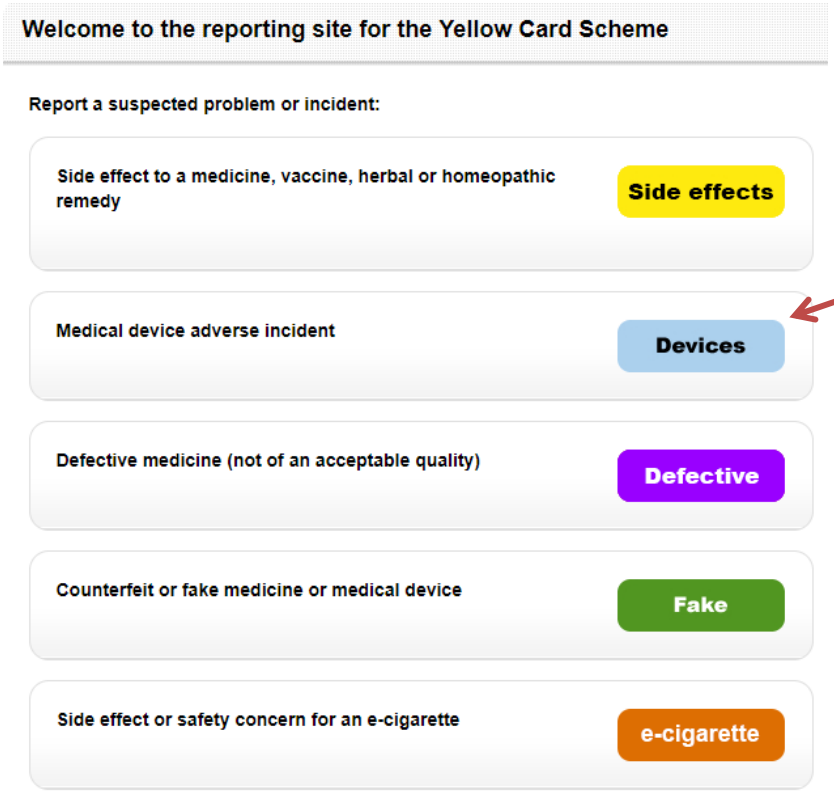
A Step by Step Guide to MHRA Reporting

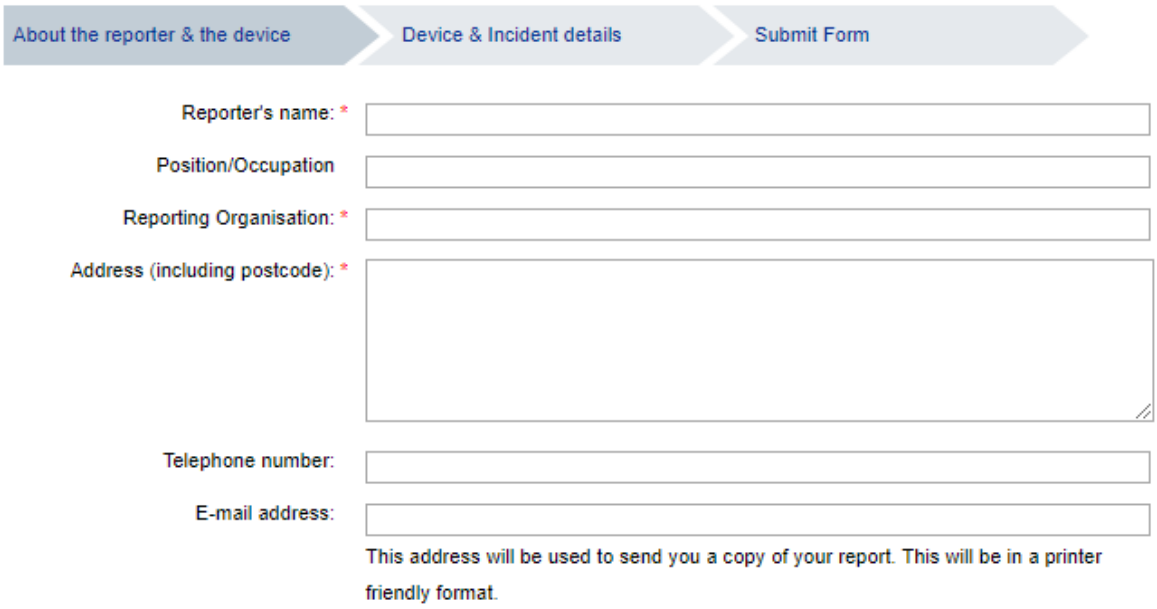
Please MHRA report all equipment defects. Examples include failed deployment of stents and balloons, coating coming away from guide wires and cannulas with defecting valves.

