

JRC TECHNICAL REPORTS

Exploiting globally available safety information on medical devices to support EU market surveillance/vigilance

An analysis of available data sources and their systematic and consistent use

Faraulo F., Griesinger C. B.

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Contact information

Name: Claudius Benedict Griesinger
Address: Via E. Fermi 2749, I-21027 ISPRA (VA), Italy
Email: claudius.griesinger@ec.europa.eu
Tel.: +39 0332 78 6726

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Abstracts

Aim of the report

This report provides a thorough analysis of the totality of globally available regulatory data sources on alerts, recalls and other safety information on medical devices that, until now, have not been systematically used by any single regulatory authority, including the EU. This amounts to a potential considerable neglect of potentially valuable information on safety-related medical device issues encountered around the world. From an EU regulatory perspective, this is of particular importance in case such devices are also on the market in the EU. However since the issues may cover a large spectrum of post-market 'adverse events' / incidents (GHTF/SG2/N54R8:2006¹), they may inform also about more general issues, even if the specific product is not on the market.

The issues may range from medical device problems and failures that had no patient effects (yet), medical device problems with clear causal effects on patient/user health as well as adverse effects in patient/users that may be linked to the use of a given device or device type. Thus, such information is valuable from various perspectives by providing an additional data source for risk/signal detection complementing manufacturers' incident reports and thus providing means for early patient protection. Importantly, it could lead to the systematic detection of associations between specific products/product categories and adverse health effects and enable a better understanding of possible issues with materials, biocompatibility, procedure of use etc, opening ultimately possibilities to assess, in a more systematic manner, specific adverse health-effect *pathways*, thus leading to improved design ('safety-by-design' concept).

With regard to data types, the report focuses on *alerts* and *recalls*, as provided by the official websites of thirteen non-EU regulatory authorities. Thus, in contrast to the JRC's MediSys analysis tool which searches and monitors only media reports on medical devices, this report addresses *curated* information, i.e. which has been thoroughly assessed and approved for publication by official bodies.

The identified sources (webpages) and data types have been deeply analysed and described.

Moreover, during a period of six weeks, all alerts and recalls from the identified sources have been compiled and listed in tabular format (see supplementary material). This compilation can serve as a basis further work in view of exploring the most effective ways to use, in the context of vigilance and market surveillance activities, this information to detect safety problems in the EU territory and prevent or promptly react to them.

The analysis conducted in this report addresses the following key questions:

1. Are the **terminology and format** used worldwide sufficiently targeted and adequate to allow for effective analysis of information and detection of signals?
2. What are the benefits and added value of **automated collection and display** of globally available safety information for patient safety in the EU? Would it support the systematic use of such information?
3. Is **automated collection of such information technically feasible**? This would include intra- and extra EU alerts, recalls and other safety communications (e.g. Field Safety Notices and Incident Reports)
4. What are the **technical tools** that are required to create an effective functional system for automated and systematic collection, translation and preliminary analysis of global safety data?

¹ Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices.

Key findings

The report sets the framework of existing sources of alerts and recalls occurred in some of the most relevant markets of medical devices worldwide.

In particular, it describes these sources and outlines the main differences regarding the information they provide.

The report is complemented by a quantitative and qualitative analysis of real cases of global alerts and recalls collected over a six week period from official websites of selected regulatory authorities.

This compilation includes inputs and suggestions for further discussion regarding the potential value and usefulness of the information.

In this respect, the report shows a number of important issues relating to four key areas:

1. Data set

The amount of available data relating to alerts, recalls and other safety relevant communications is considerable.

Importantly, the terminology used by the different regulators to label specific pieces of information is not fully harmonised.

Furthermore, the information provided by the relevant authorities is displayed in fragmented ways, ranging from simple lists to structured databases.

2. IT and translation tools

The data to be retrieved throughout the different sources showed to be extensive, complex, fragmented, and of multilingual nature.

In light of this, specific IT tools in support of effective collection, analysis and display of information seem to be needed.

This includes translation tools from various languages into English, means of checking the identity of a given entity (e.g. company) etc.

3. Relevance of existing data for the EU

Only one of the analysed sources (i.e. FDA website) provides the list of countries (including EU members) where the given product affected by a safety issue is circulated on the market.

The information regarding the presence on the Union market of safety measures occurred outside Europe is key for EU CAs to timely react to possible problems in the EU.

However, even in case the devices is not on the market, the safety issue may point to flaw or failure relating to issues such as materials, biocompatibility or procedure which may be applicable to other devices and hence provide early warnings with regard to possible imminent safety issues.

4. Practical working procedure for data management

Globally available data on alerts and recalls and other safety relevant communications are not systematically and appropriately shared.

In order for the EU to take advantage of their potential, Member State (MS) CAs should ensure effective coordination and full share of similar information.

The report finally provides, as supplementary material, a data compilation of alerts and recalls collected during a six-week scoping exercise.

This activity was mainly conducted to provide relevant actors (e.g. EU CAs, Commission, other extra-EU regulators) with a real picture of the amount and type of global information which a regular monitoring activity could provide. The results of the scoping exercise are intended to serve as a basis for the identification of key issues relating to the management and exploitation of global alerts and recalls.

However, the results would be highly relevant for discussions at the level of the International Medical Device Regulators Forum: the implementation of one single tool that collects and displays globally available curated safety information (including from EU) and provides an English translation as well as an entity check, would support competent authorities worldwide and facilitate their cooperation in view of market surveillance, vigilance and patient protection.

1 Introduction

This report provides a comprehensive overview of additional official sources of information made publicly available by thirteen regulatory authorities responsible for vigilance of medical devices² outside the European Union, as provided through their governmental websites.

In particular, the document outlines and describes these extra EU sources of information (with a special focus on alerts and recalls) and stresses the important role that these data could play in support of the EU CAs for early detection of safety problems (signals) with medical devices in Europe.

In order to benefit from this key information, it will be of utmost importance to use it in a systematic way that allows identifying the relevance of the collected extra EU alerts and recalls for European territory, including the case when the concerned products are not placed on the Union market.

In order to establish a complete framework of the available safety communications, the report also contains a description of information other than alerts and recalls, such as Field Safety Notices (FSNs) and incident reports.

The analysis covers all the members³ of the International Medical Device Regulators Forum (IMDRF), except from the EU; in order to ensure geographic balance between the different regions of the world, this report also takes into account five of the biggest and most representative medical devices' markets among the non-IMDRF countries⁴.

The set of information described and analysed in this report is part of the effort of the Joint Research Centre (JRC) to facilitate the identification of means for a strengthened vigilance and market surveillance activity of the European Union in the field of medical devices. This may include a management tool for the systematic collection and preliminary analysis of globally available safety information for possible signal detection in the EU. With MediSys the JRC has already installed a tool for monitoring international media reports on medical devices. This could, in the future, be complemented by a tool for collecting regulatory information on alerts and recalls.

² The term medical device is meant to include also *in vitro* diagnostics and active implantable medical devices.

³ AUSTRALIA-Therapeutic Goods Administration, BRAZIL-Brazilian Health Surveillance Agency, CANADA-Health Canada, CHINA-China Food and Drug Administration, JAPAN-Pharmaceuticals and Medical Devices Agency, RUSSIA-Federal Service on Surveillance in Healthcare and Social Development, USA-Food and Drug Administration.

⁴ ARGENTINA-National Administration of Drugs, Food and Medical Devices, MEXICO-Federal Commission for the Protection against Sanitary Risks, NIGERIA-National Agency for Food and Drug Administration and Control, SAUDI ARABIA-Saudi Food and Drug Authority, SOUTH AFRICA-Department of Health.

2 A possible work procedure for the management of extra EU safety information: the NCAR exchange framework

The large amount of safety information available globally poses the issue of its regular monitoring and good management. It is therefore very important for the EU CAs to set up a system allowing for effective use and share of all collected extra EU safety information.

At EU level, the Competent Authorities for medical devices have put in place a working procedure to analyse safety problems occurred in their territory and exchange views regarding the actions needed.

This procedure is based on monthly teleconferences that are coordinated by the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) of European Commission in the framework of the activities of its Medical Devices Expert Group (MDEG) on Vigilance.

These teleconferences focus on the analysis of information on adverse events as disseminated through the National Competent Authority Reports (NCARs).

