GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

FINAL DOCUMENT

Title: Post Market Resource Center

Authoring Group: Working Group 4: Post-Market

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This guidance document was the effort of Work Group 4 and drafted by Ms. Judy Cheung, Ms. Laleetha Devi, Mr. Karl Leung and Mr. Prashanth Srirangam.

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1. Introduction

The Global Harmonization Working Party (GHWP) works to encourage the convergence of regulatory standards in order to build a global framework for regulating medical devices across regulatory authorities and the industries. Additionally, it aspires to facilitate information and best practice sharing among members to hasten the convergence of medical device regulations.

2. Scope

The Post Market Resource Center is a tool developed by Work Group 4 of GHWP to provide a "one-stop" location for Regulatory Authorities (RAs) and the Medical Device Industry (Industry) to access post-market regulations and reporting information of various jurisdictions easily. The resources provided in this document will also be published on the GHWP website and regularly updated. To access the latest content, please visit the webpage of Post Market Resource Center (PMRC) (http://www.ghwp.info/node/809) . For latest post-market regulatory requirements in dividual jurisdictions, the relevant Regulatory Authority should be approached.

3. Reference

References from Regulatory Authorities are directly quoted as weblinks in Section 5 and Section 6.

Furthermore, Regulatory Authorities of GWHP and the International Medical Device Regulators Forum are:

GHWP – Regulatory Authorities of Members
http://www.ahwp.info/index.php/node/32

International Medical Device Regulators Forum – Regulatory Authorities of Members
https://www.imdrf.org/about

4. Definitions

For definitions of terms related to post-market regulatory activities of medical devices such as "reportable adverse event" in individual jurisdictions, please refer to the respective Regulatory Authority directly.

5. Adverse Event Reporting

5.1 Reporting System

(a) GHWP Members

(i) **People's Republic of China**
(Provisions for Medical Device Adverse Event Monitoring and Re-evaluation)
http://english.nmpa.gov.cn/2019-12/16/c_432476.htm

(ii) **Chinese Taipei**
https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030124

(iii) **Hong Kong SAR, China**
https://www.mdd.gov.hk/filemanager/common/mdacs/GN-03-E.pdf

(iv) **India**
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTg4NQ==

(v) **Indonesia** (Indonesian)
http://e-watch.alkes.kemkes.go.id/#home

(vi) **Republic of Korea** (Korean)
https://www.mfds.go.kr/eng/brd/m_40/list.do

(vii) **Malaysia**
https://www.mda.gov.my/industry/post-market-survellence-vigilance-pmsv/mandatory-problem-reporting.html

(viii) **Kingdom of Saudi Arabia**
https://ncmdr.sfda.gov.sa/Default.aspx
(New Reporting System)
https://ade.sfda.gov.sa/Home/NcmdrReport

(ix) **Singapore**
https://www.hsa.gov.sg/medical-devices/adverse-events

(x) **Thailand** (Thai)
https://medical.fda.moph.go.th/market-supervision/category/prepare-reports-of-abnormal

(b) International Medical Device Regulators Forum (IMDRF) Members

(i) **Australia**
(For Medical Device User)
https://apps.tga.gov.au/prod/mdir/udir03.aspx?sid=-1366318552

(For Sponsors and manufacturers)
https://apps.tga.gov.au/prod/mdir/mdirsummary.aspx?sid=-932782638

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

(iii) **European Community**

A. France (French)
https://sante.gouv.fr/soins-et-maladies/signalement-sante-gouv-fr/article/signaler-un-incident-resultant-de-l-utilisation-d-un-dispositif-medical
B. Germany
https://www.bfarm.de/EN/Medical-devices/Applications-and-reports/Incident-report/_node.html
C. Switzerland
https://www.swissmedic.ch/swissmedic/en/home/medical-devices/reporting-incidents---fscas.html

(iv) **United Kingdom**
https://www.gov.uk/government/collections/medical-devices-guidance-for-manufacturers-on-vigilance

(v) **Japan**
http://www.pmda.go.jp/english/safety/outline/0001.html

(vi) **United States**
https://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm

