

(BIA-ALCL) Anaplastic large cell lymphomas in connection with breast implants – updated information

August 3rd, 2018

Affected products: Breast implants, all types, makes and models of all manufacturers

Background information:

Anaplastic large cell lymphoma (ALCL) is a rare type of non-Hodgkin's lymphoma of which there are several subtypes. In 2016 the World Health Organisation (WHO) defined a specific provisional type of ALCL: [Breast Implant-Associated ALCL \(BIA-ALCL\)](#). This provisional entity has since been widely clinically accepted as a definitive definition. The existing publications and reports indicate that those with breast implants have a very low, but increased, risk of developing BIA-ALCL.

European Task Force on BIA-ALCL:

Since the number of cases in Switzerland is very low (since 2012 Swissmedic has received 4 reports of BIA-ALCL), Swissmedic has decided to cooperate with a European Task Force in order to be able to profit from the scientific analyses and results of European authorities.

Swissmedic would therefore like to draw your attention to the latest publications issued by the French authority responsible for the safety of medicinal products and medical devices (ANSM) and the UK authority (MHRA):

Publication by ANSM (in French): [Publications, updated website](#)

Publication by MHRA (in English): [MDA/2018/027](#)

Information for doctors:

For recommendations on diagnosis and treatment please contact the Swiss association for plastic, reconstructive and cosmetic surgery, [Swiss Plastic Surgery](#), which has also been informed of the latest publications.

The professional association recommends that patients who undergo implant-based breast enlargement should be informed of the potential risk of BIA-ALCL during the consenting interview and document this in the consent form.

We would also ask you to record all breast implantations in the association's anonymously managed register and to report all cases of BIA-ALCL to Swissmedic. Please use the following [form](#) for this purpose.

Information for patients:

Please contact the doctor treating you if you have any questions. If you have been diagnosed with BIA-ALCL, ask the doctor treating you whether your case has been reported to Swissmedic.

Contact

Swissmedic, Swiss Agency for Therapeutic Products / Medical Devices Division / Hallerstrasse 7 / CH - 3012 Bern

Tel.: +41 58 462 02 23

Fax: +41 58 462 76 46

Internet: www.swissmedic.ch/md

E-mail medical.devices@swissmedic.ch