The information contained in the NCARs as well as the extra EU alerts and recalls fall in the vigilance/market surveillance area and both require a prompt and coordinated reaction by the EU Competent Authorities.

Therefore, the work procedure based on monthly teleconferences already applied to NCARs could possibly be expanded to extra EU alerts and recalls.

A coordinated management of this information would contribute to the improvement of the protection of health and safety of patients by reducing the likelihood of recurrence of incidents and preventing their repetition through the adoption of appropriate and concerted field safety corrective actions.

It is to be noted that this activity is closely related to the NCAR Exchange Program established by the Global Harmonisation Task Force (GHTF⁵) and currently being reviewed by the IMDRF.

Following the NCAR Exchange Program, 29 regulators committed to exchange confidential information on adverse events with regard to medical devices with global distribution.

The NCAR Exchange Program and the information shared at international level should therefore be taken into account by the EU CAs when analysing extra EU safety data.

⁵ The 'Global Harmonization Task Force (GHTF)' is a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia. GHTF was conceived in 1992 in an effort to respond to the growing need for international harmonisation in the regulation of medical devices. The GHTF mission ended in December 2012.

3 Analysis of publicly available sources of alerts, recalls and other relevant information

This section illustrates and describes the sources of information on alerts, recalls and other safety relevant information made available, through their official websites, by thirteen regulators in different regions of the world (See Chapter 1).

Although focusing on alerts and recalls, the report also takes into account other safety information potentially relevant for early detection of risks, problems or incidents with medical devices in the EU.

The review of the different sources of information showed that, the terminology used and the description provided by the different regulatory authorities to identify alerts, recalls and other warning information are quite heterogeneous.

It is, therefore, important to reflect on the development of an internationally harmonised "language" for the description of safety measures.

Future possible changes of the state of play of the sources relating to the jurisdictions covered by this report will be closely monitored and regular updates will be introduced, as needed.

In the same way, additional relevant regions of the world may be taken into account in the future.

3.1 IMDRF members

3.1.1 AUSTRALIA - Therapeutic Goods Administration

The Therapeutic Goods Administration ([TGA](https://www.tga.gov.au/)⁶) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating therapeutic goods including medicines, medical devices and *in vitro* diagnostics, blood and blood products.

Before being supplied in Australia, therapeutic goods, including contents and classification details, are registered by TGA in the Australian Register of Therapeutic Goods ([ARTG](https://www.tga.gov.au/australian-register-therapeutic-goods-artg)⁷) database.

The official webpage of the TGA includes a specific section called "safety information" which provides information on current and historic recalls of medicines and medical devices, advice issued by TGA about products, monitoring communications, information on reporting problems and how the safety of therapeutic products is monitored.

TGA provides a service for automatic safety information updates that can be activated through the following sections of its website:

- *"Medical Devices Safety Update email list" (system notifying subscribers when the latest version of the Medical Devices Safety Update is available on the TGA website,*
- *"Safety Information email list" (system notifying subscribers when new alerts, recalls and advisory statements are published on the TGA website).*

The information provided by this section of the TGA webpage is divided into the following sections.

Recalls

Recalls are conceived as those actions taken to resolve a safety, quality, efficacy or presentation problem or deficiency with a device already supplied in the market.

⁶ <https://www.tga.gov.au/>.

⁷ <https://www.tga.gov.au/searching-australian-register-therapeutic-goods-artg>.

Recall actions are grouped into the following three categories:

- *Recall - permanent removal of an affected device from supply or use in the market,*
- *Recall for product correction - device repair, modification, adjustment or re-labelling,*
- *Hazard alert - information issued to healthcare professionals about problems occurred to implanted device or biological product and advice about patients' management.*

Recall actions are classified based on the potential risk posed by the deficiency to patients/consumers according to the following three classes:

- *Class I recall - product deficiency is potentially life-threatening or could cause a serious risk to health,*
- *Class II recall - product deficiency could cause illness, injury or result in mistreatment,*
- *Class III recall - product deficiency may not pose a significant hazard to health, but other reasons could justify actions (e.g. quality related issues).*

A summary of recent recall actions, from 1 July 2012, are contained in the System for Australian Recall Actions ([SARA](#)) database.

Alerts

Alerts explain the outcome of an investigation, including recommendations for consumers and health professionals, a change to the availability of a product, or advise about detection of counterfeit or illegal products. The safety information section of the TGA website contains all [alerts](#) issued since 1998.

Early warning system

This [Early Warning System](#) provides current and historical information on safety concerns identified by the TGA vigilance program:

- a. Monitoring communications - Early communications about potential safety concerns which have not been fully investigated to highlight potential safety concerns that are identified by the TGA. It is to be noted that, following a monitoring communication, consumers should not stop using a device, health professionals should not change patient's treatment and not all of these concerns will result in actions, in particular when no link between the events and the product can be established. This section contains communications since 2013.
- b. Alert communications - Alert communications are issued after a safety concern having been investigated. Alerts contain more information on the safety concerns and provide advice on actions that may need to be taken by health professionals and consumers. Safety concerns may result in a recall action (removal of the product or corrective action), especially when a defective device is identified.

Reporting problems with MD

The TGA's Incident Reporting and Investigation Scheme ([IRIS](#)⁸) focuses on adverse events or incidents related to the use of medical devices and is based on investigations of adverse events or potential adverse events' reports from devices' users that can lead to actions such as product recalls, safety alerts, product improvement, user education and compliance testing. Adverse events can be reported manually or following specific online forms by device users (clinicians, patients or their relatives) and/or MFRs/sponsors. Once introduced, the report will be investigated and discussed with the manufacturer/supplier and, if TGA considers that an action is needed, it may involve any of the following:

- *Recall - removal or corrective measure due to safety, performance or quality reasons,*
- *Safety Alert - distribution of urgent information to the responsible for the device,*
- *An alert or advisory notice - general information through the website.*

⁸ <https://www.tga.gov.au/medical-device-incident-reporting-investigation-scheme-iris>.

Medical device incident reporting & investigation scheme (IRIS)

IRIS is the tool used by TGA to manage the medical devices' reports of adverse events or problems as received from consumers, health professionals and industry.

These reports received either manually or automatically, are then collected in a database after correctness and completeness being checked by TGA.

Adverse events reports are classified on a risk basis and actions are taken following a risk assessment analysis. The actions can include:

Informing health professionals and consumers through alerts and articles on the TGA's website and other publications,

- *Request for product improvement or for changes to IFU⁹ or labelling (e.g. warnings),*
- *Product recall from the market,*
- *Withdrawal of product market approval or restriction of use,*
- *Request for additional user education,*
- *Request for quality inspections,*
- *No request for actions but regular monitoring for trends' identification.*

Safety information & education

The "Safety information" section of the TGA webpage provides links to articles about the general safety of medicines and medical devices and allows accessing the medical devices Database of Adverse Event Notifications ([DAEN](#)¹⁰) database which provides information about adverse events related to medical devices in Australia.

3.1.2 BRAZIL - Brazilian Health Surveillance Agency

The National Health Surveillance Agency ([ANVISA](#)¹¹) is the regulatory agency of the Brazilian Ministry of Health which has as its main goal the protection and promotion of public health. To this aim, ANVISA conducts vigilance and market surveillance activities in several areas such as drugs, food, cosmetics, and medical devices.

In this respect, the ANVISA website includes two sections providing information on alerts ([Alertas sobre produtos para a saúde](#)) and reports on health products ([Informes sobre produtos para saúde](#)).

It is to be noted that, with the exception of a general introduction provided in English, the ANVISA website is in Portuguese only.

3.1.3 CANADA - Health Canada

[Health Canada](#) is the Federal department responsible for medical devices through its [Therapeutic Products Directorate](#)¹² (TPD) which is in charge of conducting the pre-market assessment of medical devices' safety, effectiveness and quality ensuring as well post-approval surveillance and quality systems in the manufacturing process.

The department routinely evaluates Canadian adverse event reports and, in case safety issues are identified, takes appropriate actions such as distribution of new product safety information, recommendation of changes to the product's labelling or request for product removal from the market.

⁹ Instructions for use.

¹⁰ <https://www.tga.gov.au/database-adverse-event-notifications-daen>.

¹¹ <http://portal.anvisa.gov.br/>

¹² <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/tpd-dpt/index-eng.php>.

