Questions and answers concerning the update of the RIVM report 'Silicone breast implants in the Netherlands: A market surveillance study'

The information below belongs to the RIVM report that is published on 12 February 2018 on the website of RIVM.

1. Why did the Inspectorate commission this follow-up study?

Between 2014 and 2016 RIVM performed a study on breast implants on behalf of the Inspectorate. The results of this study were published on 9 June 2016. RIVM found several shortcomings in the technical files. In 2016, the Inspectorate requested the manufacturers to improve the technical files accordingly. In the current study, RIVM assessed the improved technical files after approximately one year.

2. What is a technical file?

Manufacturers are legally obliged to compose technical documentation for medical devices like silicone breast implants. The technical documentation should contain information on the design of the product, the risk analysis, data of the clinical evaluation, the labeling and the instructions for use. For high risk medical devices notified bodies use the technical file as part of their assessment for market authorization of the devices.

3. What is the outcome of the assessment of the technical files?

The follow-up study shows that the technical files of all manufacturers have improved. However, manufacturers still need to further improve several items. These are mainly administrative in nature. In particular the items post market surveillance (PMS) and clinical evaluation need improvement.

Complete and accurate files are essential. They are the foundation for guaranteeing the performance and safety of medical devices for the patient. Shortcomings in the technical documentation do not necessarily lead to unsafe products. Other requirements for the development and production of implants also contribute to quality assurance.

4. What is the involved health risk?

The shortcomings in the technical files are not expected to have any negative effect on patient

safety.

5. What the Inspectorate's opinion on the outcome of the study?

The Inspectorate considers it to be important that manufacturers keep working on the improvement of the technical files. Immediate action of the Inspectorate on the shortcomings found is not necessary.

6. What actions will be taken by the Inspectorate regarding the outcome of this study?

The Inspectorate will take the following actions:

- The Inspectorate will inform all manufacturers about their individual results. The Inspectorate will urge the manufacturers to improve the shortcomings in the technical files and involve their notified body in this process.
- The Inspectorate will inform the involved notified bodies about the outcome of this study. The Inspectorate will also urge the notified bodies to take appropriate actions that will lead to improvement of the technical files.
- The Inspectorate will inform the involved Member States with a manufacturer and/or notified body on their territory about the results of the study. This should allow the Member States to monitor the improvements made by manufacturers and/or notified bodies in their country.

7. Are also actions taken on a European level?

The new regulation for medical devices will impose stricter requirements on implants, manufacturers and notified bodies. This legislation will fully apply in 2020. The new legislation includes stricter requirements concerning items where RIVM found several shortcomings Among others, these items concern post market surveillance and clinical evaluation.

Pending the new legislation notified bodies are already under increased surveillance by Member States who conduct joint inspections. This has already led to several notified bodies seizing their activities and/or implementing measures for improvement. Inspectors who perform these inspections will also receive the RIVM report.

8. I have breast implants of one of the investigated manufacturers, what should I do?

It is not necessary to take any additional measures or to contact your doctor. For more information on silicone breast implants the Inspectorate refers to the webpage with frequently asked questions (only available in Dutch).

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