WG4 – Post-market

Chair: Ms Jennifer MAK (Dept of Health, HKSAR)

Co-Chair: Ms Kitty MAO (GE Healthcare, Singapore)

Advisors: Dr Jorge GARCIA (TGA, Australia)
Ms Joanna KOH (Singapore)

AHWP 21st Annual Meeting
24 Nov 2016, Cebu Philippines

AHWP
Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Updates (1)

- No. of WG members: 25 (including chair and co-chair)
  - 7 from Regulatory Authorities (Hong Kong, Indonesia, Korea, Saudi and Tanzania)
  - 18 from Industry (China, Chinese Taipei, Hong Kong, Indonesia, Korea, Malaysia and Singapore)

Updates (2)

- **Activities**
  - Review of WG4 work plan 2015-2107 & identification of work tasks in 2016
  - WG members grouped into 3 teams each working on a 2016 work task
  - Intra-team collaboration preparing draft document or taking forward the work task
  - WG telecons held on 10 Mar and 13 Oct 2016
  - Progress summary on WG4 matters for WG members (24 Dec 2015, 4 Feb , 26 Apr, 17 May, 15 Sep, 20 Oct & 17 Nov 2016)

Work Plan 2015 – 2017

Priority	Work Item	Deliverables	Timeline
1	Review and update the existing WG4 guidance documents on Adverse Events (AE) Reporting	Revised Guidance Document	2016 (completed)
2	Review the Safety Alert Dissemination System (SADS)	Review Report	2015 (completed)
3	Arrange Post-market Surveillance (PMS) Training	Training Sessions	2015 (completed)
4	Develop guidelines on Adverse Events (AE) reporting details for specific devices	Guidelines	2016
5	Review and update the existing WG4 guidance documents on SADS	Revised Guidance Documents	2016/2017
6	Develop guidance document for Adverse Event Trending based on GHTF documents	Guidance Document	2016/2017
7	Develop guidelines on proper handling of medical devices after complaint and AEs	Guidelines	2016/2017
8	Conduct survey on the status of post market systems (including both reportable AEs and FSCAs) and challenges of AWHP member economies	Survey Report	2016/2017
9	Identify post market systems (AE or safety alert) or guidance from various regulatory authorities and web sources	Hyperlinks for sharing at the AHWP website	2016

WG Progress Update (1)

since last AHWP TC Leaders Meeting in May 2016 (Seoul)

No.	Work Item	Status	Achievements	Timeline
1	Review and update the existing WG4 guidance documents on Adverse Events (AE) Reporting	**Completed**	• Proposed document conditionally endorsed in the 20th AHWP Annual Meeting and endorsed after the AHWP TC Leaders Meeting in 2016 • Finalized version available on the AHWP website	• 2016
2	Develop guidelines on Adverse Events (AE) reporting details for a specific type of devices	**In progress**	• Percutaneous Coronary Intervention (PCI) devices selected as the specific type • Proposed guidelines expected to be endorsed in Q4 2016	• Q4 2016

WG Progress Update (2)

since last AHWP TC Leaders Meeting in May 2016 (Seoul)

No.	Work Item	Status	Achievements	Timeline
3	Review and update the existing WG4 guidance documents on Safety Alert Dissemination System (SADS)	**In Progress**	• Proposed document expected to be endorsed in Q4 2016	• Q4 2016
4	Devise a post-market resource centre	**Completed with on-going updates**	• Initial version of the resource centre expected to be available in the AHWP website in Q4 2016	• 2016 and on-going

Guidelines for Adverse Event Reporting of PCI devices for Medical Device Manufacturer or its Authorized Representative (1)

- **Scope :**
  - Adverse event (AE) reporting guidelines for Percutaneous Coronary Intervention (PCI) device manufacturer or its authorized representative

- **Objective :**
  - To provide examples on reportable and non-reportable events related to PCI devices
  - To be read in conjunction with the AHWP adverse event reporting guidance of ref. AHWP/WG4/F001:2015

