E: Reporting Serious Adverse Events

Article 13.4 of the Medical Devices Decree (BMH) makes it mandatory for clinical investigations with medical devices to be performed in accordance with Annex X to Directive 93/42/EEC. Item 2.3.5 of this Annex states:

> *'All serious adverse events must be fully recorded and immediately notified to all competent authorities of the Member States in which the clinical investigation is being performed.'*

In December 2010 (most recent amendment May 2015), the "Guidelines on Medical Devices – Clinical Investigations: Serious Adverse Event Reporting under Directives 90/385/EEC and 93/42/EEC" were adopted within the European Union (MEDDEV 2.7/3). This is guidance for reporting Serious Adverse Events (SAEs) and is intended to implement the requirements contained in Directive 93/42/EEC.

1. SAEs that fall under MEDDEV 2.7/3 must be notified in accordance with this guideline and its reporting table. Please note that in this respect it is important to retain the possibility to be able to filter within columns. SAE reports will be assessed by the Inspectorate.

2. The sponsor must immediately inform the Inspectorate (within two working days and not later than four calendar days) of SAEs which indicate an inevitable risk of death, serious injuries or serious illness, and requiring prompt remedial action for patients.
   This includes SAEs that result in (temporary) suspension of inclusion of patients in the clinical investigation, discontinuation of the clinical investigation (temporarily or otherwise), or modification of the medical device.
   Events that were reasonably foreseeable and are described as such in the Protocol and the patient information ("calculated risks") are excluded from the above requirements, insofar as they do not lead to the (temporary) suspension or discontinuation of the clinical investigation or to modification of the medical device.

3. MEDDEV 2.7/3 stipulates that all other reportable events (see section 4 of MEDDEV 2.7/3) must be reported within no more than seven days. The Inspectorate applies a less intensive term in this respect. SAEs that do not fall under item 2 above may be reported quarterly in their totality to the Inspectorate by means of the reporting table, which can be found on the website of the European Commission.

   ✓ *If reportable events that occurred in the Netherlands are not reported within three months after the sponsor being made aware of them, this will constitute a breach of the law, and the Inspectorate may immediately impose an administrative fine. The Inspectorate may examine, for each individual breach of the law, whether the responsibility for the breach rests with the medical researcher (failure to forward reports to the sponsor) or with the sponsor (failure to forward reports to the Inspectorate or to forward them on time).*

Where necessary, the Inspectorate will take action based on these reports. For example, the Inspectorate may ask questions or re-examine and re-evaluate earlier SAEs. If the Inspectorate is of the opinion that irresponsible risks exist for patients who are participating in the clinical investigation, it will contact the relevant Ethics Committee(s) and/or the CCMO, with a recommendation to reconsider the positive opinion for the clinical investigation (temporarily or

otherwise). Additionally, the Inspectorate may make its findings known to other European Member States.

This page belongs to the subject ‘clinical investigations with medical devices’ on igj.nl.