Recalls and Safety Alerts Database

In addition, the Health Canada's Marketed Health Products Directorate ([MHPD](#)) has developed the [MedEffect](#) program to improve the safety, effectiveness and access to therapeutic products available. Through the MedEffect webpage it is possible to have access to a link to the [Recalls and Safety Alerts Database](#) that provides access to recalls, advisories, and safety alerts, including a newsletter with information about adverse events.

The Recalls and Safety Alerts Database includes safety alerts and recalls of different products (food, consumer products, vehicles and health products), however, the database search engine allows conducting targeted searches specific to medical devices.

Health Product Info Watch

Among the different sources of information on safety related problems, it is to be mentioned the [Health Product Info Watch](#).

It is a newsletter providing information on serious or unexpected side effects or adverse reactions suspected of being associated with health products, such as medical devices, to make people aware about safety issues with health products.

The newsletter also alerts about signals related safety issues detected during reviews of suspected adverse reaction cases, which are reported to Health Canada through the [Canada Vigilance Program](#) and the [Mandatory Problem Reporting for Medical Devices](#).

Canada Vigilance Adverse Reaction Database

Since 1965, the Canada Vigilance Program collects and assesses reports of suspected adverse reactions to health products, including medical devices, which can be accessed through the [Canada Vigilance Adverse Reaction Online Database](#).

Summary Basis of Decision documents: Medical Devices

The Health Canada web page provides access to the Summary Basis of Decision SBD documents that explain why Health Canada authorized certain MDs and IVDs for sale in Canada.

The documents include regulatory, safety, effectiveness and quality (manufacturing) considerations.

3.1.4 CHINA - China Food and Drug Administration

The China Food and Drug Administration ([CFDA](#)¹³) is the body responsible for the medical devices' legislation and its implementation, including market surveillance and vigilance. In order to carry out these activities, the CFDA is structured around two main departments dealing with medical devices:

- *Department of Registration,*
- *Department of Supervision.*

Apart from a specific section on the laws and regulations regulating the medical devices, no other information is provided through the English version of the CFDA official website.

On the opposite, the [Chinese version](#) appears to be much wider and could potentially include data on alerts and recalls and other related safety measures.

¹³ <http://eng.sfda.gov.cn/WS03/CL0755/>.

3.1.5 JAPAN - Pharmaceuticals and Medical Devices Agency

The Pharmaceuticals and Medical Devices Agency ([PMDA](#)¹⁴) is the Japanese regulatory body responsible to ensure the safety, efficacy and quality of medical devices.

The official website of the PMDA is an important source of information on recalls, alerts and other safety information as provided by the Japanese Marketing Authorization Holders (MAH) when a product that they have marketed might cause a hazard associated with the use of medical devices.

"Yellow Letter" and "Blue letter"

This section of the PMDA website includes the communications to be provided by the marketing authorisation holders to healthcare professionals by means of the so called "[Yellow Letter](#)" (Dear Healthcare Professional Letters of Emergent Safety Communications) and "[Blue Letter](#)" (Dear Healthcare Professional Letters of Rapid Safety Communications).

These letters are sent in cases where medical devices might cause hazards to patients, and measures need to be taken, including recall, suspension of sales, and information provision to prevent such hazards.

The Yellow Letter contains emergent and important medical devices' safety information.

The Blue Letter contains information that does not require emergent communications as Yellow Letter but should be promptly provided to alert healthcare professionals.

It is to be noted that this information is not always provided in English.

MHLW Pharmaceuticals and Medical Devices Safety Information

This section includes safety information collected by the Ministry of Health, Labour and Welfare (MHLW) to facilitate healthcare professionals when using medical devices. The English version of this section is for information purpose only and, in order to have a complete overview of all related data it is necessary to consult the [Japanese version](#), which also prevails in case of inconsistency with the information provided in English.

Revisions of PRECAUTIONS

This section includes [notices to revise the precautions](#) (warning, contraindications and adverse reactions/events) in product inserts. The notices are issued MHLW following a recommendation by PMDA.

It is to be noted that this information is available in English.

Notification on self-check

This section of the PMDA website contains MHLW's recommendations addressed to the marketing authorization holder to conduct self-check relating to the proper use of medical devices and, if needed, to adopt the needed revisions of the package inserts or user manuals. The English version of this section is for information purpose only and, in order to consult all related data it is necessary to consult the Japanese version, which also prevails in case of inconsistency with the information provided in English.

PMDA Medical Safety Information

"PMDA Medical Safety Information" section of the PMDA website includes the information analysed in the previous paragraphs in a more understandable and widely disseminated way, including data on medical incident reports, reporting of similar events, cases leading to notifications for revisions to package inserts and recommendations on a safe use of devices.

It is to be noted that, although this information being available in English, the Japanese version prevails.

¹⁴ <http://www.pmda.go.jp/english/about-pmda/index.html>.

3.1.6 SINGAPORE - Health Sciences Authority

The Singapore Health Sciences Authority ([HSA](#)) is structured into three main groups through which it carries out its mission. In particular, the Health Products Regulation Groups manages the regulatory framework on biomedical products which is responsible for medical devices and ensures that they meet appropriate safety, quality and efficacy standards. All information regarding medical devices registered in Singapore for use in human being under the Health Product Act (Medical Device Regulation) are made publicly available online through the Singapore Medical Device Register ([SMDR](#)) database.

HSA Vigilance/Post-market surveillance

Field Safety Corrective Action

As part of its vigilance post-market surveillance, HSA runs a system for the collection and share of Field Safety Corrective Actions (FSCA) in order to ensure safety of medical devices suspected of being potentially harmful to users, due to nonconformity to quality, safety and performance requirements. To this aim, all information on FSCA relating to both devices manufactured or supplied in Singapore and to devices that, although not supplied in Singapore, have marketing authorisation or have been imported in the country, must be reported to HAS according to specific guidelines and forms. These actions can include the removal of medical devices from the market or any other corrective action on devices in use. Usually, they are preceded by a Field Safety Notice (FSN) of the product owner (alternatively the registrant or importer) to inform operators and users regarding risks of medical devices and to advise about the measures to be taken in order to protect the health or the safety of patients, users or other persons. Also FSNs are made publicly available by HAS.

Adverse Event Reporting

In addition to FSCAs and FSNs, in order to ensure effective post-market surveillance and continued safe use of devices, HSA established a series of requirements including reporting of adverse events from healthcare professionals, mandatory reporting from manufacturers and dealers, and exchange of regulatory information with other medical device regulatory agencies. The report is to be submitted upon request of HSA. Specific guidelines and forms are established by HSA for each of the different kind of reporting. The adverse events to be reported are classified according to three main reporting criteria:

1. An adverse event (or potential adverse event) has occurred,
2. The device product is associated with the adverse event,
3. The adverse event led to one of the following outcomes:
 - *Serious threat to public health;*
 - *Death of a patient, user or other person;*
 - *Serious deterioration in state of health of patient, user or other person;*
 - *No death or serious injury occurred but the event might lead to death or serious*
 - *Injury of a patient, user or other person if the event recurs.*

The reporting timeline for adverse event reporting for dealers of device products are:

- *Within 48 hours for events that represents a serious threat to public health;*
- *Within 10 days for events that has led to the death, or a serious deterioration in the*
- *State of health, of a patient, a user of the medical device or any other person;*
- *Within 30 days for events where a recurrence of which might lead to the death, or a*
- *Serious deterioration in the state of health, of a patient, a user of the medical device or any other person*

Once the reports are received, HSA reviews them, conducts trend analysis and, if unexpected adverse effects are identified through the adverse event report, this can determine changes such as refinement of instruction of use or introduction of specific warnings. In case a hazard is considered unacceptable, the device could also be withdrawn from the market.

Safety Information on medical devices

The [safety information](#) section of the HSA website includes a series of information on enforcement, post-market vigilance and compliance activities of the HSA Authority, as well as product safety information and recalls.

As specifically regards medical devices, under this section it is possible to find alerts, safety messages (Product Safety Alerts), letters to healthcare professionals (Dear Healthcare Professional Letters), recalls, and label amendments (Safety-related Product Label Amendments).

Medical Device Alerts

As part of the HSA's post-market safety surveillance programme for medical devices, this website provides information on medical device safety issues or events in order to raise awareness amongst healthcare professionals.

In addition, it aims at encouraging reporting of adverse events by physicians, dentists and pharmacists.