Guidelines for Adverse Event Reporting of PCI devices for Medical Device Manufacturer or its Authorized Representative (2)

Guidelines for adverse event reporting of Percutaneous Coronary Intervention (PCI) devices[1] for the Medical Device Manufacturer or its Authorized Representative

To be read in conjunction with the AHWP adverse event reporting guidance of ref. AHWP/WG4/F001:2015

Reportable events[2]	Non-reportable events
• Death or heart failure that is probably or possibly device-related	• Side branch occlusion[3]
• Cardiac tamponade (pericardial effusion) or cardiogenic shock	• Distal emboli (tissue, thrombotic/ thrombus, plaque)[3]
• Creation of distal air embolus	• Acute arterial perforation/ rupture/ dissection, not associated to malfunction of the device[3]
• Difficulty deflating the balloon or other delivery system or withdrawal complications	• Arrhythmias, including atrial and ventricular[3]
• Difficulty advancing the stent or crossing the lesion, not associated to procedural or patient factor	• Angina pectoris[3]
• Acute/ sub-acute stroke/ cerebrovascular accident	• Non-fatal bleeding complications, which may require transfusion/ haemorrhage[3]
• Balloon rupture (if used within rated burst pressure).	• Coronary artery spasm[3]
• Adverse reaction associated with the stent material and/ or delivery system materials, drug or polymer carrier if the reaction is not identified in the IFU	• Premature stent dislodgement with or without migration[3]
• Thromotic/ calcific occlusion or stenosis (in-stent and target vessel) or myocardial infarction (suspected to be stent-related)	• Difficulty advancing the stent or crossing the lesion, linked to procedural or patient factor[3]
• Incomplete stent apposition/ expansion (malapposition) or excessive recoil	• Infection – local and/ or systemic[3]
• Coronary or stent embolism	• Peripheral vascular or nerve injury[3]
• In vivo stent damage or deformation or device fragmentation or device fragment emboli migration	• Death or heart failure if there is evidence that it is not device-related
• Product defect e.g. device deformation (kink, bent, flare strut, break, twisted etc.), packaging compromised, foreign material, labelling issue & etc.	• Haematoma at the vascular access site
• Unanticipated serious injury	• Hypotension or hypertension stated in the IFU
	• Fever or infection or pain at insertion site stated in the IFU
	• Pseudoaneurysm stated in the IFU and not due to malfunction of the device.

[1] PCI (Percutaneous coronary intervention) devices – they are used in treating obstructive coronary artery disease with nonsurgical technique through percutaneous methods (commonly through femoral or radial arteries) e.g. coronary stents, balloons, guide wires

[2] Reportable adverse events must be reported to the relevant regulatory authority (ies) within the required timeframe. Please refer to the AHWP guidance document of ref. AHWP/WG4/F001:2015 for details

[3] Non-reportable events shall be reported when an adverse trend is identified

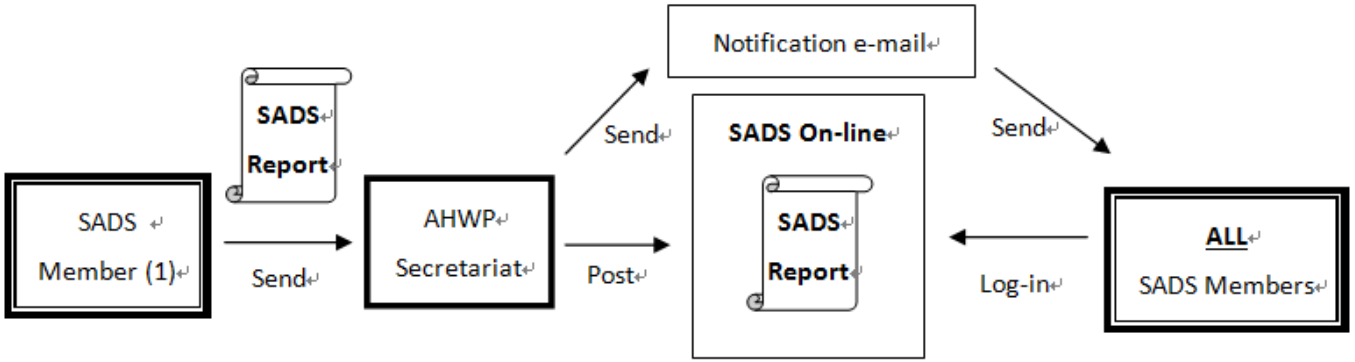
Guidance for Safety Alert Dissemination System (SADS) (1)

