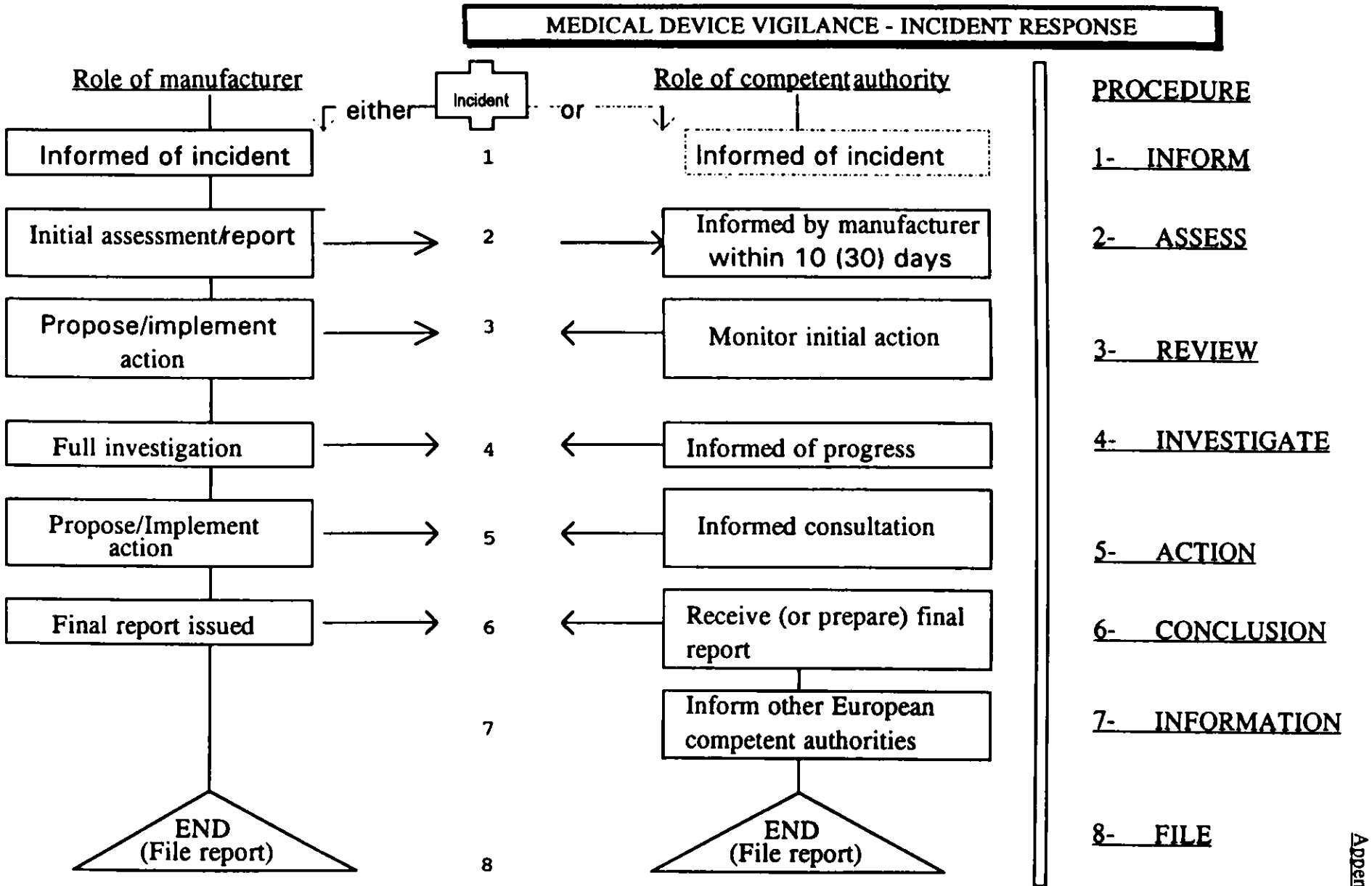
MEDICAL DEVICE VIGILANCE - INCIDENT RESPONSE
Role of manufacturer
either
Incident
or
Role of competent authority
PROCEDURE
Informed of incident
1
Informed of incident
1- INFORM
Initial assessment/report
2
Informed by manufacturer within 10 (30) days
2- ASSESS
Propose/implement action
3
Monitor initial action
3- REVIEW
Full investigation
4
Informed of progress
4- INVESTIGATE
Propose/Implement action
5
Informed consultation
5- ACTION
Final report issued
6
Receive (or prepare) final report
6- CONCLUSION
7
Inform other European competent authorities
7- INFORMATION
END (File report)
8
END (File report)
8- FILE

Appendix 6

INITIAL INCIDENT REPORT FORMAT

DESTINATION

☐ **Competent Authority**[1]

Address .....