Product Safety Alerts

This website provides safety messages on drugs, medical devices and related health products which have major impact on public health and safety.

Dear Healthcare Professional Letters

This website provides the abstracts of the Dear Healthcare Professional Letters (DHCPL), which are advisory letters to healthcare professionals by HSA, pharmaceuticals and medical device companies. For more details regarding the DHCPL, it is important to refer to the Health Professional Portal (HPP) of the Ministry of Health (MoH) Alert System (<http://www.hpp.moh.gov.sg/>).

Safety-related Product Label Amendments

This website provides information on labelling amendments made to the local package inserts.

Product Recalls

This website provides a list of products recalled by HSA as part of the Product Quality Surveillance programme. While not being an exhaustive list of all health products that could be the subject of a recall, the aim of this information is to alert consumers and healthcare professionals on some of the past recalls of health products in Singapore.

3.1.7 RUSSIA - Federal Service on Surveillance in Healthcare and Social Development

The Federal Service on Surveillance in Healthcare and Social Development ([FSSHSD](#)¹⁵) is the body of the Ministry of Health and Social development of Russian Federation responsible for the implementation of the Russian legislation on medical devices and drugs.

As regards alerts and recalls and other safety related information, although the Russian version of the FSSHSD website appears to provide this information, the English version only provides a general introduction to the different sections of the website.

¹⁵ <http://www.roszdravnadzor.ru/>.

3.1.8 USA - Food and Drug Administration

The Food and Drug Administration ([FDA](#)¹⁶) is the United States' national regulatory agency responsible for the medical devices' safety.

The FDA official website provides different kinds of information relating to the safety of medical devices which are divided in two main areas: *i) [Medical Device Safety](#)* and *ii) [Medical Device Ban](#)*.

The first area includes safety communications and medical device recalls while the second area provides information on post market surveillance measures, reporting of medical devices' problems, adverse events and news.

Medical Device Safety

Safety Communications

In this section, the FDA publishes communications addressed to consumers, health care providers, businesses and all other potential users of a specific device to alert about its malfunctioning (e.g. ineffective delivery system, chemical reactions) or about the risks relating to the use of the device and its characteristics.

The alerts contain information that may determine actions impacting both treatment and diagnostic choices for healthcare professional and patient. Therefore, the purposes of these communications can be different and go from *risk awareness rising* to *suggestion of better techniques for safe use* or *recommendation against its use of a product*.

The FDA issues such alerts after knowing about a problem with a device and this usually happens because FDA receives complaints and reports on adverse events or problems with the use of a device. Subsequently, verification such as an inspection of the relevant company's facility is conducted by the FDA to verify the problem at stake.

"[MedWatch](#)" is the FDA online tool giving access to the list of safety alerts.

Medical Device Recalls

This page of the FDA official website is dedicated to recalls of medical devices for which there is a reasonable chance that they could cause serious health problems or death.

In order to consult recalls relating to Class I and some Class II and III recalls it is possible to refer to the yearly lists of 2014, 2015 and 2016 whose the link is placed on the top left of the page. The list relating to 2013 is archived and the link is placed on the top right of the page.

The full list of Class II and III recalls is made available by the [CDRH](#) Recalls Database.

Adverse Event Reporting – Voluntary reporters

MedWatch also allows consumers or healthcare professionals voluntarily reporting significant adverse events or product problems with medical products to FDA.

In particular, through MedWatch consumers and healthcare professionals report serious adverse event, product quality problem, product use error, or failure associated with the use of a medical device. Suspected counterfeit medical products can also be reported to FDA through MedWatch.

Adverse events reporting system – Mandatory reporters

Reporting of medical adverse events is made mandatory for manufacturers, importers and user facilities (e.g., hospitals, nursing homes) through the Medical Device Reporting regulation (21 CFR 803) which sets the following reporting requirements:

¹⁶ <http://www.fda.gov/default.htm>.

- Manufacturers: - to report to FDA when one of their devices may have caused or contributed to a death or serious injury,
 - to report to FDA when one of their devices has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction happened again;
- Importers: - to report to FDA and the manufacturer when one of their devices may have caused or contributed to a death or serious injury,
 - to report only to the manufacturer when one of their devices has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to happen again;
- User Facilities: - to report suspected medical device-related death to both the FDA and the manufacturer,
 - to report a medical device-related serious injury only to the manufacturer, if known, otherwise to FDA.

Although not being obliged to do it, for the reporting of a malfunction or problems with medical devices user facilities can voluntarily use the MedWatch program to advise FDA.

Manufacturers and User Facility Device Experience Database

The Manufacture and User Facility Device Experience ([MAUDE](#)) database hosts the Medical Device Reports (MDRs) submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.

The reports include a brief description of the incident, with information about the device, manufacturer and the type of reporter. These reports, which refer to suspected device-associated deaths, serious injuries and malfunctions, are used by the FDA to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments. The MAUDE searchable database data contains the last 10 year's data and allows searching the FDA's Center for Devices and Radiological Health (CDRH). MAUDE database is updated monthly and the search page reflects the date of the most recent update.

Although being very useful for vigilance purposes, these reports present several limitations mainly due to their passive nature that could have an impact on the completeness, accuracy, MDR data alone cannot be used to establish rates of events evaluate a change in event rates over time or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices. In this respect, it should be taken into account that confirming whether a device caused a specific event can be difficult if based only on information provided in a given report and further verification of the circumstances surrounding the event or direct evaluation of the device could be needed.

It is also to be considered that safety information for a reported medical device should be interpreted in the context of other available information when taking decisions. Moreover, certain types of information contained in the reports are protected from public disclosure under the Freedom of Information Act (FOIA).

The FDA's Sentinel Initiative

The Sentinel Initiative is an FDA ongoing project aimed at developing an electronic system, complementing existing systems, to track adverse events of drugs, biologics, and medical devices on the market. The Sentinel System is based on a proactive approach, also known as active surveillance, through which the FDA actively queries diverse automated healthcare data sources such as health record systems, administrative and insurance claims databases, and registries to evaluate possible safety issues quickly and securely.

The FDA will therefore be able to actively request information from the Sentinel System data partners (e.g. academic medical centres and healthcare systems) when a safety question arises about a product. This proactive initiative complements the passive surveillance safety systems, such as MAUDE, currently in use by FDA, enabling the FDA to use existing electronic healthcare

The Sentinel Initiative has been launched in 2008 and is now being tested through a pilot project called "[Mini Sentinel](#)".

Medical Product Safety Network

The Medical Product Safety Network ([MedSun](#)) is an adverse event reporting program launched in 2002 by the FDA Centre for Devices and Radiological Health (CDRH) according to which a network of approximately 250 hospitals, nursing homes, and home health facilities, are required to report medical device problems that result in serious illness, injury, or death.

MedSun participants are also encouraged to voluntarily report problems with devices, such as 'close-calls,' potential for harm, and other safety concerns. This database collects reports with a brief description of adverse events related to devices.

As part of the MedSun network program, it is also to be mentioned the [MedSun Newsletter](#) containing information on newly approved devices, links to FDA/CDRH databases and other information sources and update list of recalls and safety alerts.

Medical Device Reporting database

The Medical Device Reporting (MDR) database allows you to search the CDRH's (Centre for Devices and Radiological Health) database information on devices which may have malfunctioned or caused a death or serious injury during the years 1992 through 1996.

The files contain reports received under both the mandatory Medical Device Reporting Program from 1984 to 1996, and the voluntary reports up to June 1993. The database currently contains over 600,000 reports.

The reports include a description of the adverse event, and information about the device and manufacturer.

It is no longer being updated, MDR after 1996 are included in MAUDE Database.

Medical Device Ban

This section of the FDA website regards those medical devices for which a ban has been declared, meaning that current and future sales, distribution, and manufacturing of the concerned devices are totally prohibited.

The decision of the FDA to adopt such a measure, which is very rare (only one till now¹⁷), is based on available data and information proving that the device presents a substantial deception to patients or users about the benefits of the device (risk-benefit analysis), or an unreasonable and substantial risk of illness or injury, which cannot be corrected by a change in the labelling.

In order to determine that a device is deceptive, the FDA considers whether users may be deceived or otherwise harmed by the device itself and the ban can be decided even in the absence of proof of illness or injury.

Once a regulation to ban a device is published in the Federal Register, the product can no longer be legally marketed except under an approved investigational device exemption.