- **Scope :**
  - Guidance on the revised Safety Alert Dissemination System (SADS)

- **Objective :**
  - To provide guidance to Regulatory Authorities (RAs) on the following:
    - Structure of the SADS;
    - Roles and responsibilities of SADS members, manufacturers or their representatives (ARs) in the SADS;
    - Reporting criteria of the SADS report; and
    - Guidelines to fill in a SADS reporting Form

Guidance for Safety Alert Dissemination System (SADS) (2)

- **Summary:**
  - An updated and combined version of the following AHWP guidance documents on SADS:
    (a) Framework for AHWP Safety Alert Dissemination System (SADS) (AHWP/WG2/SADS/001)
    (b) Safety Alert Dissemination System: Safety Alert Dissemination Criteria, Procedures and Form (AHWP/WG2/SADS/002)
  - Contents covering definitions, scope, dissemination mechanism, roles of RAs, manufacturers and their ARs, reporting criteria and reporting form in relation to SADS are updated.



Post-market Resources Centre (1)

- **Scope :**
  - Hyperlinks on post-market regulations and reports
- **Objective :**
  - To provide a "One-Stop" location for easy access of post-market regulations and reporting globally
- **Summary:**
  - Hyperlinks (currently about 77) and some documents on
    - Adverse Event Reporting System, Form & Guidance Notes
    - Field Safety information Reporting & Safety Alerts
  - Covering different places, including
    - AHWP Members Economies – China, Chinese Taipei, Hong Kong SAR, Kingdom of Saudi Arabia, Malaysia, Republic of Korea and Singapore
    - GHTF Countries – Australia, Canada, EU (France, Germany, Switzerland and UK), Japan and the US

Post-market Resources Centre (2)

- **AE Reporting System (AHWP Members)**
  - China (Login required)
  - Chinese Taipei (Login required)
  - Hong Kong SAR
  - Kingdom of Saudi Arabia
  - Malaysia
  - Republic of Korea (Login required)
  - Singapore
- **AE Reporting System (GHTF Members)**
  - Australia
  - Canada
  - EU - France
  - EU – Germany
  - …


