Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

# PROPOSED FINAL DOCUMENT

**Title:** Post Market Resource Center

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# 1. Objectives

The Post Market Resource Center is a tool developed by Work Group 4 of AHWP to provide a ” one-stop” location for Regulatory Authorities (RAs) and the Medical Device Industry (Industry) to access to post-market regulations and reporting information easily across the world.

## 1. Adverse Event Reporting

### 1.1 Reporting System

(a) AHWP Members

(i) China (required access)
http://114.255.93.220/sso/login?service=http%3A%2F%2F114.255.93.220%2FPF%2FcasAuthUser

(ii) Chinese Taipei (required access)
https://qms.fda.gov.tw/tcbw/
http://www.fda.gov.tw/TC/siteContent.aspx?sid=4243#.V1TYX_l97Dc

(iii) Hong Kong SAR
http://www.mdco.gov.hk/english/report/report.html

(iv) Kingdom of Saudi Arabia
http://ncmdr.sfda.gov.sa/

(v) Malaysia
http://www.mdb.gov.my/mdb/index.php?option=com_content&task=view&id=13&Itemid=36

(vi) Republic of Korea
(required access)
https://emed.mfds.go.kr/

(vii) Singapore:
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Safety_Information_and_Product_Recalls/Report_Adverse_Events_related_to_health_products.html

(b) GHTF Countries

(i) Australia
https://www.tga.gov.au/medical-devices-safety

(ii) Canada
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php

(iii) EU

A. France (French only)
http://ansm.sante.fr/Declarer-un-effet-indesirable/Votre-declaration-concerne-un-dispositif-medical/Votre-declaration-concerne-un-dispositif-medical/Votre-declaration-concerne-un-dispositif-medical-Vous-etes-un-fabricant-un-distributeur

B. Germany
http://www.bfarm.de/EN/MedicalDevices/vigilance/_node.html;jsessionid=72F58EBAF78E6D914DE67BA5A2BA5311.1_cid340

C. Switzerland
https://www.swissmedic.ch/medizinprodukte/02675/02677/index.html?lang=en

D. UK
https://www.gov.uk/guidance/send-and-receive-information-on-adverse-drug-reactions-adrs

(iv) Japan
http://www.e-gov.go.jp/shinsei/index.html

(v) United States
http://www.fda.gov/Safety/MedWatch/default.htm

1.2 Reporting Form

(a) AHWP Members

(i) China
http://114.255.93.201/xzzx/

(ii) Chinese Taipei
http://www.fda.gov.tw/tc/includes/SiteListGetFile.ashx?mid=133&id=10510&chk=bae3b545-aea6-4307-928d-83ae4aab790b

(iii) Hong Kong SAR
http://www.mdco.gov.hk/english/mdacs/mdacs_af/files/LRP_Adverse_Incident_Reporting_form.doc

(iv) Kingdom of Saudi Arabia
http://ncmdr.sfda.gov.sa/

(v) Malaysia
http://www.mdb.gov.my/mdb/index.php?option=com_content&task=view&id=19&Itemid=115

(vi) Republic of Korea

[서식_1]_의료기기
_이상사례_보고서(

(vii) Singapore
http://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical_Devices/Updates_and_Safety_reporting/Adverse_Event_Reporting/Interactive_Industry%20Adverse%20Event%20Report%20Form_Aug%202015.pdf

(b) GHTF Countries

(i) Australia
https://www.tga.gov.au/sites/default/files/devices-argmd-p3.pdf

(ii) Canada
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php

(iii) EU
http://ec.europa.eu/DocsRoom/documents/15506/attachments/3/translations/en/renditions/native

A. France (French only)
http://ansm.sante.fr/Declarer-un-effet-indesirable/Votre-declaration-concerne-un-dispositif-medical/Votre-declaration-concerne-un-dispositif-medical/Votre-declaration-concerne-un-dispositif-medical-Vous-etes-un-fabricant-un-distributeur

B. Germany
http://www.bfarm.de/EN/Service/Formulare/medDev/mp-forms-startseite_en.html

C. Switzerland
https://www.swissmedic.ch/medizinprodukte/02675/02677/index.html?lang=en

(iv) Japan
http://www.pmda.go.jp/safety/reports/mah/0014.html

(c) GHTF
http://www.imdrf.org/documents/doc-ghtf-sg2.asp

1.3 Guidance Notes

(a) AHWP

(i) China
http://114.255.93.201/zcfg/ylqx/

(ii) Chinese Taipei
http://www.fda.gov.tw/TC/includes/GetFile.ashx?mID=133&id=28272&chk=0a6a912d-ee52-4e08-ad74-9d882c91aaba

(iii) Hong Kong SAR ([GN-03] Guidance Notes for Adverse Incident Reporting by Local Responsible Persons)
http://www.mdco.gov.hk/english/mdacs/mdacs_gn/files/gn_03.pdf

(iv) Kingdom of Saudi Arabia
http://ncmdr.sfda.gov.sa/

(v) Republic of Korea

- **Reporting Manual for Health Care Professional, Industry, and Patient**
  http://www.mfds.go.kr/index.do?searchkey=title:contents&mid=695&searchword=부작용&cd=&pageNo=1&seq=11503&cmd=v
- **Guidelines per specific product categories**
  - Soft Contact Lens, Filler, Cardiac Stent
    http://www.mfds.go.kr/index.do?searchkey=title:contents&mid=1161&searchDivision=의료기기&searchClass=&searchword=유해사례&searchSubDivision=&pageNo=1&seq=7285&cmd=v
  - Breast Implant, Hip Implant, Knee Implant
    http://www.mfds.go.kr/index.do?searchkey=title:contents&mid=1161&searchDivision=의료기기&searchClass=&searchword=유해사례&searchSubDivision=&pageNo=1&seq=5997&cmd=v

