DECISION

No. 11/22.04.2013

on approval of the formats concerning statements of serious non-compliance with Wholesale Distribution Practice and Good Distribution Practice for active pharmaceutical substances

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 158/18.02.2013, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 22.04.2013, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organisation and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following

DECISION

Sole article. – The following forms are approved for statements of serious non-compliance with Wholesale Distribution Practice and Good Distribution Practice for active substances for use as starting materials in medicinal products for human use in accordance with the community legislation (the Compilation of Community Procedures on Inspections and Exchange of Information), in accordance with the Annexes which are integral part of this Decision:

- Annex A: Form - Statement of serious non-compliance with Good Distribution Practice (medicinal products for human use)
- Annex B: Form - Statement of serious non-compliance with Good Distribution Practice for active substances to be used as starting materials in medicinal products for human use.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,

Acad. Prof. Dr. Leonida Gherasim

ANNEX A

FORM

STATEMENT OF SERIOUS NON-COMPLIANCE WITH GOOD DISTRIBUTION PRACTICE

(MEDICINAL PRODUCTS FOR HUMAN USE)

(LETTERHEAD OF COMPETENT AUTHORITY)

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

STATEMENT OF NON-COMPLIANCE WITH GDP
MEDICINAL PRODUCTS FOR HUMAN USE

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.

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

The wholesale distributor.....

Authorisation number.....

Site address.....

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.

Part 2

Wholesale distribution activity affected: <free text>

Part 3

1. Nature of non-compliance: <free text >
2. Action taken/proposed by the NCA: <free text >
3. 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, email in case of enquiries]

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

ANNEX B

FORM
STATEMENT OF SERIOUS NON-COMPLIANCE WITH GOOD DISTRIBUTION PRACTICE OF A DISTRIBUTOR OF ACTIVE SUBSTANCES FOR USE AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

(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 FOR HUMAN USE

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.

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

The active substance distributor.....

Site address .....

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.

Part 2

□ All registered active substances distributed are affected

□ Specify which Active Substances are affected : <free text >

Part 3

4. Nature of non-compliance: <free text >
5. Action taken/proposed by the NCA: <free text >
6. 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]*[2]

.....

.....

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

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