http://114.255.93.220/sso/login?service=
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Translate
国家药品不良反应监测系统
版本 CDR1.0-06
系统使用注意事项
下载IE8
1、 显示器的分辨率要求在1024*768或以上；
2、 系统支持微软IE 7、8、9、10版本浏览器，推荐使用IE8；
3、 系统在微软IE11及以上版本中，部分功能将无法正常使用；
4、 支持操作系统：Windows 2003、Windows XP或Windows 7;
5、 要求安装OFFICE2003或者更高版本；
6、 系统使用注意事项,请登录系统后在公告中下载。
用户登录
用户名：
密 码：
验证码：
5425
登 录
基层注册 忘记密码
联通
电信通
地址：中国，北京市西城区三里河一区3号院6号楼 邮编：100045
总机：8610-68586296 传真：8610-68586295
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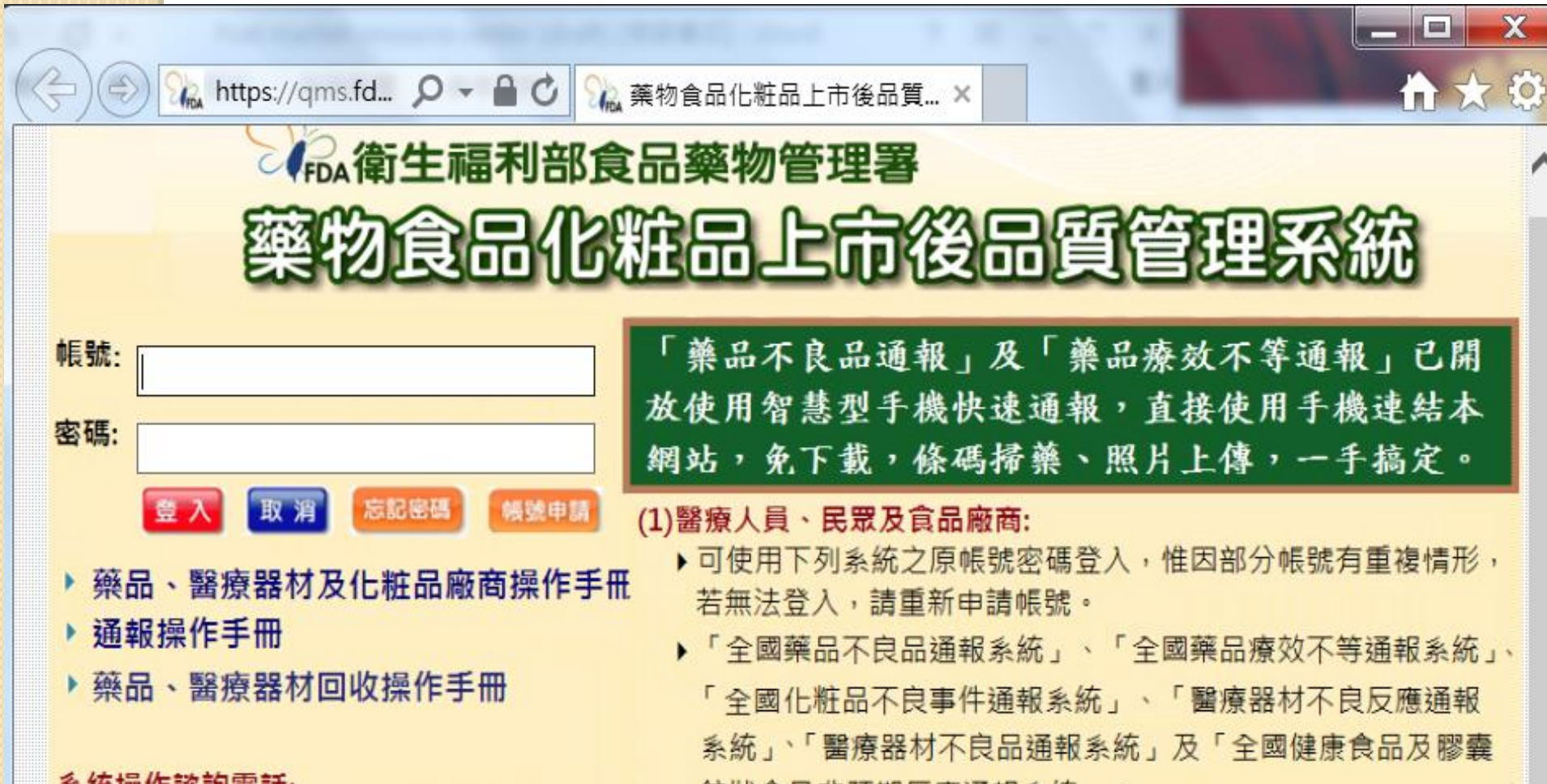
京ICP备05021355号-1


