MHRA statement on Allergan

Medicines &
Healthcare products
Regulatory Agency

> We are aware Allergan have stopped selling textured breast implants and tissue expanders and intend to withdraw remaining supply in European markets.
>
> There is currently no evidence of an increased risk to patients and there is no need for people who have Allergan breast implants to get them removed or have any additional clinical follow-up.
>
> We are monitoring the situation closely and will provide updates as necessary.
>
> If you have any questions about your implants, please speak to your implanting surgeon or clinic.

Further information

The CE certificate for textured breast implants and tissue expanders manufactured by Allergan expired as of 16 December.

Allergan are working with their notified body GMED, based in France, to resolve the issue. In the interim, they have stopped selling textured breast implants and tissue expanders and intend to withdraw any remaining supply in European markets.

MHRA is acting as lead co-ordinator to make sure Allergan takes a consistent EU-wide approach.

We encourage anyone, patient, carer or healthcare professional, who is aware of a complication or adverse event associated with a medical device, to report to us via the Yellow Card scheme.

Allergan have issued a Field Safety Notice.

Allergan's global recall of Biocell textured breast implants and tissue expanders – 24 July 2019

Allergan have initiated a global recall of Biocell textured breast implants

and tissue expanders. This does not impact the EU market (including the UK) as Allergan suspended sales of the Biocell textured breast implants and tissue expanders, and withdrew remaining supply from the European market in December 2018. This means the affected devices do not currently hold CE mark and are not available for use in the UK.

The FDA (the US regulator) have noted Allergan's global recall of Biocell implants on their webpage, and in line with the UK advice, have not recommended the removal of devices already implanted from asymptomatic patients.

ANSM announcement 4 April 2019

We are aware of ANSM's announcement on specific types of breast implants, including Allergan's Biocell implants. Our advice has not changed and there is no need for people with these breast implants to have them removed. For more information see our BIA-ALCL guidance.

Published 19 December 2018
Last updated 25 July 2019 + show all updates

1. 25 July 2019 Added information about Allergan's global recall of Biocell textured breast implants and tissue expanders.
2. 24 December 2018 Updated to include a link to the Yellow Card Scheme.
3. 21 December 2018 Updated to include link to Field Safety Notice from Allergan.
4. 19 December 2018 First published.