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Compliance and Inspection

Distant/virtual pharmacovigilance inspections of MAHs during a crisis situation- Points to consider

This document is intended to provide guidance on the steps to be followed during distant / virtual pharmacovigilance (PhV) inspections of MAHs.

Agreed by PhV IWG	14 December 2012

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1. Introduction

The necessity to be able to perform pharmacovigilance inspections during crisis situations has been identified as an important issue.

Under situations such as transport restrictions or situations which give rise to concerns of inspectors' safety (e.g. pandemics, natural disasters, high criminality areas), distant/virtual inspections could replace on site inspections.

The inspectorate, in agreement with the committee requesting the inspection, should decide on a case by case basis whether a distant/virtual inspection will prove sufficient to gain an adequate overview of the functioning of the MAH's PhV system or not (e.g. in the case that the MAH is "high risk" based on intelligence information a virtual inspection may not be adequate on its own).

Distant/virtual inspections should follow the guidelines that already exist for the conduct of PhV inspections, but should take into consideration the limitations imposed by using a virtual process.

It is the purpose of this document to outline the specificities of distant/virtual PhV inspections identifying the points that should be considered during the preparation and conduct of such PhV inspections.

2. Inspection announcement

In the inspection announcement letter, the technical requirements (means of communication) as well as the preparation procedure, including a list of documents required pre-inspection, should be clearly described. The importance of the timely provision of all necessary documentation as well as a robust set-up of the virtual facilities, should be stressed.

3. Preparation of the inspection

3.1. Technical preparation

3.1.1. Communication

Due to the nature of this type of inspection, direct contact with company personnel is likely to be minimal or non-existent.

- It is imperative that reliable tele-conference facilities are available during the inspection. They are likely to form a larger part of the inspection, which should be taken into consideration for the length of the inspection. If possible, the telecommunications arrangements should be tested in advance.

3.1.2. Provision of documents

There will be greater difficulties in obtaining documentation in a timely manner compared to an inspection at company offices. Considerations should include:

- Discussion and agreement of the document request process in advance. Arrangement for documents to be requested and sent by Eudralink or through the agency portal if applicable.

3.2. Documentation preparation

- More documentation should be requested pre-inspection (requests could be sent in the announcement letter). Pre-empting routine requests can save time during the inspection.
- Some documentation may require translation (the burden on the MAH should be considered and only translation of key documents should be requested).
- The amount of documentation to be reviewed should be decided in advance. Performing extensive document review in advance may assist one to ask targeted interview questions. It may be appropriate to add a day to the inspection to review documentation during the inspection and subsequently conduct more focussed interviews.
- Listings and case files should be requested in advance / prior to the inspection.
- For product-specific triggered inspections, involving the assessor in document requests and line listing/case reviews may be important. If the inspection is performed at the office of the regulatory authority, there may be more opportunity to involve assessors.

3.3. Conduct preparation

The following points should be considered:

- Has another NCA Inspectorate inspected the MAH PV system? Where appropriate for e.g. triggered inspections, a summary of the inspection findings of GCP/GMP inspections from relevant competent authorities could be requested. The inspection should be tailored, as appropriate, in accordance with what may already have been reviewed by another authority.
- Relevant intelligence information should be reviewed e.g. compliance data, communications from worldwide authorities (e.g. FDA Warning Letters) etc.
- The process by which company personnel are to obtain documents during the inspection should be considered. One way would be to ensure internet access and those documents required to be in hardcopy could be e-mailed (Eudralink) or sent through the agency portal (if applicable) and printed by CA's Admin staff/inspection team.
- The interviewees' language abilities should be considered prior to the inspection.
- An agenda (plan) for the inspection, which accounts for time for telephone discussions and time for reviewing documents offline, should be prepared. Actual times for discussions will need to be scheduled.
- If the inspection is triggered and product-specific, involvement of the relevant assessor(s) in the inspection should be considered.

4. Conduct phase

- A good internet connection is essential for document review using a laptop. However, it is useful to save key documents on to a USB pen (ensuring confidentiality), in case the wireless connection is disrupted. All documents used should be exchanged and stored in way that ensures confidentiality.
- If there are problems encountered with communication during the conduct of the inspection e.g. internet connection problems, language issues, the inspectors could consider asking fewer questions, conducting fewer interviews and reviewing more documentation in order to confirm

activities. Sometimes the use of a translator may be helpful, but this adds substantially to the time needed to conduct the interview.

- General points should be considered with respect to teleconference interviews i.e.
  - Speak slower in order to be clearly understood,
  - If more than one inspector/assessor is in the room, agree some signals to indicate when you wish to interrupt or when you wish to place the call on mute,
  - Repeat and summarise where necessary in order to confirm understanding.
- MAH personnel should not have to be on teleconference throughout, thus specific times for interviews and to follow-up issues should be arranged.
- Any time difference (where relevant) should be considered allowing for breaks during long interviews.
- Additional days may be needed to be added to the virtual inspection, perhaps after additional documents have been requested and reviewed.

5. Post-inspection

If it is believed that significant issues have been identified that have not been able to be adequately reviewed during a virtual inspection, other options should be considered e.g.

- If considered necessary and if practical, an inspection of the MAH's pharmacovigilance headquarters should be arranged.

6. Reporting of inspections

The procedure for reporting such inspections will follow the same procedure as for the face-to-face inspections, clearly indicating what was and what was not covered during the virtual inspection.