https://qms.fd...
藥物食品化粧品上市後品質...
FDA衛生福利部食品藥物管理署
藥物食品化粧品上市後品質管理系統
帳號:
密碼:
登入
取消
忘記密碼
帳號申請
「藥品不良品通報」及「藥品療效不等通報」已開放使用智慧型手機快速通報，直接使用手機連結本網站，免下載，條碼掃藥、照片上傳，一手搞定。
(1)醫療人員、民眾及食品廠商:
可使用下列系統之原帳號密碼登入，惟因部分帳號有重複情形，若無法登入，請重新申請帳號。
「全國藥品不良品通報系統」、「全國藥品療效不等通報系統」、「全國化粧品不良事件通報系統」、「醫療器材不良反應通報系統」、「醫療器材不良品通報系統」及「全國健康食品及膠囊
藥品、醫療器材及化粧品廠商操作手冊
通報操作手冊
藥品、醫療器材回收操作手冊

Medical Device Control Office

Report Adverse Incidents

Report Medical Device Adverse Incidents

The objective of this Medical Device Adverse Incident Reporting System is to improve the protection of health and safety of patients, users and others through information dissemination that may reduce the likelihood of, or prevent, repetition of adverse incidents, or alleviate consequences of such repetition.

This System is designed for the Local Responsible Persons to submit the reportable adverse incidents related to their listed products, and which are suspected to have caused death or serious injury, or which may lead to death or serious injury if it recurs. *The act of reporting an incident is not to be construed as an admission of manufacturer, user, or patient liability for the incident and its consequences. Submission of an adverse incident report does not, in itself, represent a conclusion by the manufacturer that the content of this report is complete or confirmed, that the devices listed failed in any manner. It is also not a conclusion that the device caused or contributed to the adverse incident.*

The Local Responsible Person is responsible to conduct investigations into the incidents of their listed devices and submit the report to the Medical Device Control Office as required under the Medical Device Administrative Control System. The incident could be reported by filling in the

Safety information

- Reporting problems & complaints
- Alerts
- Recalls
- Early warning system
- Safety information & education
  - Medicines safety
  - **Medical devices safety**
  - Database of Adverse Event Notifications (DAEN)

Home › Safety information › Safety information & education

A- A+ Share

Medical devices safety

Once a medical device has been included in the ARTG, the device must continue to meet all the regulatory, safety and performance requirements and standards that were required for the approval.

The TGA has mandatory requirements for all manufacturers and sponsors of medical devices.

Related information

- Medical Devices Safety Update

On this page: Adverse events | Medical devices safety monitoring

Adverse events

- Medical device incident reporting & investigation scheme (IRIS)
  The IRIS is responsible for the management of all reports of adverse events or problems associated with medical devices that are reported to the TGA
- IRIS inSite
  The IRIS inSite program works closely with health facilities to improve awareness about medical device adverse event reporting
- Database of Adverse Event Notifications (DAEN)
  Information from reports of adverse events that the TGA has received in relation to medical devices used in Australia

Medical devices safety monitoring

Post-market Resources Centre (3)

- **Guidance Notes (AHWP Members)**
  - China
  - Chinese Taipei
  - Hong Kong SAR
  - Kingdom of Saudi Arabia
  - Malaysia
  - Republic of Korea
  - Singapore
- **Guidance Notes (GHTF Members)**
  - Australia
  - Canada
  - EU - France
  - EU – Germany

  …

HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

SEPTEMBER 2013

MEDICAL DEVICE GUIDANCE

GN-05: Guidance on the Reporting of Adverse Events for Medical Devices

Revision 2

HSA
Health Sciences Authority

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MedEffect Canada

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Transparency
Regulatory Transparency and Openness
Completed Access to Information Requests
Proactive Disclosure

Drugs and Health Products

Guidance Document for Mandatory Problem Reporting for Medical Devices

Effective Date: October 3, 2011
Supersedes: January 2011
Cat.: H164-145/2011E-PDF
ISBN: 978-1-100-19423-3

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section.

(PDF Version - 201 K)

Foreword

Guidance documents are meant to provide assistance on **how** to comply with governing statutes and regulations. They also serve to provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document **may be** acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of marketed health products. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with relevant sections of other applicable guidance documents.

