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Quality and Safety of Medicines Department

Remote 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 remote pharmacovigilance (PhV) inspections of marketing authorisation holders (MAHs).

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| Agreed by PhV IWG | 14 December 2012 |
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*Note: Revision 1 contains the following:

- Change of the wording from distant/virtual pharmacovigilance inspections to remote pharmacovigilance inspections, in the title and in the text.
- Clarifications on the necessity to assess before the inspection whether the inspectee meets the technical requirements to provide remote access to electronic systems and maintain communication with and support to inspectors.
- Further guidance on the documentation preparation and the conduct preparation.



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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 crisis situations (e.g. pandemic), on-site inspections may not be possible due to multiple factors such as difficulties and restrictions related to travelling between and within the borders of countries (including travel warnings / restrictions, border controls, transportation difficulties), restrictions to accessing facilities justified by health hazards and local authorities' recommendations / orders, as well as additional health risks for inspectors and inspectees.

Under such circumstances, remote inspections could replace on-site inspections.

The inspectorate, in agreement with the relevant EMA's scientific committee, when applicable, should decide on a case by case basis whether a remote inspection will prove sufficient to gain an adequate overview of the functioning of the MAH's PhV system. Otherwise a postponement of the on-site inspection should be considered.

Remote inspections should follow the guidelines and procedures that already exist for coordinating, preparing and conducting PhV inspections, but should take into consideration the limitations imposed by using a remote process. It is the purpose of this document to outline the specificities of remote PhV inspections by identifying the points that should be considered during the preparation, conduct and reporting of such PhV inspections of marketing authorisation holders (MAHs) with centrally authorised products (CAPs) and national authorised products (NAPs).

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 technical facilities to ensure that a remote inspection is feasible, 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 therefore fundamental to assess whether the inspectee meets the technical requirements to provide remote access to electronic systems and maintain communication with and support to inspectors. The technical nuances of these systems as well as the IT policies (of the inspectee and competent authority(ies) performing the inspection) especially IT-security and data protection aspects are likely to cause additional challenges. For this purpose, an early contact between inspectorate and inspectee is strongly recommended. It should also be taken into account that the technical conditions within the inspectorate must be ensured to allow an efficient communication.

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. Therefore, considerations should include the discussion and agreement of the document request and reconciliation process in advance and sharing of documents via a platform.

3.2. Documentation preparation

- The extent of documentation to be reviewed should be decided in advance. This does not preclude further requests during and following the inspection as performing extensive document review in advance may assist one to ask targeted interview questions, as due to technical reasons there is limited time during the inspection. E.g. presentations by the inspectee could be provided in advance. It may be appropriate to add a day to the inspection to review documentation during the inspection and subsequently conduct more focussed interviews.
- For product-specific triggered inspections, involving the assessor in document requests and line listing/case reviews may be important. Technical support for the assessor must be ensured when participating in the inspection.

3.3. Conduct preparation

The following points should be considered:

- Video conference would be preferable, if possible and a function check and dry run in advance can be useful as well as checking backup support from IT, test of relevant access from different locations, max. number of participants etc.
- A detailed inspection agenda should be submitted in advance by the Lead Inspector to the inspectee in accordance with SOPs in place at their inspectorate. The agenda should list all (planned) sessions and anticipated time slots, with extra time in between to account for potential technical issues. Sessions that require subject matter experts to be present for interviews or to deliver presentations should be marked in the agenda.
- According to national legislation any recording (audio / video / screenshots) during the inspection process should be notified and agreed upfront between all involved parties.

4. Conduct phase

- Essential components of the inspection include interviews, presentations (by the inspectee) relating to the topics requested by inspectors in the agenda and documentation review.
- A good internet connection is essential for a remote document review. All documents used should be exchanged and stored in a way that ensures confidentiality.
- If there are problems encountered with communication during the conduct of the inspection, e.g. internet connection problems or language issues, the inspectors should consider to adapt the schedule.
- It is recommended to use an electronic document request form that can be exchanged between the inspectee and the inspection team.
- General points should be considered with respect to teleconference interviews i.e.

- All participants should be introduced at the beginning. Inspectors should be able to confirm that in each session the people present are the ones that have been included in the detailed inspection agenda and it may be useful to mention the name briefly when requested to speak;
 - 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 remote inspection, perhaps after additional documents have been requested and reviewed.

5. Post-inspection

If significant issues that have been identified cannot be adequately reviewed during a remote inspection, other follow up options should be considered e.g.

- If considered necessary and if practical, an on-site inspection should be arranged.

6. Reporting of inspections

The procedure for reporting remote inspections will follow the same procedure as for the on-site inspections, clearly indicating what was addressed and what was not covered during the remote inspection. Inspection-derived records should be maintained according to standard procedures.