Device-specific guidance for manufacturers on reporting adverse incidents under the European vigilance system

Breast implants

To be read in conjunction with the European Commission's guidelines on a medical devices vigilance system MEDDEV 2.12/1

What should be reported?

Manufacturers should notify the relevant competent authority (the MHRA in the UK) if:

- they know of any deterioration or malfunction of a breast implant, or any inadequacy in the instructions for use which has led, or might lead, to a serious deterioration in the state of health. This would include circumstances where:
  - a breast implant related problem results in a clinically relevant increase in the duration of a surgical procedure, as defined by the operating surgeon,
  - the cause of the breast implant related incident is not well defined, or involves a number of aetiological factors, and the manufacturer is unable to obtain further clarification within the reporting timescale.

- the breast implant has been subject to a Field Safety Corrective Action.

Many adverse incidents associated with breast implants will be reportable under the vigilance system. It is the manufacturer's responsibility to judge each incident on its own merit, and to ensure compliance with the statutory reporting requirements contained within the relevant national regulations.

The following examples are for illustrative purposes only and do **not** constitute an exhaustive list:

- valve failure (during or after implantation)
- unexpected breast swelling
- unexpected inflammatory reaction
- seroma / fluid collections
- infections related to sterility of implant
- inadequacy in the instructions for use
- systemic adverse reaction
- siliconoma
- lymphadenopathy
- silicone migration.

Periodic summary reporting

Some adverse incidents are appropriate for periodic summary reporting. Details of the timing and content of periodic summary reports should be arranged on an individual basis with the competent authority.

The following are examples of adverse incidents which may be considered for period summary reporting:

- shell rupture
- capsular contracture.

Adverse incident trending

Some adverse incidents are expected and foreseeable, and as a result may be considered not routinely reportable. These must all be clearly identified in the manufacturer's labelling, clinically well recognised and quantifiably predictable, well documented in the device master record with an appropriate risk assessment, and clinically acceptable in terms of individual patient benefit.

All such incidents should, however, be subject to trend analysis as part of the manufacturer's wider post-market surveillance process. The expected prevalence or rate of such events should be specified, and if an adverse trend emerges, this should trigger a vigilance report by the manufacturer to the relevant competent authority.

Examples of incidents which are generally only reportable if an adverse trend is identified are given below:

- infections if unrelated to implant sterility
- wrinkling of breast
- folding of implant
- swelling in immediate post-operative phase
- loss of nipple sensitivity.