(vi) Singapore (GN-05: Guidance on the Reporting of Adverse Events for Medical Devices)
http://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical_Devices/Overview_Framework_Policies/Guidances_for_Medical_Device_Registration/GN-05-R2_Guidance%20on%20the%20Reporting%20of%20Adverse%20Events%20for%20Medical%20Devices.pdf

(b) GHTF Countries

(i) Australia
https://www.tga.gov.au/database-adverse-event-notifications-daen

(ii) Canada
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php

(iii) EU
https://ec.europa.eu/growth/sectors/medical-devices/guidance_en

(iv) Japan
http://www.pmda.go.jp/safety/reports/mah/0014.html

(v) United States
http://www.fda.gov/Safety/MedWatch/default.htm

## 2. Safety Information

2.1 Field Safety Information Reporting

(a) AHWP Members

(i) China (each CFDA at province level post its own information, a few key provincial CFDA website listed as follows:)
http://www.sda.gov.cn/WS01/CL0861/
http://www.shfda.gov.cn/gb/node2/yjj/aqgz/cpzh/ylqxcpzdzh/n5110/index.html

(ii) Chinese Taipei
http://www.fda.gov.tw/TC/siteList.aspx?sid=4275
http://www.fda.gov.tw/TC/site.aspx?sid=4232

(iii) Hong Kong SAR
http://www.mdco.gov.hk/english/safety/safety.html

(iv) Kingdom of Saudi Arabia
http://ncmdr.sfda.gov.sa/

(v) Malaysia

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(vi) Republic of Korea
(required access)
https://emed.mfds.go.kr/

(vii) Singapore
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Safety_reporting/Field_Safety_Corrective_Action.html

(b) GHTF Countries

(i) Australia
https://www.tga.gov.au/medical-devices-safety

(ii) Canada
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php

(iii) EU (Guidance Section 2.12 Market Surveillance)
(Guidance) https://ec.europa.eu/growth/sectors/medical-devices/guidance_en
(Form)
http://ec.europa.eu/DocsRoom/documents/15506/attachments/5/translations

A. France (French only)
http://ansm.sante.fr/Declarer-un-effet-indesirable/Votre-declaration-concerne-un-dispositif-medical/Votre-declaration-concerne-un-dispositif-medical/Votre-declaration-concerne-un-dispositif-medical-Vous-etes-un-fabricant-un-distributeur

B. Germany
(Guidance)
http://www.bfarm.de/EN/MedicalDevices/vigilance/_node.html;jsessionid=72F58EBAF78E6D914DE67BA5A2BA5311.1_cid340
(Form) http://www.bfarm.de/EN/Service/Formulare/medDev/mp-forms-startseite_en.html

C. Switzerland
https://www.swissmedic.ch/medizinprodukte/02675/02677/index.html?lang=en

D. UK
https://www.gov.uk/government/publications/report-a-non-compliant-medical-device-

enforcement-process

(iv) Japan
http://www.pmda.go.jp/safety/reports/mah/0014.html

(v) United States
http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm

2.2 Safety Alert Information

(a) AHWP Members

(i) China
http://114.255.93.201/xxtb_255/ylqxblsjxxtb/

(ii) Chinese Taipei
http://www.fda.gov.tw/TC/siteList.aspx?sid=4275
http://www.fda.gov.tw/TC/site.aspx?sid=4232

(iii) Hong Kong SAR
http://www.mdco.gov.hk/english/safety/safety.html

(iv) Kingdom of Saudi Arabia
http://ncmdr.sfda.gov.sa/

(v) Malaysia

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(vi) Republic of Korea
http://www.mfds.go.kr/index.do?mid=734

(vii) Singapore
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Safety_reporting/Field_Safety_Corrective_Action.html

(b) GHTF Countries

(i) Australia
https://www.tga.gov.au/alerts

(ii) Canada
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php

(iii) EU

A. France
(Safety Alert) http://www.ansm.sante.fr/S-informer/Informations-de-securite-Autres-mesures-de-securite#dm
(Recall)
http://www.ansm.sante.fr/S-informer/Informations-de-securite-Retraits-de-lots-et-de-produits#dm

B. Germany
http://www.bfarm.de/SiteGlobals/Forms/Suche/EN/kundeninfo_Filtersuche_Formular_en.html?nn=3497208&searchEngineQueryString=search+item

C. Switzerland
https://www.swissmedic.ch/rueckrufe_medizinprodukte/index.html?lang=en

D. UK
https://www.gov.uk/drug-device-alerts?keywords=&alert_type%5B%5D=devices&issued_date%5Bfrom%5D=&issued_date%

5Bto%5D

(iv) Japan
http://www.pmda.go.jp/english/safety/info-services/0014.html
(Urgent Notice)
http://www.pmda.go.jp/safety/info-services/devices/0092.html
(Safety Information- Japanese)
http://www.pmda.go.jp/safety/info-services/drugs/calling-attention/safety-info/0043.html
(Safety Information – English)
http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0002.html

(v) United States
http://www.fda.gov/safety/recalls/enforcementreports/