removed the superseded information but retaining the original date of inspection.

Issue a further new certificate with new information and the most recent inspection date.

5.2 Administrative updates and re-issue

An updated certificate may be issued to a wholesale distributor and input into Union database by the authority that issued the last certificate at the request of a wholesale distributor when administrative changes occur that affect the details appearing on the certificate and where the competent authority

agrees that a re-inspection is not required. An example would be a change in the name of the wholesale distributor. These new certificates will supersede the existing certificate but will maintain the original date of inspection, as an inspection will not have been carried out.

6. Closure of wholesale distribution site

Member states should take steps to ensure that when a site under its supervision ceases to operate, any GDP certificate is withdrawn from the Union database along with any wholesale distribution authorisation and non-compliance information.

Appendix 1

