## D: Frequently Asked Questions about notification

1. **Where must I send my notification?**

   ✓ You can send your registration digitally to the Inspectorate's information desk at meldpunt@igz.nl. If it is transmitted successfully, you will receive an automatic confirmation of receipt.

   IMPORTANT! Sending messages that contain numerous or large attachments may result in the Inspectorate not receiving your registration. It is possible you might not receive an error message. Spreading numerous/large attachments over multiple e-mails can avoid a situation where your registration is not processed. Try not to send e-mails where the total size of the attachments exceeds 10 MB.

2. **Can I submit the notification even though I have not yet received a positive opinion/advice from the Ethics Committee?**

   ✓ No. The Inspectorate will process registrations only if the Ethics Committee has already given a positive opinion, which must accompany the notification.

3. **How long will it take for the Inspectorate to get back to me after I have submitted the notification?**

   ✓ You will receive an automated confirmation of receipt when you send an e-mail to the Inspectorate's information desk. If your e-mail does not arrive via the information desk, the Inspectorate will also usually send you confirmation of receipt, but this will be done manually. If you e-mail your registration to the information desk, it will generally take about four weeks to complete an initial evaluation and to inform you of the outcome.

   ✓ If the registration is accepted for processing, the Inspectorate will assign a code to the clinical investigation (a so-called "VGR number"). This code must be stated in all correspondence concerning the clinical investigation.

   ✓ If the registration meets the legal requirements, you will be informed accordingly. The Inspectorate will send a letter to the manufacturer, with a request to inform the Principal Investigator and/or researchers of the Inspectorate's letter. The Inspectorate will also e-mail a PDF of the letter back to the person who submitted the investigation.

4. **What does the Inspectorate examine in the registration?**

   ✓ In the first place, the Inspectorate will examine compliance with the Medical Devices Act (WMH). This means the Inspectorate's task differs from that of the Ethics Committee, which will examine the investigation from the point of view of the Medical Research (Human Subjects) Act (WMO). The Inspectorate will assess whether it really concerns a manufacturer's clinical investigation involving the use of a medical device, as intended by the Act and as described under section B of this page.

- ✓ The Inspectorate will then examine whether the notification is complete (i.e. contains all documents mentioned under section D), whether the manufacturer has taken out the insurance as required by law, and whether the registration is accompanied by a positive opinion of the Ethics Committee.

- ✓ The Inspectorate will examine the information for patients and determine whether it meets the principle of responsible care by informing the patient in an entirely objective way about the risks of the clinical investigation and the available alternatives.

- ✓ The Inspectorate will examine the clinical investigation in the light of information it gathers from its general supervision of medical devices (such as risks with medical devices of which the Ethics Committees cannot yet be aware), including information that the Inspectorate obtains from its contacts with other European Member States.

**5. May I immediately start the investigation after submitting the registration to the Inspectorate, or must I await a response from the Inspectorate?**

- ✓ The law requires the manufacturer to meet certain legal requirements before starting a investigation. The Inspectorate will examine whether the registration meets the legal requirements. If the Inspectorate informs the manufacturer that all legal requirements have been met, it is certain that there will be no breach of the law at the time the clinical investigation will start. If the investigation starts before the Inspectorate has examined the notification, both the manufacturer and the (Dutch) Principal Investigator risk breaking the law. The Inspectorate actively enforces compliance with the law and can take action where necessary, including the imposition of administrative fines. Both the manufacturer and the principal investigator can be fined in this way.

**6. What happens if the Inspectorate has questions or comments about the clinical investigation, or asks for changes to be made in the documents?**

- ✓ In the first instance, the Inspectorate will communicate only with the manufacturer. This is in line with the Inspectorate's role as competent authority on medical devices and of overseeing legislation concerning medical devices, whereby the manufacturer is the party to contact. The Inspectorate does not maintain any supervision (at least not directly) over Ethics Committees. Changes requested by the Inspectorate must be made through the manufacturer and subsequently must be resubmitted to the relevant Ethics Committee(s), in the same way as required for all amendments to documents associated with clinical research.

**7. Is it necessary to register a clinical investigation involving the use of a prototype of a medical device if there is no immediate intention to put it on the market?**

- ✓ Yes. Clinical investigations with non-CE-marked medical devices may be performed only within the legal framework as described under section B of this page. If patients are exposed to the prototype, the legal requirements must be met, and the investigation must be notified.

**8. If the clinical investigation for a medical device will be performed at the same institution where it is being developed, will the investigation still have to be notified?**

- ✓ No. If the medical device is developed entirely within one and the same institution and will not be used by any parties outside your own institution, your actions will not be subject to the legal definition of a manufacturer. Therefore, you do not need to meet

the legal obligations of a manufacturer and you do not need to notify the investigation to the Inspectorate. The provisions made in the Medical Research (Human Subjects) Act (WMO) remain fully in force, however, so virtually always the investigation will need to be submitted to the relevant Ethics Committee.

**9. Do amendments to the documents associated with the clinical investigation involving the use of a medical device also need to be submitted to the Inspectorate?**

- ✓ No. The obligation does not exist after the initial registration of the clinical investigation. Nevertheless, numerous manufacturers do this anyway on account of obligations in other EU Member States. The Inspectorate will take cognizance of such amendments and add them to its dossier of the clinical investigation. In most cases, you will not receive a detailed response. However, the Inspectorate does wish to be informed if institutions are added to the clinical investigation, and in such cases, the Inspectorate would like to receive the permission granted by the Executive Board / Board of Directors or by the person who holds authority to grant such permission on behalf of the Board.

**10. Does the Inspectorate want to receive interim reports about the investigation?**

- ✓ It is mandatory for the sponsor to report Serious Adverse Events (SAEs). The procedure for doing this is described under section E. Additionally, the manufacturer may send interim reports to the Inspectorate but is not obliged to do so. The Inspectorate will add the reports to its dossier of the clinical investigation. As and when necessary, the Inspectorate may ask questions about the interim reports. The Inspectorate does not respond to received interim reports in all instances.

**11. I'm a manufacturer or custom-made medical devices, do I need to meet the notification requirements?**

- ✓ Yes, that may be the case. In case your deliver multiple serially produced custom-made devices (or customized devices) with the objective to perform a clinical investigation, it may be the case that legislation for clinical investigations with non-CE-marked medical devices are also applicable and that you commit a violation of the law if you do not notify us of your clinical investigation. De inspectorate advices you to notify when in doubt.

This page belongs to the subject 'clinical investigations with medical devices' on www.igz.nl.