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  - EU - France
  - EU - Germany

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Medical Device Control Office

Safety Alerts and Communications

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Important Safety Alerts

[9 Nov 2016] Medical Device Safety Alert: Medimaps TBS iNsight

[8 Nov 2016] Medical Device Safety Alert: Leonhard Lang Defibrillation electrode SCHILLER DF87C and Defibrillation electrode SCHILLER DF56C

[7 Nov 2016] Medical Device Safety Alert: Teleflex LMA MAD Nasal Intranasal Mucosal Atomisation Device

[2 Nov 2016] Medical Device Safety Alert: Boston Scientific Lotus Edge Valve System

[31 Oct 2016] Medical Device Safety Alert: GE Healthcare XR 6000 systems

[27 Oct 2016] Medical Device Safety Alert: SynCardia Systems Temporary Total Artificial Heart Companion 2 Driver System and Freedom Driver System

[25 Oct 2016] Medical Device Safety Alert: Codonics Virtua / Virtua XR Medical Disc Publisher

[25 Oct 2016] Medical Device Safety Alert: Depuy Synthes FACET WEDGE System

[13 Oct 2016] Medical Device Safety Alert: Oscor Adelante Breezeway 8F and 10F

[13 Oct 2016] Medical Device Safety Alert: Abbott ARCHITECT Lactic Acid

[11 Oct 2016] Medical Device Safety Alert: Medtronic Pipeline Embolization Device (Pipeline Classic), Alligator Retrieval Device, Xcelerator Hydrophilic Guidewire, UltraFlow HPC Flow Directed Microcatheter and Marathon Flow Directed Microcatheter

[11 Oct 2016] Medical Device Safety Alert: St. Jude Medical Implantable devices- Fortify, Fortify Assura, Quadra Assura, Quadra Assura MP, Unify, Unify Assura and Unify Quadra

[6 Oct 2016] Medical Device Safety Alert: Boston Scientific Interject Injection Therapy Needle Catheter & Mustang PTA Balloon Peripheral Angioplasty Catheter

[28 Sep 2016] Medical Device Safety Alert: Medela UK (Type G) detachable power plugs of three models of Medela breast pump

Vigilance System

In according with the Act on Medical Devices (MPG) and the German Safety Plan for Medical Devices (MPSV), the Federal Institute for Drugs and Medical Devices (BfArM) ensures the central collection, analysis and evaluation of risks arising from the use or application of medical devices, in particular, adverse effects, interactions with other substances or products, contra-indications, falsifications, operational defects, malfunctions and technical defects and in so far co-ordinates the necessary measures to be taken.

In fulfilling these tasks, the Federal Institute for Drugs and Medical Devices collaborates with the authorities of the other states party to the Agreement on the European Economic Area and the Commission of the European Communities, the World Health Organization, the authorities of other countries responsible for public health as well as occupational safety and health, the authorities of the *Laender* responsible for public health, occupational safety and health, radiation protection, and metrology and other higher federal authorities which are concerned from a technical viewpoint, notified bodies in Germany, the competent occupational accident insurance funds, the medical advisory service of social health insurance, the pertinent professional societies, the manufacturers and distributors, as well as other bodies which compile data on risks associated with medical devices in the fulfilment of their tasks. If an incident is suspected to have been caused by an electromagnetic interaction with any device other than a medical device, the Federal Network Agency for Electricity, Gas, Telecommunications, Post and Railway (Bundesnetzagentur) shall be involved.

The MPG and the MPSV is available on the › Legislation website.

What types of incidents or recalls have to be notified?

Proposed Work Items in 2017

- Conduct a survey on the post-market system of AHWP members
- Develop guidelines on adverse events reporting of another type of device
- Compare global and local adverse event reporting
- Perform the biannual routine maintenance (hyperlink verification) of the post-market resource centre

ASIAN HARMONIZATION WORKING PARTY

Thank you