EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medical products: quality, safety, innovation

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Statement of non-compliance with good distribution practice

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Title	**Statement of non-compliance with good distribution practice**
Date of adoption	May 2023
Date of entry into force	1 January 2024
Supersedes	Version published in April 2022
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
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(LETTERHEAD OF COMPETENT AUTHORITY)

Report No: _ _ _/_ _ _/_ __/_ _

STATEMENT OF NON-COMPLIANCE WITH GDP

Exchange of information between National Competent Authorities (NCAs) of the EEA following the discovery of serious GDP non-compliance at a wholesale distributor

Part 1

Issued following an inspection in accordance with Art. 111(7) of Directive 2001/83/EC as amended and/or <National legal basis/statement from authority>.

The competent authority of..... *[Member State]* confirms the following:

The wholesale distributor.....

Distributor's alternative name: .....

Authorisation number.....

Site address.....

Additional details on units inspected: .....

From the knowledge gained during inspection of this wholesaler distributor, the latest of which was conducted on …../……/ .....*[date]*, it is considered that **it does not comply with the Good Distribution Practice** requirements referred to in Article 84 of Directive 2001/83/EC and/or Article 99(6) of Regulation (EU) 2019/6.

Part 2

Wholesale distribution activity affected: <free text>

Part 3

• Nature of non-compliance: <free text>
• Action taken/proposed by the NCA: <free text>
• Additional comments: <free text>

• Teleconference Date:	• Teleconference Time (CET):	• Dial in no.:

…../……/…….. *[date]*

Name and signature of the authorised person of the Competent Authority of *[country]*[1]

.....

.....

[name, title, name of authority, phone and email in case of enquiries]

[1] The signature, date and contact details should appear on each page of the statement.