Breast Implant Yellow Card form updates

The Yellow Card reporting form for reporting adverse incidents associated with breast implants and tissue expanders has been updated and is now available to use via the Yellow Card website.

Key updates to this form include, new questions to gain further information regarding the patients implant. In addition, safety specific questions related to Breast implant associated- anaplastic large cell lymphoma (BIA-ALCL) have been added to include prompts for diagnostic markers, presenting symptoms and patient treatment.

The updates to the form will be piloted with the aim to capture more information at the time of reporting and reduce the need for extensive follow-up questionnaires. During the pilot stage, we encourage reporters to provide as much information as possible.

Any feedback on the content and functionality of the Yellow Card form can be sent to yellowcard@mhra.gov.uk.

What to report

We strongly encourage healthcare professionals and anyone experiencing any symptoms they believe to be associated with their breast implants to report these through the Yellow Card scheme and include the following information where possible:

- Details of the implants, including manufacturer, model, batch number and surface texture.
- Details of problems with implants and when the problems started, including any diagnosis, tests and treatment.
- The implantation date and the age of the patient at the time.
- Whether the implants have been removed or replaced? Please give dates of when this happened and details of any replacement implants
- Whether the implants were put in for reconstructive or cosmetic reasons
- whether the patient had previous breast implants or tissue expanders and for how long

Every report contributes to our knowledge about breast implants and their usage and helps us to develop suitable safety guidance and take appropriate action where necessary.

There are specific reporting arrangements for healthcare professionals to follow in each region. Healthcare professionals should report incidents:

- in England and Wales to the Yellow Card scheme or via the Yellow Card app
- in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system

- in Northern Ireland to the Northern Ireland Adverse Incident Centre and their local incident recording system

Patients, parents, carers and their representatives across the UK should report adverse incidents involving medical devices directly to the MHRA using the Yellow Card scheme or via the Yellow Card app.

More information on medical devices incident reporting to the Yellow Card scheme can be found here.