Summary of market surveillance report concerning IUB Ballerine IUD midi 2021

The Health and Youth Care Inspectorate [Inspectie Gezondheidszorg en Jeugd] (hereinafter referred to as the Inspectorate) has assessed the placing on the market and use of the IUB™ Ballerine® intrauterine contraceptive device on the Dutch market. A group of women experienced expulsion or perforation of the device and some of them have become pregnant as a result.

The aim of our inspection was to investigate whether the manufacturer sufficiently assesses the performance of the device after placing it on the market (post-market surveillance). The manufacturer has the legal obligation to perform such surveillance in accordance with the applicable (European) legislation. The Inspectorate also assessed whether the notified body has performed its statutory tasks satisfactorily. Lastly, the Inspectorate checked whether the healthcare providers that are using the device have sufficiently balanced the benefits and risks of using the device and have sufficiently taken care to ensure that the device is safely used.

The IUB™ Ballerine® is a hormone-free contraceptive device. The device's frame has copper spheres on it and takes on a round shape after insertion into the uterus. The manufacturer recommends the device to be used for women aged between 16 and 45. Only the IUB™ Ballerine® midi has been available on the Dutch market since April 2019.

The device has been CE-marked since December 2014. This means that a European notified body has assessed that the device fulfils the essential requirements laid down in the applicable European legislation, Directive 93/42/EEC on medical devices. The notified body has renewed the device's CE-certificate on multiple occasions during a short period of time. The most recent renewal of the CE-certificate was issued on 22 February 2021 under European Directive 93/42/EEC and is valid until 26 May 2024. On 16 July 2021 the notified body suspended the CE-certificate for a period of 12 months because the technical file does not fully permit verification of compliance with the essential requirements of Directive 93/42/EEC.

In October 2020 the Dutch Reporting Centre for Adverse Effects of Medical Implants [Meldpunt Bijwerkingen Implantaten] (MEBI) informed the Inspectorate that, over a brief period of time, they had received a number of complaints regarding this device from women and healthcare providers. The complaints in question are described as adverse effects in the instructions for use but have been reported more frequently to MEBI compared to other copper intrauterine contraceptive devices. As a consequence, the reporting centre decided to issue an alert, which was published on 8 March 2021.

The Inspectorate believes it is important that women can be confident that a device available on the Dutch market and its use are sufficiently safe. Although no form of contraception provides 100% protection against pregnancy, the risk of unwanted pregnancies must be as low as reasonably possible. That is why it is important that manufacturers market devices which have been clinically proven to be safe and effective. Prior to placing on the market, a notified body must carefully assess whether the devices fulfil the essential requirements. Finally, healthcare providers must carefully balance the benefits and risks of these devices both prior to procurance and introduction and before they are actually implanted in patients. The use of the device always involves a risk. Any safely developed and responsibly applied IUD can lead to an undesirable outcome for women, such as expulsion, perforation or unwanted pregnancy. Healthcare providers should therefore women about this.

The Inspectorate has submitted questions to the manufacturer, distributor, notified body, the designating authority that supervises the notified body and the relevant Dutch scientific societies. The questions were related to market authorisation, the post-market surveillance (PMS) activities performed by the manufacturer after the device became available on the market and use of the device by healthcare providers.

The Inspectorate has concluded from its assessment that the manufacturer has been fulfilling its vigilance obligation. The notified body performed its supervisory task by suspending the CE-certificate, because of an incomplete technical file. The Inspectorate has also concluded that some of the healthcare providers did not sufficiently balance the benefits against the risks before the

device was used. It has also transpired that the device is not always implanted in accordance with the manufacturer's instructions.

The Inspectorate advises all professional societies to draw up a joint guideline or protocol for the use of intrauterine contraceptive devices. These can be based on the standards contained in the Covenant on Medical Technology [Convenant Medische Technologie] (CMT) and the Guideline on new interventions in clinical practice [Leidraad nieuwe interventies in de klinische praktijk] (NIKP). The Inspectorate believes it is important that professional societies adopt a position with regard to the use of intrauterine contraceptive devices by women less than 36 weeks after childbirth and while they are still breastfeeding. The Inspectorate also recommends that a joint clinical quality register for these devices should be set up. The Inspectorate also emphasises the importance of providing women with proper patient education and obtain informed consent. The Inspectorate calls on the Royal Dutch Organisation of Midwives [Koninklijke Nederlandse Organisatie voor Verloskundigen] (KNOV) to promote a clear policy with regard to the use of new implants. The Inspectorate recommends using alternative contraceptives while the IUB Ballerine’s CE -certificate has been suspended.