5.2 Reporting Form

(a) GHWP Members

(i) **People's Republic of China** (Chinese)
[Log In Required]
(National Medical Devices Adverse Event Monitoring Information System)
https://maers.adrs.org.cn/console/login.ftl

(ii) **Chinese Taipei** (Chinese)
[Log In Required]
https://www.fda.gov.tw/TC/siteContent.aspx?sid=2248
(Online Reporting Page [Log In Required])
https://qms.fda.gov.tw/tcbw/index.jsp

(iii) **Hong Kong SAR, China**
(For Local Responsible Persons)
https://eform.cefs.gov.hk/form/dh0038/en/
(For Medical Device Users)
https://eform.cefs.gov.hk/form/dh0039/en/

(iv) **India**
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDMwNg==

(v) **Indonesia** (Indonesian)
http://e-watch.alkes.kemkes.go.id/#laporan

(vi) **Republic of Korea** (Korean)
(Online Reporting Page)
https://uvoice.mfds.go.kr/guide.do#
(Reporting Form)
https://www.mfds.go.kr/eng/brd/m_40/view.do?seq=69732&srchFr=&srchTo=&srchWord=report&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=3

(vii) **Malaysia**
[Log In Required]
https://medcrest.mda.gov.my/login

(viii) **Kingdom of Saudi Arabia**
(Online Reporting Page)
https://ncmdr.sfda.gov.sa/ProblemReport.aspx
(For Medical Devices Manufacturer, Authorized Representative, Importer & Distributor [Log In Required])
https://ncmdr.sfda.gov.sa/Login.aspx

(ix) **Singapore**
https://www.hsa.gov.sg/adverse-events

(For Medical Device Dealer)
https://www.hsa.gov.sg/docs/default-source/hprg-mdb/mdar1_adverse-event-report_31-may-2023.docx?sfvrsn=1db7f78f_2
(For Medical Device User)
https://www.hsa.gov.sg/docs/default-source/medical-devices/adverse-report/mduae-form_22-jan-2020_interactive-form.pdf
(Online Reporting Form)
https://form.gov.sg/5c89abc277ef5300174c1ec7

(x) **Thailand** (Thai)
https://hpvcth.fda.moph.go.th/

(b) IMDRF Members

(i) **Australia**
(Online Report Page For Sponsor/ Manufacturer [Log In Required])
https://apps.tga.gov.au/prod/mdir/mdirsummary.aspx?sid=-1963842096
(Online Report Page For User)
https://apps.tga.gov.au/prod/mdir/udir03.aspx?sid=1910539005

(ii) **Canada**
https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/medical-device.html

(iii) **European Community**

A. France (French)
https://signalement.social-sante.gouv.fr/#/accueil
B. Germany
(For Clinical Trials or Performance Evaluation by Sponsors)
https://www.bfarm.de/SharedDocs/Formulare/EN/MedicalDevices/report_form_clinical_trials_SAE.html
(For Manufacturers)
https://www.bfarm.de/EN/Medical-devices/Applications-and-reports/Incident-report/_node.html
C. Switzerland
https://www.swissmedic.ch/swissmedic/en/home/medical-devices/reporting-incidents---fscas.html
(For Users & Operators)
https://www.swissmedic.ch/swissmedic/en/home/medical-devices/reporting-incidents---fscas/users---operators.html
(For Manufacturers & Placers on the market)
https://www.swissmedic.ch/swissmedic/en/home/medical-devices/reporting-incidents---fscas/hersteller---inverkehrbringer.html

(iv) **Japan** (Japanese)
https://ikw.info.pmda.go.jp/fuguai/kiki-new.html
(v) **United Kingdom**
https://yellowcard.mhra.gov.uk/

(vi) **United States**
https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities#2

