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 of a distributor of active substances for use as starting materials in medicinal products

## Table of contents:



| **Title** | **Statement of non-compliance with good distribution practice of a distributor of active substances for use as starting materials in medicinal products** |
|---|---|
| Date of adoption | May 2023 |
| Date of entry into force | 1 January 2024 |
| Supersedes | Version published in May 2012 |
| 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 |
| Last publication date: | 1 August 2024 |
| Document version | 1 |

*(LETTERHEAD OF COMPETENT AUTHORITY)*

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

# STATEMENT OF NON-COMPLIANCE WITH GDP OF A DISTRIBUTOR OF ACTIVE SUBSTANCES FOR USE AS STARTING MATERIALS IN MEDICINAL PRODUCTS

**Exchange of information between National Competent Authorities (NCAs) of the EEA following the discovery of serious GDP non-compliance at an active substance 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 active substance distributor.....

Distributor's alternative name:
.....

Site address:
….....

Additional details on units inspected:
.....

From the knowledge gained during inspection of this active substance distributor, the latest of which was conducted on …/…/… *[date]*, it is considered that **it does not comply with the Good Distribution Practice** for active substances referred to in Article 47 of Directive 2001/83/EC and/or in Article 95(8) of Regulation (EU) 2019/6.

**Part 2**

| |
|---|
| ☐ All registered active substances distributed are affected<br>☐ Specify which Active Substances are 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 this statement.