¹⁷ Prosthetic hair fibers - Decision Effective from June 3, 1983.

3.2 Non-IMDRF members

3.2.1 ARGENTINA – National Administration of Drugs, Food and Medical Devices

The National Administration of Drugs, Foods and Medical Devices (ANMAT) is the medical devices' regulatory authority of the Argentinian Ministry of Health.

In particular, ANMAT is responsible for the authorization, registration, standardization, and vigilance and monitoring of devices with the specific purpose of ensuring their compliance with efficacy, safety and quality requirements.

Techno-vigilance Program

As regards the vigilance area, the ANMAT developed a [techno-vigilance program](#) aimed to collect, assess and manage medical devices' adverse events and carry out the most appropriate corrective actions, as needed.

This program achieves the early detection of adverse and/or unexpected events and also performance fails in the stage of widespread use.

The techno-vigilance dedicated page of the ANMAT website includes a form used to notify adverse events or technical fails with MD.

These notifications are assessed by a consultant committee composed of academic representatives, medical national associations and recognised professionals.

When it is proved a MD causing an adverse event, appropriate actions to prevent, reduce and eliminate the risk for the health are taken.

These actions can be modifications in the register of the product, in the instructions of use, manual of use, manufacturing, importing or commercialization suspension and also register withdrawn.

The notified adverse events are also included into a non-publicly available database to perform trend analysis.

Alerts and Recalls

With specific reference to medical devices' safety related information, the ANMAT website contains a section, "[Alerts and Recalls of Medical Devices](#)" where alerts and recalls are publicly available. Up to date two alerts are published, one of 20 March 2015 and the other of 5 February 2016.

The ANMAT website also includes a section on products for which a "[Prohibition of use and/or marketing](#)" has been issued due to regulatory irregularities in the manufacturing/marketing process.

Press and communication

As part of the sources of information, it is to be mentioned the section on "[Press and Communication](#)" which includes recent safety notices, alerts, articles on safety issues, technical information documents and scientific publications.

3.2.2 MEXICO – Federal Commission for the Protection against Sanitary Risks

The Federal Commission for the Protection against Sanitary Risks (COFEPRIS) is the Mexican body responsible for the protection of the population against sanitary risks, through sanitary regulation, control and promotion.

In the medical devices field, the COFEPRIS is in charge of ensuring high quality, effectiveness and safety of these products.

Alerts

As regards the sources of information on alerts or other safety related information on medical devices, the COFEPRIS website includes a webpage [dedicated to alerts](#) covering tobacco, health services, food and dietary supplements, drugs and health consumable goods and other products and services.

No specific section on medical devices is available.

The COFEPRIS website provides information in Spanish only.

3.2.3 NIGERIA - National Agency for Food and Drug Administration and Control

The National Agency for Food and Drug Administration and Control (NAFDAC) is the Nigerian Agency responsible for regulating and controlling the manufacture, importation, exportation, advertisement, distribution, sale and use of food, drugs, cosmetics, chemicals and packaged water, and medical devices.

Alerts and recalls

A specific section of the NAFDAC website is dedicated to [medical devices](#) where it is possible to consult recently published alerts and recalls of medical devices. At the moment, only 4 measures taken from 13 to 17 May 2016 are visible.

However, under the section "[Publications](#)" of the website it is possible to consult the archive where alerts and recalls relating to medical devices are available along with drugs, cosmetics, food and other products.

All information is provided in English.

3.2.4 SAUDI ARABIA - Saudi Food and Drug Authority

The [Saudi Food & Drug Authority \(SFDA\)](#) is the Saudi regulatory authority for food, drugs and medical devices. The main purpose of the SFDA is to regulate, oversee, and control food, drug, medical devices, as well as to set mandatory standard specifications thereof, whether they are imported or locally manufactured.

As specifically regards medical devices, the SFDA set up the National Centre for Medical Devices Reporting ([NCMDR](#)) to ensure safety of medical devices and to protect patients and public from deficient products.

The NCMDR maintains an up-to-date database of medical-devices recalls and adverse event reports and supports hospitals and healthcare providers to take appropriate corrective actions, whereas needed.

The National Centre for Medical Devices Reporting (NCMDRC)

NCMDRC treats reports and feedback information about both malfunctions and suspected adverse events and confirmed recalls from hospitals and healthcare facilities all around the Saudi Arabia Kingdom.

Once received, these reports are analysed by the SFDA in collaboration with manufacturers and suppliers in order to identify the best action to be taken in view of ensuring that the concerned product performs safely.

The centre also collects Fields Safety Notices (FSNs) and recalls from healthcare facilities as well as manufacturers as published by both the SFDA and other MD Competent Authorities abroad (UK-MHRA, US-FDA, DE-BfArM, IE-HPRA, Hong Kong-MDCO, EU National Competent Authority Reports-NCARs, CH-Swissmedic and AUS-TGA).

3.2.5 SOUTH AFRICA – National Department of Health

The [Department of Health](#) of the South African government is the department in charge of health issues with a view to improve the healthcare delivery system.

As specifically regards medical devices, currently only electronic medical devices are regulated, therefore, medical devices other than these are not regulated in South Africa.

No publicly available information with regard to the safety of MDs and In Vitro Diagnostics (IVDs) relevant for the European market has been found.

Table 1. Sources of alerts, recalls & other relevant info (IMDRF members)

| Member | Alerts | Recalls | Other safety related information |
|-----------|---|---|--|
| Australia | Alerts | System for Australian Recall Actions SARA | Incident Reporting and Investigation Scheme IRIS |
| | | | Database of Adverse Event Notifications DAEN |
| | | | Early Warning System |
| Brazil | http://portal.anvisa.gov.br/alertas2 | | Informes sobre produtos para saúde |
| Canada | Recalls and Safety Alerts Database | Recalls and Safety Alerts Database | Health Product Info Watch |
| | | | Canada Vigilance Adverse Reaction Online Database |
| China | N/A | N/A | N/A |
| Japan | "Yellow Letter" | "Yellow Letter" | Notices to revise the precautions |
| | "Blue Letter" | | MHLW Pharmaceuticals and MD Safety Information (JN only) |
| Russia | N/A | N/A | N/A |
| Singapore | Medical Device Alerts | Product Recalls | Dear Healthcare Professional Letters |
| | Product Safety Alerts | | Safety-related Product Label Amendments |
| USA | MedWatch - Safety Information and Adverse Event Reporting Program | CDRH – Medical Device Recalls | MAUDE Manufacture and User Facility Device Experience |
| | | | MedSun - Medical Product Safety Network |

Source: JRC MDTF, 2017.

Table 2. Sources of alerts, recalls & other relevant info (Non-IMDRF members)

| Member | Alerts | Recalls | Other safety related information |
|-----------|---|---|---|
| Argentina | Alerts and Recalls of Medical Devices | Alerts and Recalls of Medical Devices | Techno-vigilance program |
| Mexico | Alertas sanitaria | | |
| Nigeria | Recalls & Alerts Published by NAFDAC | Recalls & Alerts Published by NAFDAC | |
| S. Arabia | NCMDRC – The National Centre for MD Reporting | NCMDRC – The National Centre for MD Reporting | NCMDRC – The National Centre for MD Reporting |
| S. Africa | N/A | N/A | N/A |

Source: JRC MDTF, 2017.

3.3 Quantitative analysis of extra-EU alerts and recalls

Quantitative analysis

In December 2013, in an attempt to provide a quantitative overview about the amount of alerts and recalls expected to be identified on a daily basis outside the EU, the JRC conducted a preliminary monitoring of the alerts and recalls occurred from January to November 2013 in the thirteen regions that were made the subject of this report (Chapter 2.2), with the exception of Singapore which became official member of the IMDRF on 15 September 2016¹⁸.

It is to be noted that Japan and Russia are not included in this activity because the information provided through their websites is in national language only and translation was not available at the time of the analysis.

The main objective of the JRC was to provide an overview about the average number of safety measures (alerts/recalls) potentially affecting the EU and for which the presence on the European market would need to be verified.

As showed in the table below (Table 4), on average, 23 alerts and/or recalls are expected to be daily published through the official webpages of the relevant regulators.