5.3 Guidance Notes

(a) GHWP Members

(i) **People's Republic of China** (Chinese)
(Guidance for Medical Devices Registrant to Carry Out Adverse Event Monitoring)
https://www.nmpa.gov.cn/xxgk/ggtg/ylqxggtg/ylqxqtggtg/20200410153001855.html
(Code of Practice for Writing Periodic Risk Evaluation Reports for Medical Devices)
https://www.nmpa.gov.cn/xxgk/ggtg/ylqxggtg/ylqxqtggtg/20200702155401886.html
(Guidance for Medical Devices Registrant to Conduct Risk Evaluation of Adverse Events)
https://www.nmpa.gov.cn/xxgk/ggtg/ylqxggtg/ylqxqtggtg/20201127173533191.html

(ii) **Chinese Taipei** (Chinese)
https://www.fda.gov.tw/TC/siteList.aspx?sid=4273

(iii) **Hong Kong SAR, China**
https://www.mdd.gov.hk/filemanager/common/mdacs/GN-03-E.pdf

(iv) **India**
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTg4NQ==

(v) **Indonesia** (Indonesian)
http://e-watch.alkes.kemkes.go.id/files/flTYgsoof4wZ_Juknis%20Pelaporan%20KTD%20Alkes%202020.pdf

(vi) **Republic of Korea** (Korean)
(Public Official's Guide/Guidelines for Civil Petitioners)
https://www.mfds.go.kr/brd/m_210/list.do
(Medical Device Act Enforcement Regulation)
https://www.mfds.go.kr/eng/brd/m_40/view.do?seq=70111&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=2

(vii) **Malaysia**
https://www.mda.gov.my/industry/vigilance-unit/mandatory-problem-reporting.html
https://www.mda.gov.my/documents/guidance-documents/1476-mandatory-problem-reporting-60-60-10-june2020-2/file.html

(viii) **Kingdom of Saudi Arabia**
https://www.sfda.gov.sa/sites/default/files/2023-05/MDS_REQ%2011_V2_En.pdf

(ix) **Singapore**

(GN-05: Guidance On the Reporting of Adverse Events for Medical Devices)
https://www.hsa.gov.sg/docs/default-source/hprg-mdb/guidance-documents-for-medical-devices/gn-05-r2-1-guidance-on-the-reporting-of-adverse-events(2022-nov)_pub.pdf

(x) **Thailand** (Thai)
https://medical.fda.moph.go.th/market-supervision/category/prepare-reports-of-abnormal

(b) IMDRF Members

(i) **Australia**
(Medical Device Incident Reporting Guide)
https://www.tga.gov.au/resources/resource/guidance/medical-device-incident-reporting-mdir-guide
(Reporting Adverse Event FAQ)
https://www.tga.gov.au/resources/resource/guidance/reporting-adverse-events#faq

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

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

A. France (French)
https://sante.gouv.fr/soins-et-maladies/signalement-sante-gouv-fr/article/signaler-un-incident-resultant-de-l-utilisation-d-un-dispositif-medical
B. Germany
https://www.bfarm.de/EN/Medical-devices/Applications-and-reports/Incident-report/_node.html
C. Switzerland
https://www.swissmedic.ch/swissmedic/en/home/medical-devices/reporting-incidents---fscas.html

(iv) **United Kingdom**
https://www.gov.uk/government/collections/medical-devices-guidance-for-manufacturers-on-vigilance

(v) **Japan**
http://www.pmda.go.jp/english/safety/outline/0001.html

(vi) **United States**
https://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm
https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities

6. Safety Information

6.1 Field Safety Information Reporting

(a) GHWP Members

(i) **People's Republic of China**

(Regulations For Medical Device Recalls)
(Provisions For Administration Of Medical Device Recall)
http://english.nmpa.gov.cn/2022-10/25/c_824564.htm
(Guidance)
(Interpretation Of The Regulation For Medical Device Recalls)
https://www.nmpa.gov.cn/xxgk/zhcjd/zhcjdylqx/20170208143001854.html (Chinese)
(Interpretation Of The Regulation For Medical Device Recalls-Part 2)
https://www.nmpa.gov.cn/xxgk/zhcjd/zhcjdyp/20170524180901502.html (Chinese)
(Interpretation Of The Regulation For Medical Device Recalls-Part 3)
https://www.nmpa.gov.cn/xxgk/zhcjd/zhcjdylqx/20220411163131170.html(Chinese)
(Report Form)
(Notice On Matters Related To The Implementation Of The Regulation For Medical Device Recalls)
https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjylqx/20170428110901597.html
(Chinese)

