Follow-up RIVM report "Silicone breast implants in the Netherlands - A market surveillance study"

State of affairs October 2017

Discrepancy silicone gel manufacturer SBI06 resolved
For manufacturer SBI06 RIVM found a gel in the implants that deviated from the gel described in the corresponding technical file. This discrepancy has been solved. Manufacturer SBI06 has been able to sufficiently demonstrate that they indeed use the gel RIVM found in the chemical analysis. Upon submission of the technical file in 2014, the manufacturer mistakenly added a 'technical specification sheet' to the technical file which belonged to another type of (also medical grade) silicone gel. NuSil Technology, the supplier of the raw silicone material, has confirmed that they provided the silicone gel to manufacturer SBI06 corresponding to the one found by RIVM. The Inspectorate and RIVM consider this shortcoming has been resolved.

Discrepancy silicone gel manufacturer SBI08 resolved
Manufacturer SBI08 provided a statement from NuSil Technology (the current owner of Applied Silicone which supplied the raw material at the time) which confirms that they provided a silicone gel to manufacturer SBI08 that chemically corresponds to the one found by RIVM. As a consequence, it was concluded that the discrepancy in the report concerning the gel used by this manufacturer was based on unintentionally provided erroneous information. The Inspectorate and RIVM consider this shortcoming has been resolved.

Implant with cyclosiloxanes
One single implant from manufacturer SBI08 contained a relatively high concentration of cyclosiloxanes. The level of cyclosiloxanes was higher than specified in the technical file submitted in 2014. The submitted documentation specified the levels of D4 and D5 cyclosiloxanes to be <20 ppm. However, one implant from manufacturer SBI08 contained >150 ppm D5 cyclosiloxanes. This specific implant was manufactured in 2009 and expired in 2014. Other implants from the same batch or production period were no longer available at the manufacturer, due to the date being expired. Therefore, it is unknown whether other implants from the same batch had a high concentration of cyclosiloxanes. Seventeen other implants from the same manufacturer with a later manufacturing date were tested and did not contain a high concentration of cyclosiloxanes. According to manufacturer SBI08, every manufacturer had the same specifications in 2009 and any manufacturer could have produced implants with similar levels of cyclosiloxanes. Nusil Technologies (the current owner of Applied Silicone which supplied the raw material at the time), has confirmed that manufacturer SBI08 received the same raw material as other manufacturers. NuSil Technologies also stated that the maximum volatile content (a mixture of volatile substances including D4/D5) was lowered in 2009 and also in 2012. This resulted in a 20 ppm maximum allowable D4/D5 content. However, NuSil Technologies did not specify the levels of D4/D5 in Applied Silicone gels in 2009. Therefore, it is not possible to compare the >150 ppm D5 found in one implant of SBI08 with the gels produced at that time.

Do the cyclosiloxanes pose a health risk?
Extensive research has been conducted into the risk of cyclosiloxanes. The scientific committee of the European Commission (SCENIHR) has published two reports, in 2012 and 2014. In addition, several other countries, such as France, the United Kingdom, Sweden and Australia conducted research into cyclosiloxanes. These studies were conducted after PIP implants were removed from the market because the manufacturer had fraudulently used silicone gel that was non-medical grade and had falsified the documentation. The study results indicate that cyclosiloxanes do not pose an increased health risk. The studies only differ regarding the opinion on possible local

problems like inflammation as a consequence of the cyclosiloxanes.

Transparency of RIVM study results
At the start of the study it was decided to publish the results anonymously. However, the findings raised questions with plastic surgeons, hospitals and patients, in particular regarding the name of the manufacturer to which results belong. In an effort to reach more transparency, the Inspectorate called upon involved manufacturers by letter of November 18th (PDF file, 136 Kb), 2016 to lift the anonymity themselves. During discussions between the Inspectorate and the involved manufacturers, they appeared to be willing to lift the anonymity provided it would be lifted collectively. Agreement was reached on publishing the identification numbers and corresponding manufacturer names. They are provided in the table below.

Number	Name
SBI01	Groupe Sebbin SAS, France
SBI02	Nagor Ltd, UK
SBI03	Polytech Health & Aesthetics GmbH, Germany
SBI04	Allergan, UK
SBI05	Pérouse Plastie SAS, France
SBI06	Establishment Labs SA, Costa Rica
SBI07	Laboratoires Arion SAS, France
SBI08	Silimed, Brazil
SBI09	Eurosilicone SAS, France
SBI10	Mentor Medical Systems BV, Netherlands

Current state of affairs regarding actions of the Inspectorate
At publication of the RIVM report in June 2016, the Inspectorate announced several actions. They can be found below with the current state of affairs:

- The Inspectorate will inform each manufacturer about their individual results. The Inspectorate shall urge manufacturers to improve the shortcomings and contact their notified body.
  On June 9th, 2016 the Inspectorate informed the involved manufacturers of their individual results and urged them to improve the shortcomings. They have been working on these improvements in the past year. Furthermore, manufacturers indicated that several improvements had already been made in the period after the technical documentation was requested by the Inspectorate in 2014.

- The Inspectorate will inform the involved notified bodies about the study results. The Inspectorate also urges the notified bodies to take actions that will lead to the improvement of the technical documentation and quality assurance.
  On June 9th, 2016 the Inspectorate also informed the notified bodies about the study results. The Inspectorate urged them to improve the shortcomings. Currently, there is a limited number of notified bodies involved in the conformity assessment of breast implants. Following the Joint Action Plan of the European Commission, the surveillance of notified bodies has been intensified. As a consequence, several notified bodies have ceased

or limited their activities.

- Furthermore, the Inspectorate will inform the European regulators of the countries where the manufacturers and/or notified bodies are established about the study results. These regulators can monitor the improvements of manufacturers and/or notified bodies and take action when necessary.
  The Inspectorate informed all European medical device authorities about the report. Additionally, it was sent to the 'Joint Assessment Team' that is involved in the supervision of notified bodies.

- Together with the European regulators, the Inspectorate will establish a taskforce to ensure that involved manufacturers take the necessary improvement measures.
  In the week of publication of the report, the Inspectorate organised a teleconference with the authorities from the European countries where the involved manufacturers and/or notified bodies are established. Several regulators already contacted the notified body in their country. All manufacturers and notified bodies declared to have started working on improvements at that time. The regulators monitor these improvements.

The Inspectorate requested RIVM to conduct a follow-up study, allowing RIVM to assess the improvements made in the technical files. An additional report is expected before the end of 2017.