



# **Request for a scientific opinion on the safety of breast implants in relation to ALCL**

**SCHEER Hearing  
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# Background

- U.S.A. Food and Drug Administration first identified a possible association between breast implants and the development of ALCL in 2011

“FDA Update on the Safety of Silicone Gel-Filled Breast Implants” – June 2011 <https://www.fda.gov/media/80685/download>

- EU Taskforce on breast implants and ALCL + international partners
- May 2016 revision of the World Health Organization classification of lymphoid neoplasms

BIA-ALCL: “New provisional entity distinguished from other ALK<sup>-</sup> ALCL; noninvasive disease associated with excellent outcome.”

<https://ashpublications.org/blood/article/127/20/2375/35286/The-2016-revision-of-the-World-Health-Organization>

# Background

- Request to SCHEER for scientific advice on the current state of scientific knowledge on the possible association between breast implants and anaplastic large cell lymphoma

Advice October 2017

“Although the very low incidence of ALCL and the methodological limitations of the available information/studies do not currently allow for a robust risk assessment, the SCHEER recommends that a more in-depth evaluation be conducted on the possible association of breast implants with the development of ALCL.”

[https://ec.europa.eu/health/sites/health/files/scientific\\_committees/sc heer/docs/scheer\\_o\\_007.pdf](https://ec.europa.eu/health/sites/health/files/scientific_committees/sc heer/docs/scheer_o_007.pdf)

# Current mandate to SCHEER - general

- A significant body of scientific information was published between October 2017 and July 2019
- In July 2019 *“Request for a scientific opinion on the safety of breast implants in relation to anaplastic large cell lymphoma”*
- Wide involvement of experts and stakeholders was requested

# Current mandate to SCHEER - ToR

- Specific clinical indications and uses for various types of breast implants.
- BIA-ALCL clinical entity.
- State of the art knowledge in terms of incidence.
- Characterisation and classification of textures of the breast implant shells.
- Causal relationship; pathogenesis mechanisms; preventive explanation.
- Factors that may determine the risk; characterisation of breast implants in relation to ALCL and control measures to reduce the identified risks.
- Alternatives to breast implants.
- Needs for further research.

Reconstructive and augmentation

**Thank you for your attention!**