The analysis also suggested that, in order for a daily monitoring system of extra EU alerts and recalls to be effective, the following issues will need to be preliminarily ascertained:

- *The product is a medical device or an in vitro diagnostics,*
- *The product bears a "Conformité Européenne" (CE) marking,*
- *The device is placed on the EU market,*
- *The specific issue impacts the EU,*
- *The device is available for sale in the EU,*
- *The real manufacturer/authorised representative and its legal base in the EU,*
- *Real nature of the action taken (alert, recall or other).*

¹⁸ <http://www.imdrf.org/docs/imdrf/final/meetings/imdrf-meet-160913-brazil-meeting-outcome-statement.pdf>.

Table 3. Quantitative analysis of alerts/recalls occurring outside the EU

| Month | Australia | | Brazil | Canada | United States | | Mexico | Nigeria | Saudi Arabia | All | Average per day by month (22 wd) |
|-------|-----------|--------|---------|----------------|---|-----------------|--------|-------------------------|--------------|------|----------------------------------|
| | Recalls | Alerts | Recalls | Alerts/recalls | Medical & Radiation Emitting Device Recalls | Medwatch Alerts | Alerts | Recalls & Safety Alerts | Recalls | | |
| Jan | 39 | 1 | 7 | 54 | 125 | 32 | 0 | 0 | 11 | 269 | 12 |
| Feb | 47 | 1 | 6 | 74 | 132 | 28 | 0 | 0 | 6 | 294 | 13 |
| Mar | 49 | 3 | 5 | 86 | 124 | 30 | 0 | 0 | 2 | 563 | 47 |
| Apr | 66 | 5 | 10 | 103 | 160 | 42 | 0 | 0 | 13 | 399 | 18 |
| May | 62 | 2 | 15 | 79 | 251 | 37 | 0 | 0 | 7 | 453 | 20 |
| Jun | 42 | 3 | 7 | 69 | 177 | 24 | 0 | 0 | 13 | 852 | 39 |
| Jul | 59 | 11 | 7 | 85 | 213 | 32 | 0 | 0 | 9 | 416 | 19 |
| Aug | 52 | 5 | 13 | 57 | 277 | 33 | 0 | 0 | 5 | 442 | 20 |
| Sep | 37 | 3 | 7 | 66 | 169 | 28 | 0 | 0 | 2 | 858 | 39 |
| Oct | 54 | 5 | 22 | 42 | 112 | 33 | 0 | 0 | 2 | 270 | 12 |
| Nov | 58 | 4 | 10 | 6 | 303 | 34 | 0 | 0 | 6 | 421 | 19 |
| Dec | | | | | | | | | | | |
| Total | 565 | 43 | 109 | 721 | 2043 | 353 | 0 | 0 | 76 | 3910 | 23 |

Analysis of the EU relevance

In a second phase, through a search into the European databank on Medical Devices (EUDAMED), the JRC verified whether the affected devices analysed were distributed in one or more countries within the EU market.

In order to ensure the coverage of the different categories of devices existing on the market, the analysis took into account alerts and recalls relating to **ten device types**:

Configurable MD systems

1. Recall - PET Discovery 600 and Discovery 690 Systems - S.A
2. Recall - Home Choice dialysis equipment - BRA
3. Recall - Autopulse resuscitation system model 100 - BRA
4. Recall - iPlan RT Dose - BRA
5. Recall - Puritan Bennett 840 Series Ventilator - US
6. Recall - Imaging system software, CardiacVX and CardiacVX Flow - S.A

Implantable MD

7. Alert - Journey Bi-Cruciate Stabil. (BCS) knee repl. system - femoral imp. - AUS
8. Recall - Segmental System, Polyethylene Inserts - CAN
9. Alert - Medtronic Mosaic Porcine Aortic Bioprosthesis - AUS

Active Implantable MD

10. Alert - Implantable infusion pumps - US
11. Recall - Animas 2020 Infusion Insulin Pumps - US

MD for dentistry

12. Recall - SEAC Dental System - Model 2020 - CAN
13. Recall - Toothbrush for kids - US

MD for ophthalmology

14. Recall - ACUVUE ADVANCE Brand Contact Lenses - US

MD for respiratory/anaesthesia

15. Recall - Compressor Mini - S.A.
16. Recall - Puritan Bennett™ 840 ventilator - BRA
17. Recall - Fabius Series Anesthesia Machines - US

In vitro diagnostic devices

18. Recall - Citrate Activated Partial Thromboplastin Time Cuvettes - AUS
19. Alert - TRUEtrack blood glucose meters - CAN
20. Recall - ABL90 FLEX Analyser - AUS
21. Recall - Vitros Immunodiagn. Prod.s Anti-HBS Calibrator and Reagent Pack - CAN

Surgical instruments

22. Alert - Endo GIA Articulating™ 60-3.5mm Surgical Stapler Reloads - CAN
23. Alert - 27G Sterile Cannula Packed in Amvisc and Amvisc Plus - US
24. Recall - Hi- Torque connect guidewire - BRA
25. Recall - Steris Fine Traction Device - CAN

Single use/Sterile MD

26. Recall - INSUPEN- Sensitive Needles - BRA
27. Recall - Vented Spike with Clearlink - AUS
28. Recall - Femoral Arterial and Venous Cannulae - S.A.

Hospital equipment

29. Recall - S3 and Secure II Medical/Surgical Beds. - S.A.
30. Alert - Liko overhead lifts ceiling-mounted rail systems – AUS

The analysis focused on the alerts and recalls occurred in five of the thirteen countries that were made the subject of the current report (See Chapter 2.2) and takes into consideration 30 safety measures (7 alerts / 23 recalls) adopted in the time frame May 2013-January 2014.

The five selected countries (Australia, Brazil, Canada, Saudi Arabia and United States) were chosen because their official webpages provide relevant information on alerts and recalls either in English or in a language easily understandable and translatable by the JRC staff working on this project.

As the summary table below shows (Table 4), the analysis of the 30 safety measures carried out through EUDAMED provided information relevant to the EU, with different degrees of approximation, in 18 cases.

This information helped identifying the Competent Authority/s that might be affected by the concerned safety issues occurred outside the EU.

It is to be noted that, although the devices found in EUDAMED seem to be corresponding to the products affected by the alerts/recalls issued outside the EU, the information provided by EUDAMED is, in most cases, insufficient to ensure that they are exactly the same products.

This question, along with the general issue regarding the development of an automated system for early detection of signals outside the EU, will be further explored under section 2.5.

Table 4. Analysis of the EU relevance

| | Country | Alert | Recall | MD type | Related NCAR | Findings | European relevance |
|---|-------------------------|--|---|------------------------|--|---|--|
| 1 | Australia 6/1/2014 | Journey Bi-Cruciate Stabilised (BCS) knee replacement system – femoral implant | | Implantable MD | INC-DE-09-11-000109 (This NCAR does not seem to refer to the same problem) | DVC-DE-09-11-000036 This entry seems to be related to the concerned device | DE, BE, NL (Source: DVC module) |
| 2 | Australia 6/1/2014 | Liko overhead lifts ceiling-mounted rail systems | | Hospital equipment | | No entry relevant to the concerned device | |
| 3 | Australia 23/1/2014 | | Vented Spike with Clearlink | Single use MD | | No entry relevant to the concerned device | |
| 4 | Australia 24/12/2013 | | Citate Activated Partial Thromboplastin Time Cuvettes | IVD | | No entry relevant to the concerned device | |
| 5 | Australia 6/11/2013 | | ABL90 FLEX Analyser | IVD | INC-DK-12-07-000009 (This NCAR does not seem to refer to the same problem) INC-DK-13-11-000013 (This NCAR seems to refer to the same problem) | DVC-DK-11-02-000005 This entry (and possibly others) seems to be related to the concerned device | AT, BE, CZ, DE, DK, ES, FI, FR, UK, IT, NL, NO, PL, SE, CH (Source: DVC module) |
| 6 | Australia 28/1/2014 | Medtronic Mosaic Porcine Aortic Bioprosthesis | | Implantable MD | | DVC-NL-12-01-000250 This entry seems to be related to the concerned device | NL |
| 7 | Brazil 18/6/2013 | | iPlan RT Dose | Configurable MD system | INC-DE-13-01-000104 (This NCAR does not seem to refer to the | DVC-DE-12-12-005534 This entry seems to be related to the concerned device | DE |