1) Go to https://yellowcard.mhra.gov.uk/ you can contact IT to add a link on your Trust's intranet

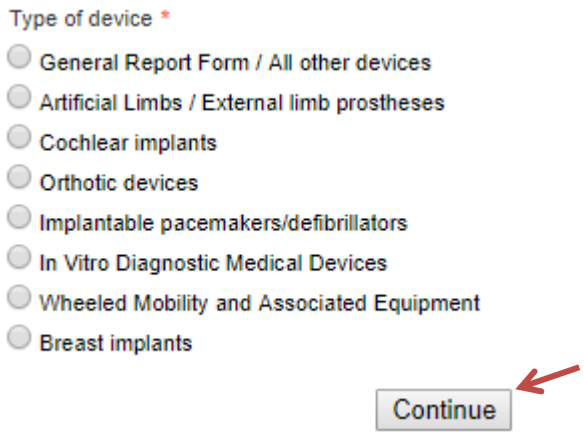
2) Select devices:



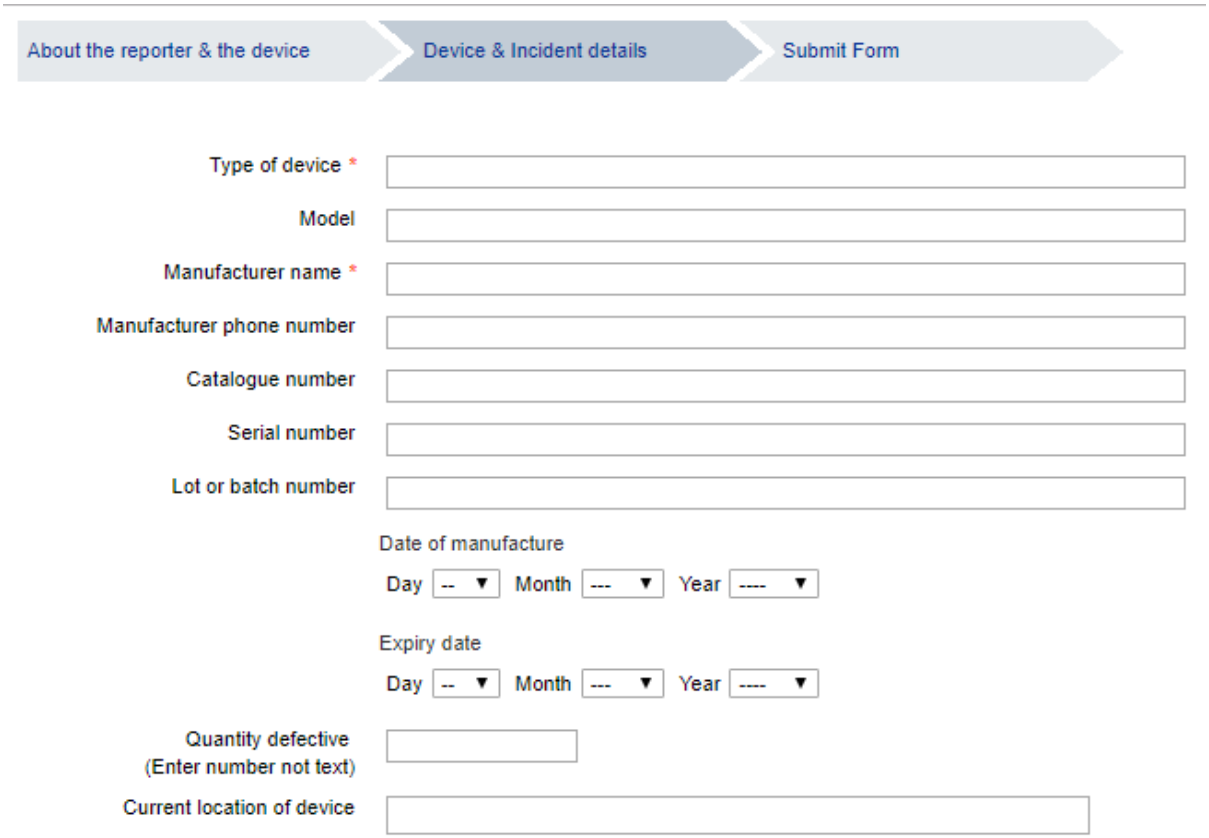
3) Fill in your details



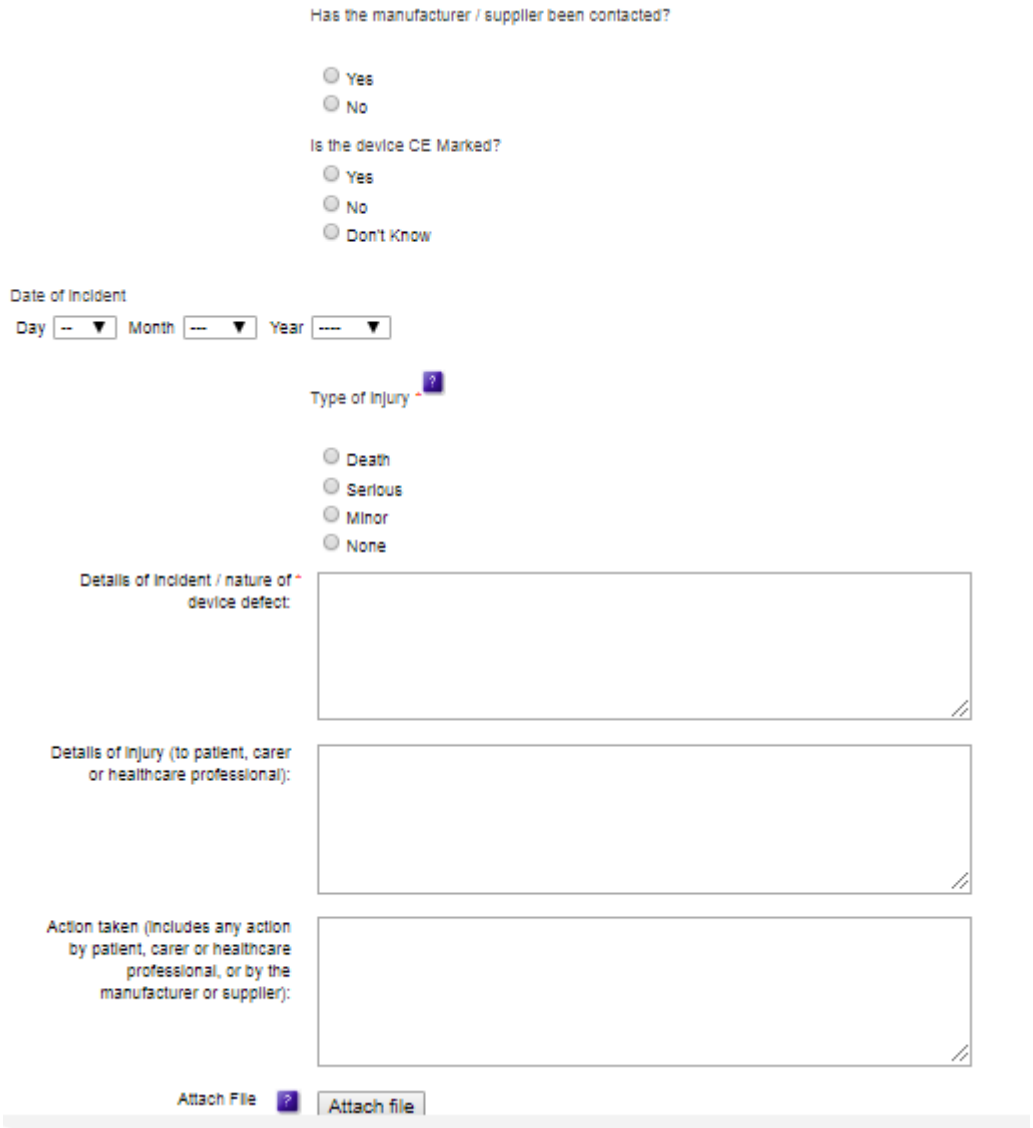
4) Select the type of device and the continue



5) Fill in the device details. Always keep the defective device as this will need returning to the manufacture for investigating:

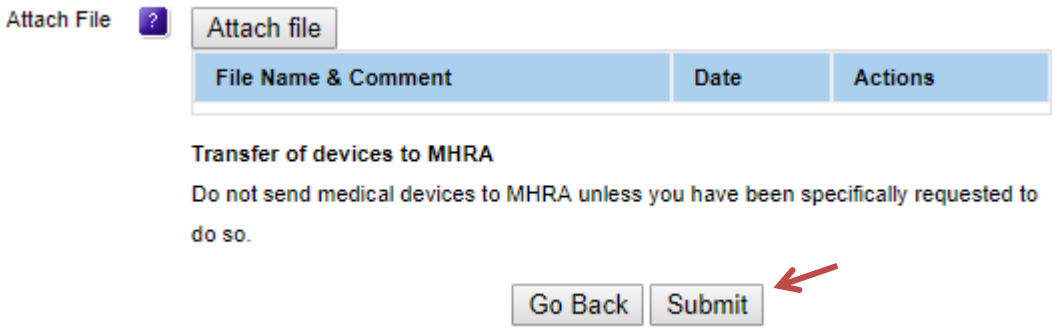


6) Additional Details: A bit like a regular incident/Datix form complete date of incident, whether manufacture is aware, is the product CE marked, injury to patient or outcome of incident



7) Attach any pictures or defect, product details (batch number and expiry in case a whole batch has to be recalled) or another other information that you think is relevant and click submit (for example: picture of the unemployed stent/balloon, wire coating becoming detached).

Note: Please keep in mind that even faults and defects in cannulas should be MHRA reported with the batch number and relevant details, otherwise batches cannot be re called for checking if there is a manufacturing defect/issue rather than a one off incident.



This process takes around 15 minutes and the more we report the better our records are and the better our evidence becomes on product safety. MHRA reporting can be completed by anyone at all levels and should be encouraged throughout departments. Treat MHRA reporting exactly the same as if you would record adverse drug reactions through the yellow card scheme, it is just as important.