Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Phase 1: Reporting

1 a). All Health Care professionals should report their complaints through the yellow card system. (*Please note each complaint should only be reported once and through the yellow card system will suffice for healthcare professionals.)*

1 b). Once the report has been logged via the Yellow card system the complaint will be assigned a **UNIQUE MDR#** number. *(Please note a new MDR# number is generated for each complaint so please retain for your records.)*

1c). If Healthcare professionals have provided consent to be contacted, please await further instructions from the Marketing Authorisation Holder/manufacturer before any other actions.

Phase 2: Response from Marketing Authorisation Holder

2 a). Once the Marketing Authorisation Holder/manufacturer has your MDR# response. A unique company reference number will be generated for each complaint. *(Please note a new unique reference number is generated for each complaint so please retain for you records)*

2b) The Marketing Authorisation Holder/manufacturer will acknowledge the information and share information with the DMRC (and reporter if consent has been shared) stating the unique MDR# and unique company reference number and further actions required to by reporter to aid our investigations.

Phase 3: Sample and Image Handling

The Marketing Authorisation Holder will be requesting samples/high definition images within the initial acknowledgement letters if required Please do not send any samples without prior notification by the MHRA or Marketing Authorisation Holder.

3a) To attach the description of complaint/yellow card/ initial email correspondence along with the company reference number and the MDR# numbers. (Adding *the description of complaint along with samples will help us manage samples more effectively*)

3b) Samples should not be sent to without being reported through the yellow card system and must have attached the description of complaint/yellow cards and reference numbers. As unidentifiable samples will be destroyed.

3c) Samples to be sent should be addressed accordingly (information available from DMRC) and packaged appropriate.

3d) Please note that the **MAH cannot** return the sample once the investigation is completed and for health and safety reasons the MAH **cannot accept any** exposed or contaminated needles; therefore, please **do not send** these onwards.

Please contact DMRC@mhra.gov.uk for any further queries.