Kuwait Medical Device Incident Report
**Kuwait Medical Device Incident Report Investigation Scheme**

### What is it?

The Scheme is a responsibility under the umbrella of Pharmaceutical and Herbal Medicines Registration and Control Administration, Ministry of Health, Kuwait. It is intended to help maintain the standard of devices used in healthcare through voluntary co-operation between users, government and industry. Users could be patients or healthcare professionals. It should be used in conjunction with local reporting channels to provide additional means by which unsafe products or procedures can be identified quickly so that appropriate action is taken.

Use this form to report any suspected problems with a therapeutic device, which has or may present a health hazard.

Reports originating in Kuwait should be sent to the Pharmacovigilance team in the Pharmaceutical and Herbal Medicines Registration and Control Administration being the hub for receiving all safety reports. Such reports will be scrutinized and sent to the responsible entity for evaluation.

### What should be reported?

Typical problems include deficiencies in labelling, instructions or packaging, defective components, performance failures, poor construction or design. Suggestions for rectifying the problem or improving product performance would be appreciated.

### What happens to your report?

The report will be investigated and discussed with the manufacturer/supplier. You may be contacted for further information. If appropriate, the MDV team will assess the issue and it may also be reported to other Health Authorities. If action is considered necessary it may involve any of the following:

1. Recall - removal of goods from sale or use, or their correction, for reasons relating to safety, efficiency or quality.
2. Therapeutic Device Alert – urgent information to inform those responsible for the device, or affected by the problem.
3. Safety communication produced by the Pharmaceutical and Herbal Medicines Registration and Control Administration and distributed in Kuwait to convey information on medical devices or other appropriate channel(s).

### Medical Device Reporting Form for End Users and Healthcare Professionals

Use this form to report any suspected problem with a therapeutic device which may create a health hazard. A therapeutic device is any material instrument, apparatus, machine implement, contrivance, implant etc including any component, part or accessory which is used in healthcare and includes diagnostic reagents.
### A. Product Identification

*(Provide all available details. Where * appears, delete whichever is not applicable)*

<table>
<thead>
<tr>
<th>1. Product Type/ Application:</th>
<th>2. Brand/Trade* Name &amp; Model Number:</th>
<th>3. Serial/Batch/Lot* No.:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>4. Date of Purchase:</th>
<th>Date of Manufacturer:</th>
<th>Date of Expiry:</th>
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<table>
<thead>
<tr>
<th>5. Manufacturer’s Name/ Origin:</th>
<th>6. Supplier’s name:</th>
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<tr>
<th>7. Has the manufacturer been informed of the problem?</th>
<th>☐ Yes ☐ No</th>
</tr>
</thead>
</table>

*If yes, please supply the date and contact name:*

<table>
<thead>
<tr>
<th>8. Is the product/packaging* available for inspection?</th>
<th>☐ Yes ☐ No</th>
</tr>
</thead>
</table>

*(Please do not discard these items)*

### B. Problem Description:

**Consequences and history of problem**

*(Please include history, circumstances, consequences and where relevant sketches or explanatory information)*

### C. Report Identification

<table>
<thead>
<tr>
<th>1. Name or Initials:</th>
<th>2. Position/occupation:</th>
<th>3. Dept or institution:</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>5. Phone:</th>
<th>6. Fax:</th>
<th>7. Email:</th>
</tr>
</thead>
</table>

### D. Submitting the Form

Kuwait Ministry of Health
Drug and Food Control
Pharmaceutical and Herbal Medicines Registration and Control Administration

Email: [ADR_reporting@moh.gov.kw](mailto:ADR_reporting@moh.gov.kw)
Phone: +965 24811532
Fax: +965 24811507