Adverse Incident Reporting

Guidance for practitioners working in the non-surgical cosmetic sector.

This statement acts as a reminder to all regulated healthcare cosmetic practitioners of their professional obligations in reporting adverse incidents. It also serves to highlight the ethical responsibility that unregulated practitioners have in doing the same. This statement concerns the reporting of both medicines and medical devices of all types that fall within the remit of the Medicines Healthcare products Regulatory Agency, and where facility is provided through its Yellow Card scheme to enable such reporting.

It is important to be aware that the function of adverse incident reporting is solely to provide a layer of assurance and protection for patient safety. It is not intended to find fault or blame with individuals, including practitioners. For the mechanism to be fully effective, data are required, that is, information generated from the incidents reported. In this way trends can be identified, and problems detected at the earliest moment and action taken to minimise risk. Perhaps a notable example concerns PIP breast implants which resulted in the implementation a new registry to permit more efficient implant identification.

This statement further aims to provide cosmetic specific guidance on the factors to consider when determining whether or not to report an adverse incident. The decision to provide such guidance comes as a response to the growing understanding of the lack of information available, and the increasing evidence of underreporting of adverse incidents when compared to the anecdotal evidence. This is a concern shared by the MHRA and the JCCP.

Therefore, it should be understood that in the event of any doubt to report, a report should always be made.

The role of the patient in reporting adverse incidents is discussed in separate guidance. However, regulated professionals are reminded of their professional duty to advise those under their care that they can also report adverse incidents. Patients should be directed to the Yellow Card scheme accordingly:

Yellow Card | Making medicines and medical devices safer (mhra.gov.uk)

In addition to adverse incidents that have occurred or could occur, fake or counterfeit medicines and medical devices represent a significant risk to public safety. These can also be reported using the MHRA Yellow Card scheme and practitioners are encouraged to do so.

Adverse incident reporting permits the MHRA to take timely intervention to ensure the ongoing safety of medicines and devices and it is a key feature of the regulatory mechanism. The JCCP firmly believe that the process of reporting adverse incidents, and the information and understanding that is derived from this process, is key to patient safety and to the credible and professional standing of the sector.

What is an adverse incident?

With regard to medical devices, the MHRA has defined an adverse incident as:
"An event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons."

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What is meant by ‘potential’?

It is important to remember that incidents should be reported even in the event that no harm occurs. Such incidents would include ‘near misses’ and events that ‘almost’ or might cause harm to anyone involved directly or incidentally with the device.

What is meant by ‘unexpected’?

Practitioners should be familiar with the known risks that are summarised in the summary of product characteristics (SmPC), in the patient information leaflet (PIL) or in the instructions for user (IFU). At a national level, these events are expected to occur at a given rate or incidence and should still be reported. However, the practitioner must also report new or ‘unexpected’ adverse incidents not previously recorded in the product literature. This ensures the rapid detection of unrecognised hazards so that regulatory action can be taken to safeguard health.

Examples of reporting adverse events with medical devices in cosmetic procedures.

During a dermal filler treatment, the syringe (or needle) breaks. No harm came to the patient or practitioner but the potential for harm is evident. A report should be made.

A patient receives a vascular occlusion during a dermal filler procedure. The event is managed without harm to the patient. This event must be reported. The potential for harm remains a significant factor and the fact that the occlusion may be the result of practitioner error is not relevant in the decision to report.

A client notes that they suffered bruising after dermal fillers, although they are not concerned because the bruising presents no difficulty, and they understood that bruising might be expected. In this scenario the practitioner may decide not to report the incident since bruising was expected and caused no harm. However, should bruising be significant, for instance to cause significant emotional distress, or where a haematoma is present which may have negative physiological consequences, then a report should be made.

An adverse incident occurs as a result of an injectable cosmetic procedure, but the practitioner is uncertain if the product used is regulated as a medical device or not. In the event of doubt, it remains important to report this incident.

A client attends for hair removal using IPL and suffers with crusting after the procedure. This was not intended nor expected and the incident should be reported. The same would apply to other unwanted outcomes such as scarring, hyper and hypopigmentation or folliculitis, from all forms of light-based treatment.

It is important to remember that component parts, including needles, cannulae and syringes, are medical devices. Any failure of these that could lead to harm to the user, the patient or anyone involved must be reported.

Adverse Drug Reactions.

You should report suspected adverse drug reactions through the Yellow Card scheme to medicines, vaccines, herbal or complementary products, whether self-medicated or prescribed. This includes suspected adverse drug reactions associated with misuse, overdose, medication errors or from use of licensed, unlicensed, and off-label medicines. If in doubt whether to report a suspected adverse drug reaction, please complete a Yellow Card. It includes serious suspected reactions with a medicine and those that may be novel or a new medicine. You can also report suspected interactions. The events you report do not have to be considered serious and the practitioner, or person making the report, has only to ***suspect*** that the medicine caused the reaction to report it, rather than have the confidence of a definitive diagnosis.

Examples of reporting ADRs in cosmetic procedures.

A patient complains of an ‘itchy rash’ shortly after receiving botulinum toxin. The product was reconstituted with bacteriostatic 0.9% saline which is an unlicensed medicine. Despite the mixing of medicines, the use of an unlicensed medicine and any uncertainty regarding cause or diagnosis, this event should be reported.

Anecdotal evidence suggests to JCCP that the use of botulinum toxins on the platysma of the neck has caused dysphagia which was well tolerated and not reported. Not only is this an unwanted and unexpected result, but it also has the potential for serious consequences and must be reported accordingly.

A patient complains of brow (or eyelid) ptosis after treatment with botulinum toxin, which presents them with some difficulty. This is a known risk of botulinum toxin treatment. Despite this known risk and making the decision without reference to causative factors including, for instance, adherence to aftercare, the incident should be reported.

JCCP are aware of the increasing trend in procedures providing vitamins and other ingredients for wellbeing purposes by intramuscular injection or intravenous infusion. These procedures employ prescription medicines and adverse incidents associated with them must be reported. The incident may be directly associated with the medicine, for example nausea and vomiting after an injection of vitamin B12, or with the procedure, such as phlebitis after an infusion.

Other reporting requirements

Practitioners should, in addition, be familiar with other national, local and organisational reporting requirements, including those required by any professional regulator. In addition to reporting via the Yellow Card scheme, either online or using the MHRA app, practitioners are advised to inform the manufacturer or MHRA authorised distributor. For practitioners operating under the jurisdiction of the devolved administrations, they should be familiar with the reporting requirements in those countries.

For Northern Ireland: Northern Ireland Adverse Incident Centre (NIAIC) | Department of Health (health-ni.gov.uk)

For Scotland: Report an incident | National Services Scotland (nhs.scot)