| | | | | | | | |
|----|----------------------|--|--|--------------------------------|---|---|---|
| | | | | | same problem) | | |
| 8 | Brazil 02/12/2013 | | INSUPEN- Sensitive Needles | Single use MD | | No entry relevant to this device | |
| 9 | Brazil 05/12/2013 | | Puritan Bennett™ 840 ventilator | MD for respiratory/anaesthesia | INC-IE-14-01-000005 | DVC-IE-14-01-000022 This entry seems to be related to the concerned device | AT, BE, BU, CY, CZ, ES, FI, FR, DE, GR, IE, IT, LV, LI, NL, PL, PT, RO, SL, SK, CH, TU, UK (Source: DVC module) |
| 10 | Brazil 04/11/2013 | | HomeChoice dialysis equipment | Configurable MD system | INC-CH-13-01-000008 INC-CH-13-11-000106 (These NCARs seem to refer to the same problem) | DVC-CH-13-01-000034 DVC-CH-13-01-000035 DVC-CH-13-11-000359 DVC-CH-13-05-000151 DVC-CH-13-05-000150 These entries seem to be related to the concerned device | AT, BE, BU, CY, CZ, DK, ET, DE, ES, FI, FR, GR, HU, IE, IT, LV, LI, MT, NL, NO, PL, PT, RO, SL, SK, SE, CH, TU, UK (Source: NCAR module) |
| 11 | Brazil 08/11/2013 | | Autopulse resuscitation system model 100 | Configurable MD system | | CRF-DE-12-06-001467 CRF-DE-12-06-003910 CRF-DE-12-06-000976 These entries seem to be related to the concerned device | DE |
| 12 | Brazil 11/12/2013 | | Hi- Torque connect guidewire | Surgical instrument | | DVC-IE-13-04-000140 DVC-IE-13-10-000547 DVC-IE-13-10-000527 These entries seem to be related to the concerned device | IE |
| 13 | Canada 6/1/2014 | | SEAC Dental System – Model 2020 | MD for dentistry | | No entry relevant to this device | |
| 14 | Canada 22/5/2013 | Endo GIA Articulating™ 60-3.5mm Surgical Stapler Reloads | | Surgical instrument | | DVC-AT-13-05-000242 This entry seems to be related to the concerned device | DE |
| 15 | Canada 14/1/2014 | TRUEtrack blood glucose meters | | IVD | | DVC-BE-11-10-000207 DVC-BE-11-10-000208 DVC-BE-11-10-000206 | BE |

| | | | | | | | |
|----|----------------------------|--|---|--------------------------------|---|--|--|
| | | | | | | These entries seem to be related to the concerned device | |
| 16 | Canada 27/12/2013 | | Segmental System, Polyethylene Inserts | Implantable MD | | No entry relevant to this device | |
| 17 | Canada 10/7/2013 | | Steris Fine Traction Device | Surgical instrument | | DVC-GB-13-03-006385 DVC-GB-09-11-011711 These entries seems to be related to the concerned device | UK |
| 18 | Canada 25/10/2013 | | Vitros Immunodiagnostic Products Anti-HBS Calibrator and Reagent Pack | IVD | | DVC-GB-09-11-002278 DVC-GB-09-11-011246 DVC-GB-09-11-002280 These entries (and possibly others) seem to refer to the concerned device | UK, AT, BE, CZ, DE, DK, ET, ES, FI, FR, UK, GR, HU, IT, LI, NO, PL, PT, SE, SL (Source: DVC module) |
| 19 | Saudi Arabia 9/1/2014 | | PET Discovery 600 and Discovery 690 Systems | Configurable MD system | INC-FR-13-12-000031 (This NCAR seems to refer to the same problem) | DVC-FR-13-12-000067 This entry seems to be related to the concerned device | FR AT, BE, KR, CZ, DK, FI, DE, IT, NO, PL, RO, ES, CH, UK (Source: NCAR module) |
| 20 | Saudi Arabia 17/12/2013 | | Compressor Mini | MD for respiratory/anaesthesia | | No entry relevant to this device | |
| 21 | Saudi Arabia 2/1/2014 | | S3 and Secure II Medical/Surgical Beds. | Hospital Equipment | | No entry relevant to this device | |
| 22 | Saudi Arabia 26/12/2013 | | Femoral Arterial and Venous Cannulae | Sterile/Single use MD | | DVC-DE-12-06-002826 This entry seems to be related to the concerned device | DE |
| 23 | Saudi Arabia | | Imaging system software, CardiacVX and CardiacVX Flow | Configurable MD system | | No entry relevant to this device | |
| 24 | United States 20/1/2014 | | Toothbrush for kids | MD for dentistry | | No entry relevant to this device | |

| | | | | | | | |
|----|-----------------------------|--|---|--------------------------------|---|---|---|
| 25 | United States 28/6/2013 | Implantable infusion pumps | | Active implantable MD | | No entry relevant to this device | |
| 26 | United States 17/5/2013 | | ACUVUE ADVANCE Brand Contact Lenses | MD for ophthalmology | | ACT-GB-11-10-000060 (AR) No entry relevant to this device (Distribution in EU is indicated in the recall) | AT, BE, DK, FR, DE, HU, IE, IT, LU, NL, PT, NO, SL, ES, SE, UK (Source: FDA Recall) |
| 27 | United States 10/1/2014 | | Puritan Bennett 840 Series Ventilator | Configurable MD system | INC-IE-14-01-000005 | DVC-IE-14-01-000022 This entry seems to be related to the concerned device | AT, BE, BU, CY, CZ, ES, FI, FR, DE, GR, IE, IT, LV, LI, NL, PL, PT, RO, SL, SK, CH, TU, UK (Source: NCAR module) |
| 28 | United States 23/01/2013 | 27G Sterile Cannula Packed in Amvisc and Amvisc Plus | | Surgical instrument | INC-GB-09-11-000071 (This NCAR seems to refer to the same problem) | DVC-GB-09-11-000031 This entry seems to be related to the concerned device | AT, BE, CY, CZ, DE, ES, FR, HU, IE, IT, MT, NL, NO, PT, SE, SL (Source: DVC module) |
| 29 | United States 4/5/2013 | | Animas 2020 Infusion Insulin Pumps | Active implantable MD | | No entry relevant to this device | |
| 30 | United States 14/8/2013 | | Fabius Series Anesthesia Machines | MD for respiratory/anaesthesia | INC-DE-13-09-000437 (This NCAR seems to refer to the same problem) | DVC-DE-13-09-003922 This entry seems to be related to the concerned device | DE |

3.4 Compilation of recalls and alerts occurring over a six week period

As a completion of the quantitative analysis carried out in December 2013 and described under paragraph 3.3 of this report, in July 2016 the JRC conducted a scoping exercise collecting available recalls and alerts made available by selected non EU regulators from the 2nd of May 2016 to the 12th of June 2016 (6 weeks).

For practical reasons, this exercise takes into account only the four regulators (US FDA, Health Canada, TGA Australia and Saudi Arabia SFDA) of which the official websites provide comparable information in English.

This activity aims to provide a realistic picture regarding the nature of information that can be expected through a regular monitoring of the sources made available by non EU authorities.

In this respect, the scoping exercise shows which device types are mainly affected by alerts and recalls, gives indications about the most frequent problems encountered and actions undertaken, and allows to compare all data in view of possible trending analysis.

Moreover, US FDA website also provides information about the countries (including EU MS) where an alert or recall has occurred.

This information allows appreciating the amount and kind of actions that would be needed, on a daily basis, to properly react to the relevant information coming from outside Europe.

Nevertheless, the distribution list provided by the FDA authority only concerns those products for which an alert or recall has been taken in the United States.

Therefore, in order to be able to ascertain whether the products affected by an alert or recall in all the countries (other than US) have been placed on the European territory, the EU competent authorities would need to explore and possibly identify additional methods or ways, such as systematic check into EUDAMED.

The figures below provide a summary of the main findings relating to the collected data:

- *83 alerts/recalls per week (12 per day), on average,*
- *10 Alerts,*
- *486 Recalls,*
- *201 alerts and recalls relevant for the EU,*
- *42 IVDs and 454 non IVDs affected.*

Full information regarding the data collected through the scoping exercise is available in the table attached to this document (See Supplementary material).

This table will serve as a basis for the EU CAs to further explore the actual usefulness of the analysed information, the most appropriate way to take advantage of it and possible technical solutions supporting its effective management for prompt reaction to/early detection of safety problems in the EU.

