European Medicines Agency
Inspections

London, 9 February 2007
Doc. Ref. EMEA/INS/GMP/75468/2007

EUROPEAN GROUP FOR PRODUCT DEFECTS

In order to deal successfully with a product defect, a European Group is created. For logistical reasons, and rapid and efficient management, the core members of the European Group for product defects must be kept to a minimum. Furthermore, for logistical and time reasons, some meetings may need to take place without all members being present, especially during out-of-office hours. Of course additional members and expertise may be co-opted into the European Group as need arises.

In the case of a non-critical (e.g. major or minor) product defect (e.g. packaging problems: wrong or missing batch number or expiry date), the procedure should be handled by a reduced European Group composed of the Supervisory Authority and the EMEA Inspections Sector. The decision to convene this reduced European Group for non-critical product defects will be taken by the Inspection Sector co-ordinator (ISC) in consultation with the Supervisory Authority and with the agreement of the EMEA Inspections Head of Sector (HoS) and/or Head of Unit (HoU). This simplified procedure will reduce the administrative workload for the other competent authorities, (Co)Rapporteur and EMEA staff in the assessment of minor suspected product defect.

Composition of the European Group (or reduced European Group)

The European Group is composed of the following parties:

- EMEA Inspections Sector Co-ordinator (ISC): acts as an overall co-ordinator.
- EMEA Project Manager[1].
- A designated representative from the Supervisory Authority (if there is more than one Supervisory Authority, they should reach an agreement which one takes the responsibility for evaluating the product defect).
- The Rapporteur of the product concerned, supported by his/her scientific assessment team (if the Rapporteur is not able to fulfil the functions of such evaluation, the Co-Rapporteur may take this responsibility. If this is not possible, it is at the discretion of the CxMP chairman to appoint another person to act on behalf of the Rapporteur).
- If necessary, a designated representative from the Member State(s) where the problem was first identified.
- A pharmacovigilance EMEA staff Member (only for safety issues, if appropriate).
- EDQM, when originated from the CAP testing program.

The reduced European Group is composed by:

- EMEA Inspections Sector Co-ordinator (ISC): acts as an overall co-ordinator.
- A designated representative from the Supervisory Authority.

[1] For human products: Project Manager of the Quality of Medicines Sector

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 95
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

A prerequisite in this respect is the availability of designated contact points within the Member States and MRA partners. A consolidated list of all contact points at the level of the Member States, involved in the MP, should be maintained by the EMEA. This list shall continuously be updated and it is the responsibility of the Member States to inform the EMEA of any changes to be implemented.

The following members should be notified of any serious (critical or major) product defect for information, potential feedback and/or voluntary participation in the European Group:

- Executive Director of the EMEA.
- Chairman of the CxMP.
- Head of Inspections Sector and Head of Veterinary and Inspections Unit.
- Head of Post-Authorisation Evaluation of Medicines for Human Use (for human products).
- Head of Veterinary marketing authorisation procedures (for veterinary products) or Head of Sector, Quality of medicines (for human products).
- Product Team Leader (for human products) or Project Manager (for veterinary products).
- Representative from Regulatory Affairs.
- For live vaccines, immunological products and medicinal products derived from human blood or human plasma, the Official Medicines Control Laboratory (OMCL) responsible for official batch release .
- European Commission.

Role of the European Group (or reduced European Group)

The decision to convene the European Group or a reduced group for suspected product defects will be taken by the ISC in consultation always with the Supervisory Authority and with the agreement of the EMEA Inspections Head of Sector (HoS) and/or Head of Unit (HoU). The Supervisory Authority should take the leading role in this procedure for product defects, acting to evaluate all issues relevant to the CAP.

The ISC should act as an overall co-ordinator and he should collect internal and external information on an on-going basis in order to update the European Group and/or other parties at any moment.. The ISC has the overall responsibility to make the group operational within the shortest timeframe. It should be organised in such way that he is also able to deal with problems arising during weekends or public holidays. When necessary, the ISC will inform his respective HoS and HoU, who can then inform the Executive Director and/or Press Officer as appropriate.

The role of the European group (or reduced European Group) is to:

- Confirm and determine the extent of the problem.
- Co-ordinate all activities, including communication.
- Manage the crisis situation by:
    - Defining a strategy to handle the procedure.
    - Preparing a decision.
    - To refer the matter to the next CxMP meeting in order to define what possible action should be taken considering the seriousness of the problem for minor crisis.
    - Convening an exceptional CxMP meeting with the agreement of the CxMP chairman and all EMEA Head of Units concerned for crisis that may pose a significant hazard to public/animal health.
    - Agreeing on the final conclusion, once the crisis is considered finalised.