(ii) **Chinese Taipei**

(Regulations for Medical Device Recalls)
https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030126
(Enforcement Rules On Medical Devices Act)
https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030121
(Guidance on Recall) (Chinese)
https://qms.fda.gov.tw/tcbw/%E8%97%A5%E5%93%81%E9%86%AB%E6%9D%90%E5%9B%9E%E6%94%B6%E4%BD%9C%E6%A5%AD%E9%80%9A%E5%A0%B1%E6%93%8D%E4%BD%9C%E6%89%8B%E5%86%8A.pdf
(Reporting Form [Log in required] (Chinese))
https://qms.fda.gov.tw/tcbw/

(iii) **Hong Kong SAR, China**

(Code of Practice for Local Responsible Persons)
https://www.mdd.gov.hk/filemanager/common/mdacs/COP-01E.pdf

(iv) **India**

(Guidance)
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTg4NQ==
(Report Form)
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDMwNQ==

(v) **Indonesia** (Indonesian)

(Guidance)
http://e-watch.alkes.kemkes.go.id/#download
(Online Reporting Form)
http://e-watch.alkes.kemkes.go.id/#laporan

(vi) **Republic of Korea** (Korean)
http://www.mfds.go.kr/eng/brd/m_40/view.do?seq=69732&srchFr=&srchTo=&srchWord=report&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=3
(Medical Device Act)
https://mfds.go.kr/eng/brd/m_40/down.do?brd_id=eng0011&seq=69729&data_tp=A&file_seq=6

(vii) **Kingdom of Saudi Arabia**
(Guidance)
https://www.sfda.gov.sa/sites/default/files/2023-05/MDS_REQ%2011_V2_En.pdf
(Reporting Form [log In Required])
https://ncmdr.sfda.gov.sa/Login.aspx
(New Reporting Form [log In Required])
https://ade.sfda.gov.sa/Account/Login?ReturnUrl=%2FNcmdr%2FNcmdrGhadRequest

(viii) **Malaysia**
https://portal.mda.gov.my/documents/guidance-documents/1436-field-corrective-action-gdac-29june2020-syedited/file.html

(ix) **Singapore**
(Guidance on Field Safety Corrective Action)
https://www.hsa.gov.sg/docs/default-source/hprg-mdb/guidance-documents-for-medical-devices/gn-10-r3-6-guidance-on-medical-device-field-safety-corrective-action(20jan-pub).pdf
(Guidance on Recall)
https://www.hsa.gov.sg/docs/default-source/medical-devices/gn-04-r2-2_guidance-on-medical-device-recall(17nov-pub).pdf
(Reporting Form [Log in Required])
https://www.hsa.gov.sg/medical-devices/field-safety-corrective-action/how-to-report

(x) **Thailand** (Thai)
https://www.fda.moph.go.th/sites/Medical/Pages/Main.aspx

(b) **IMDRF Members**
(i) **Australia**

(Recall Procedure)
https://www.tga.gov.au/resources/resource/guidance/uniform-recall-procedure-therapeutic-goods-urptg
(Online Web Form)
https://www.tga.gov.au/sites/default/files/2022-07/recalls-online-web-form-information-and-example-submission.pdf

(ii) **Canada**
(Guidance)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/problem-reporting/medical-devices-recall-guide-0054.html
(Report Form)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/medical-devices.html

(iii) **European Community**
(Guidance)
https://ec.europa.eu/growth/sectors/medical-devices/guidance_en

A. France (French)
(Guidance)
https://ansm.sante.fr/documents/reference/declarer-un-effet-indesirable/comment-declarer-si-vous-etes-fabricant-ou-distributeur-de-dispositifs-medicaux
(Report Form)
https://ec.europa.eu/docsroom/documents/32305/attachments/4/translations

