DECISION

No. 12/23.05.2008

on the delegation of responsibilities for GMP inspections for medicinal products for human use authorised via the centralised procedure

The Scientific Council of the National Medicines Agency,
set up based on Order of the Minister of Health No. 1027/22.05.2008, as amended, reunited on summons of the National Medicines Agency President in the ordinary meeting of 23.05.2008 in accordance with Article 10 of Government Ordinance No. 125/1998 related to the set up, organisation and functioning of the National Medicines Agency, approved as amended through Law No. 594/2002, with further changes and completions, agrees on the following

DECISION

Single article. – The procedure on the delegation of responsibilities for GMP inspections for medicinal products for human use authorised via the centralised procedure is approved, according to the Annex which is integral part of this decision.

PRESIDENT
of the Scientific Council
of the National Medicines Agency

Acad. Prof. Dr. Victor Voicu

ANNEX

PROCEDURE

on the delegation of responsibilities for GMP inspections for medicinal products for human use authorised via the centralised procedure

CHAPTER I
Scope

Art. 1. – This procedure is a translation and adaptation into Romanian of the Procedure EMEA/INS/GMP/392920/2006 on the delegation of responsibilities for GMP inspections for medicinal products for human use authorised via the centralised procedure, issued by the European Medicines Agency (EMEA).

CHAPTER II
Introduction

Art. 2. – Eudralex, Volume 2A: Pharmaceutical Legislation –Notice to Applicants states the following: „When the Supervisory Authority is not able to inspect in a third country, the Rapporteur and the Supervisory Authority together designate another competent authority as the Leading Inspection Service for the inspection".

Art. 3. - Such a delegation of responsibilities is also covered in the Community procedure – „Guideline on the Verification of the GMP Status of Manufacturers in Third Countries" (transposed via the NMA Scientific Council Decision No. 23/28.09.2007), as follows: „Where the NMA, as a Supervisory Authority, is unable to verify the GMP status of any third country manufacturer(s) on the above basis it may request another EEA Competent Authority to carry out an inspection and to provide confirmation of the manufacturer's GMP compliance status. For centralised medicinal products for human use, this arrangement should be subject to obtaining the written consent of any other Supervisory Member States involved."

CHAPTER III
Procedure for the delegation of responsibilities

Art. 4. – The following procedure will be used for the delegation of responsibility for carrying out an inspection for centralised products in third countries:

- EMEA will write to the Member State responsible for carrying out the inspection in the Third country (i.e. future Supervisory Authority) in line with the normal procedure.

- The Supervisory Authority will reply to EMEA, formally stating that they are unable to carry out the Inspection.

- EMEA will then write to the Rapporteur requesting delegation of the inspection to the Rapporteur or Co-Rapporteur Member State Inspectorate; the Rapporteur will confirm the replacement of the Competent Authority.

- In the event that neither Rapporteur nor Co-Rapporteur Member State inspectorate can carry out the inspection, EMEA will write to one of the Member States Inspectorates who have indicated to EMEA an interest in taking on such delegated inspections, requesting them to carry out the inspection; the Rapporteur and future Supervisory Authority will be informed of the replacement of the Competent Authority.

- EMEA will send the contract to the replacement Competent Authority; all correspondence relating to the logistic arrangements for carrying out the inspection will then be sent to the replacement Competent Authority.

- The replacement Competent Authority will then carry out the inspection.

- The replacement Competent Authority will be responsible for providing the report to the manufacturer who has been inspected and obtaining their comments and completing the report.

- If the inspection findings indicate a need for urgent or non-urgent regulatory action, they must be discussed with the Supervisory Authority before finalisation so that any follow up action can be initially agreed.

- The final report of the inspection will be provided to the future Supervisory Authority, together with copies of any follow up correspondence with the company.

- The replacement Competent Authority will be responsible for providing the report to the manufacturer who has been inspected and obtaining their comments and completing the report.

Art. 5. – (1) The replacement Competent Authority is responsible only for the carrying out of the Inspection and delivery of the completed report.

(2) Any follow up of the inspection required after the report has been issued and all future activities relating to the manufacturing site are the responsibility of the Supervisory Authority.

(3) It should be particularly noted that responsibility for entry of information into EudraGMP rests with the Supervisory Authority and agreement must be reached with the replacement Authority on how this task will be fulfilled.

Art. 6. – Where multiple medicinal products for human use are sourced from a site outside the EEA and imported through different importers in more than one Member State, or where justified by the applicant, a product is imported and its batch released through more than one Member State (hence there will be several Supervisory Authority), the EMEA will consult the Supervisory Authorities involved in order to reach agreement on who will take responsibility.