.....

.....

REPORTING FIRM NAME : .....

.....

☐ *MANUFACTURER* ☐ *AUTHORISED REPRESENTATIVE*

ADDRESS .....

.....

.....

CONTACT PERSON NAME .....

.....

TELEPHONE NUMBER .....

TELEFAX NUMBER .....

REPORT DATE .....

MANUFACTURER NAME .....

.....

MEDICAL DEVICE COMMERCIAL NAME .....

.....

TYPE OF DEVICE [e.g. pacemaker, diathermy machine,...] .....

.....

MODEL OR CATALOGUE NUMBER .....

.....

SERIAL NUMBER(S) OR LOT NUMBER(S) .....

.....

ACCESSORIES/ASSOCIATED DEVICES (IF APPLICABLE) .....

.....

SOFTWARE VERSION (IF APPLICABLE) .....

.....

IDENTIFICATION NUMBER OF NOTIFIED BODY INVOLVED IN CONFORMITY ASSESSMENT

.....

.....

REPORTING FIRM HAS PREVIOUSLY REPORTED INCIDENTS INVOLVING THIS DEVICE?

.....Y/N

IF YES, TO WHICH COUNTRY (OTHER EEA COUNTRIES WHERE THE DEVICE IS ON SALE) .....

.....

INCIDENT REPORTED BY (USER OR OTHER SOURCE) .....

.....

ADDRESS .....

.....

TELEPHONE NUMBER .....

DATE REPORTED .....

INCIDENT DATE .....

INCIDENT DESCRIPTION .....

.....

.....

.....

OUTCOME : (E.G. DEATH, DETERIORATION IN HEALTH, ...) .....

.....

.....

MANUFACTURER'S PRELIMINARY COMMENTS .....

.....

.....

EXPECTED DATE OF FOLLOW-UP REPORT .....

.....

CORRECTIVE ACTION (IF ANY) .....

.....

.....

PROJECTED TIMING .....

.....

Note : submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the competent authority that the content of this report is complete or accurate, that the device(s) listed failed in any manner and/or that the device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

FINAL REPORT FORMAT

DESTINATION

☐ Competent Authority
Address .....

.....

.....

REPORTING FIRM NAME : Viamed Ltd .....

.....

☐ *MANUFACTURER* ☐ *AUTHORISED REPRESENTATIVE*

ADDRESS 15, Station Road Crosshills, Keighley West Yorkshire .....

UK BD20 7DT .....

.....

CONTACT PERSON NAME .....

.....

TELEPHONE NUMBER 44 1535 634542 .....

TELEFAX NUMBER 44 1535 635582 .....

INITIAL REPORT DATE .....

MANUFACTURER NAME .....

.....

MEDICAL DEVICE COMMERCIAL NAME .....

.....

TYPE OF DEVICE [e.g. pacemaker, diathermy machine,...] .....

.....

MODEL OR CATALOGUE NUMBER .....

.....

SERIAL NUMBER(S) OR LOT NUMBER(S) .....

.....

ACCESSORIES/ASSOCIATED DEVICES (IF APPLICABLE) .....

.....

SOFTWARE VERSION (IF APPLICABLE) .....

.....

IDENTIFICATION NUMBER OF NOTIFIED BODY INVOLVED IN CONFORMITY ASSESSMENT

.....

.....

REPORTING FIRM HAS PREVIOUSLY REPORTED INCIDENTS INVOLVING THIS DEVICE?

.....Y/N

IF YES, TO WHICH COUNTRY (OTHER EEA COUNTRIES WHERE THE DEVICE IS ON SALE) .....

.....

RESULT AND CONCLUSION OF MANUFACTURER'S INVESTIGATION .....

.....

.....

.....

.....

FURTHER INVESTIGATION (IF ANY) .....

.....

.....

.....

.....

CORRECTIVE ACTION (IF ANY) .....

.....

.....

.....

PROJECTED TIMING .....

.....

.....

.....

.....

Note : **submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the competent authority that the content of this report is complete or accurate, that the device(s) listed failed in any manner and/or that the device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.**