B. Germany
https://www.bfarm.de/EN/Medical-devices/Applications-and-reports/Recall-report/_node.html

C. Switzerland
https://www.swissmedic.ch/swissmedic/en/home/medical-devices/reporting-incidents---fscas.html
(For Users & Operators)
https://www.swissmedic.ch/swissmedic/en/home/medical-devices/reporting-incidents---fscas/users---operators.html
(For Manufacturers & Placers on the market)
https://www.swissmedic.ch/swissmedic/en/home/medical-devices/reporting-incidents---fscas/hersteller---inverkehrbringer.html

(iv) **United Kingdom**
(Guidance)
https://www.gov.uk/government/collections/medical-devices-guidance-for-

manufacturers-on-vigilance
(Reporting Form [Log In Required])
https://more.mhra.gov.uk/login

(v) **Japan**
(Guidance)
https://www.pmda.go.jp/english/safety/outline/0001.html
(Reporting Form) (Japanese)
https://ikw.info.pmda.go.jp/fuguai/kiki-new.html

(vi) **United States**
(Guidance)
https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices
(Guidance of eSubmitter)
https://www.fda.gov/media/107333/download
(eSubmitter)
https://www.fda.gov/industry/fda-esubmitter/esubmitter-download-and-installation

6.2 Safety Alert Information

(a) GHWP Members

(i) **People's Republic of China** (Chinese)
(Safety Alerts)
(Medical Device Adverse Event Information Notification)
https://www.cdr-adr.org.cn/ylqx_1/Medical_aqjs/Medical_aqjs_xxtb/
(Recall)
https://www.nmpa.gov.cn/xxgk/chpzhh/ylqxzhh/index.html

(ii) **Chinese Taipei** (Chinese)
http://www.fda.gov.tw/TC/siteList.aspx?sid=4275
https://consumer.fda.gov.tw/Light/List.aspx?code=2010&nodeID=35
(Safety Monitoring List)
https://consumer.fda.gov.tw/People.aspx
(Safety Alerts)
https://consumer.fda.gov.tw/Light/List.aspx?code=2010&nodeID=35

(iii) **Hong Kong SAR, China**
https://www.mdd.gov.hk/en/safety-alerts-communications/safety-alerts-special-alerts/index.html

(iv) **India**
https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/Medical-Device-Diagnostics/

(v) **Indonesia** (Indonesian)
http://e-watch.alkes.kemkes.go.id/#download

(vi) **Republic of Korea** (Korean)
(Medical Device Safety Letter)
https://www.mfds.go.kr/brd/m_550/list.do
(Medical Devices Subject to Recall)
https://udiportal.mfds.go.kr/recall/MNU10035

(vii) **Malaysia**
https://portal.mda.gov.my/profesional/safety-alert.html

(viii) **Kingdom of Saudi Arabia**
https://ncmdr.sfda.gov.sa/Secure/CA/CaCompositeListing.aspx

(ix) **Singapore**
https://www.hsa.gov.sg/announcements

(x) **Thailand** (Thai)
https://hpvcth.fda.moph.go.th/category/safety-news/field-safety-notice-for-medical-devices/

(b) IMDRF Members

(i) **Australia**
(Safety Alert)
https://www.tga.gov.au/resources/alert
(Recall)
https://apps.tga.gov.au/PROD/SARA/arn-entry.aspx

(ii) **Canada**
http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php?cat=3

(iii) **European Community**

A. France (French)
(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
https://www.bfarm.de/EN/Medical-devices/Tasks/Risk-assessment-and-research/Field-corrective-actions/_node.html
C. Switzerland
https://fsca.swissmedic.ch/mep/#/

(iv) **United Kingdom**
https://www.gov.uk/drug-device-alerts?keywords=&alert_type%5B%5D=devices&issued_date%5Bfrom%5D=&issued_date%5Bto%5D

(v) **Japan**
(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
(Medical Device Recalls)
https://www.pmda.go.jp/safety/info-services/devices/0054.html

(vi) **United States**
https://www.fda.gov/MedicalDevices/Safety/default.htm