

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.

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Press release: New environment protections set out in flagship bill

Today the Environment Secretary [published draft clauses on environmental principles and governance](#) to be included in an ambitious, broader Environment Bill set for introduction next year.

Announced by the Prime Minister in July, the Environment Bill will be an essential step to put environmental ambition and accountability at the heart of government.

It will create a new framework for environmental governance, demonstrating this government's strong commitment to maintain environmental protection as we leave the EU.

The body will provide independent scrutiny and advice, and hold government to account on development and implementation of environmental law and policy. The government believes the independent body should have a clear remit, acting as a strong and objective voice for environmental protection.

It builds on one of the largest responses to a [Defra consultation](#) on the requirements for this draft legislation. The level of public interest in the Environment Bill is clearly demonstrated through the 176,746 responses.

Environment Secretary, Michael Gove said:

Today we have published our [draft clauses for the Environment Bill](#) which place our environmental ambition and accountability at the heart of government.

They set out how we will create a pioneering new system of green governance, placing our 25 Year Environment Plan on a statutory footing. We will explore options for strong targets to improve our environment, and provisions on air quality, waste and water resource management, and restoring nature.

Our ambition is to be the first generation to leave the environment in a better state than that in which we found it. We will keep building on our successes by enhancing our environmental standards and delivering a Green Brexit.

Alongside the draft clauses, the government has published a policy paper setting out a broader vision for the UK's environment when we leave the EU.

These draft clauses will be part of a broader Environment Bill – introduced early in the second session of parliament – which will include legislative measures to take direct action to address the biggest environmental priorities of our age: air quality; the protection and enhancement of our

landscapes, wildlife and habitats; more efficient handling of resources and waste, and better management of our surface, ground and waste water. The policy paper also sets out how we will explore options to include additional cross-cutting targets for environmental improvement as part of our legislative framework.

The core elements [published in the draft clauses](#) are:

Environmental principles

- The environmental principles – such as the “polluter pays” principle or that the public should be able to participate in environmental decision-making – are fundamental to achieving our environmental ambitions. These will act as guiding principles to help protect the environment from damage and will encourage decision-makers to further consider the environment in the development of government policy.

The Office for Environmental Protection:

- A world-leading, green governance body will be established – the Office for Environmental Protection (OEP) – to uphold environmental legislation. The OEP will be an independent, statutory environmental body that will hold government and public bodies to account on environmental standards, including taking legal action to enforce the implementation of environmental law where necessary, once we leave the EU, replacing the current oversight of the European Commission.

25 Year Environment Plan

- The [25 Year Environment Plan](#) sets out how we will recover nature, replenish depleted soils, rid seas and rivers of the rubbish damaging our planet, cut greenhouse gas emissions, cleanse our air of toxic pollutants, and develop cleaner, more sustainable energy sources.
- The draft Bill proposes making it a legal requirement for government to have a plan for improving the environment, to monitor and report annually to Parliament on progress and update it at least every 5 years. The [25 Year Environment Plan](#), published in January, would become the first such plan, giving it the status and permanence to deliver our ambitious goals.

Currently environmental decisions made in the UK – from improving air and water quality to protecting endangered species – are overseen by the European Commission and underpinned by a number of these principles, such as the precautionary principle, sustainable development and the ‘polluter pays’ principle. While these principles are already central to government environmental policy, they are not set out in one place besides the EU treaties.

Our proposals are concerned with environmental governance in England and

reserved matters throughout the UK, for which the UK government has responsibility. However, we continue to explore with the devolved administrations whether they wish to take a similar approach. We would welcome the opportunity to co-design proposals with them to ensure they work across the whole UK, taking account of the different government and legal systems in the individual nations.

More detail on all policy areas will be published in due course.