3.5 IT tools for automated collection and analysis of alerts and recalls

The large amount of data on alerts and recalls that are expected to be published on a daily basis shows that they cannot be treated manually due to excessive workload.

Conversely, an automated system for collection and analysis of this information would be ideal to support prompt and accurate reaction to safety issues.

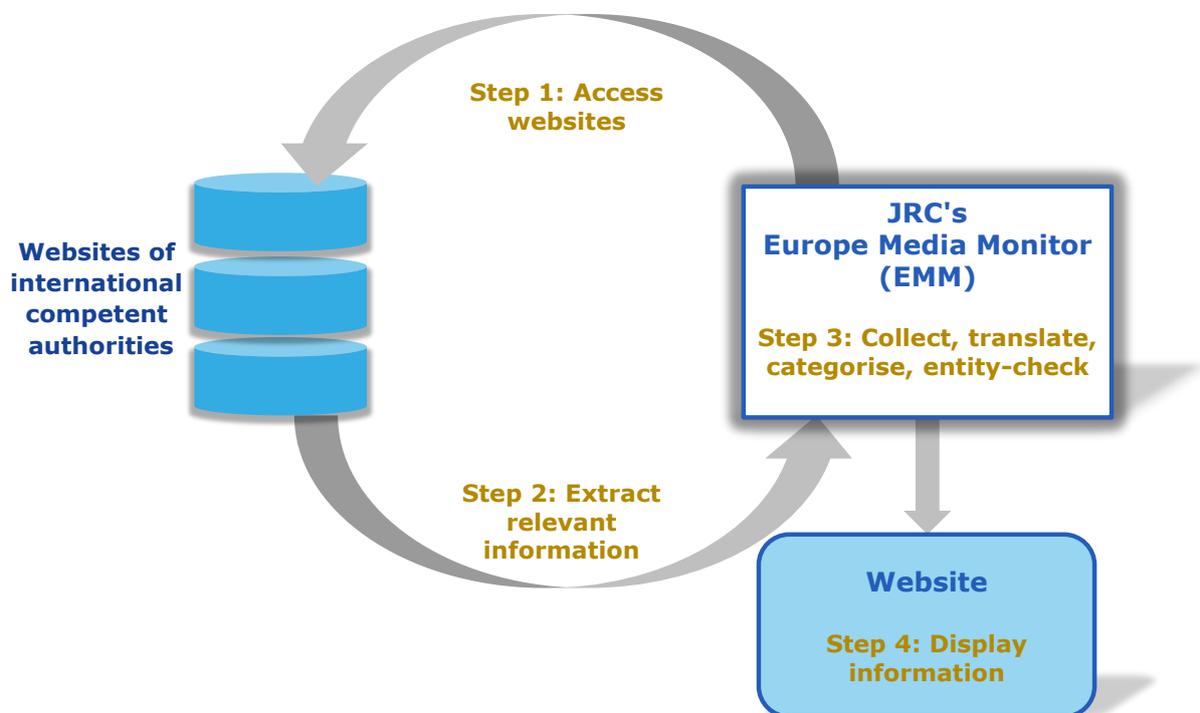
In particular, a series of IT tools is needed to ensure that the relevant information is appropriately collected, checked, stored and translated.

Therefore, it appears of utmost importance to start working on the development of key IT tools serving for:

- *Centralised collection of the information,*
- *Targeted data mining throughout the identified sources/websites,*
- *Appropriate entity check,*
- *Automatic translation into English of retrieved alerts and recalls,*
- *Effective display of all relevant information (i.e. through a dedicated webpage), e.g. on a weekly basis and including an effective archiving function.*

The figure below (Fig. 1) shows a schematic depiction of the IT infrastructure that would potentially support automated collection and analysis of extra EU alerts and recalls.

Figure 1. Potential IT infrastructure for automated collection & analysis of data



3.5.1 DG JRC's translation tool

In order to ensure an effective use of the collected data on alerts and recalls, it is important that the relevant information, as provided through the analysed sources (See Chapter 3), is appropriately translated from the local languages to English. In this respect, the JRC identified the "Optima News Translation System" (ONTS) as a potentially ideal solution.

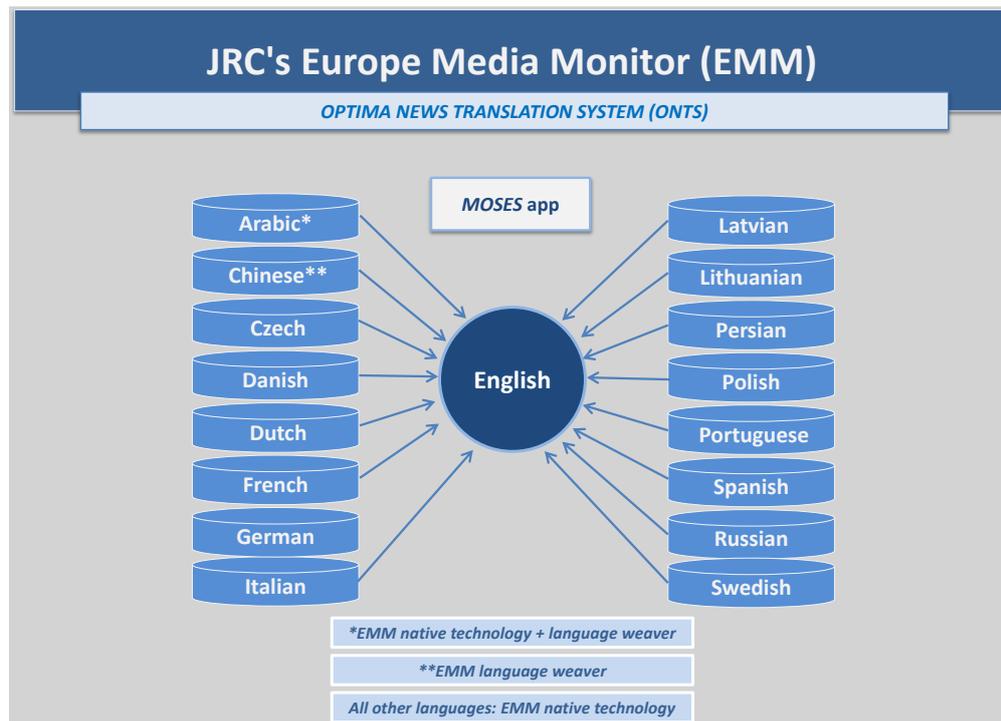
The "Optima News Translation System" (ONTS) is an application embedded into the Europe Media Monitor¹⁹ (EMM) system and was developed in-house by researchers of the JRC's Directorate I "Competences". Based on the open source software MOSES²⁰, the ONTS translation engine translates news from 16 languages²¹ into English using statistical methods and large amounts of data to identify the correct translation of each phrase and to link them together in a comprehensive English sentence.

Although acting on a unidirectional basis, the ONTS system is able to cover a very wide range of languages (See Fig. 2).

Moreover, beside the languages already covered, the JRC's tool may, in the future, also allow translations from additional languages.

This would be particularly relevant for languages like Russian and Japanese referring to two countries which are members of the International Medical Device Regulators Forum (IMDRF) and represent very important markets of medical devices and, therefore, are precious sources of safety information.

Figure 2. JRC's ONTS translation system



¹⁹ EMM is a live media monitoring system which gathers around 150,000 news articles every day from over 3750 internet news websites from around the world in over 62 different languages. <https://ec.europa.eu/jrc/en/scientific-tool/europe-media-monitor-newsbrief>.

²⁰ Moses is a statistical machine translation system that allows automatically training translation models for any language pair. <https://ec.europa.eu/jrc/en/scientific-tool/europe-media-monitor-newsbrief>.

²¹ De (EMM native technology), It (EMM native technology), Es (EMM native technology), Fr (EMM native technology), Fa (EMM native technology), Pt (EMM native technology), Cs (EMM native technology), Sa (EMM native technology), Pl (EMM native technology), Ru (EMM native technology), Sv (EMM native technology), Nl (EMM native technology), Lt (EMM native technology), Lv (EMM native technology), Ar (EMM native technology + language weaver), Zh (EMM language weaver).

4 Supplementary material

The supplementary material to this report (electronic form) provides a compilation of information relating to alerts and recalls occurred in Australia, Canada, United States and Saudi Arabia and published through the websites of their medical devices agencies from the 1st of May to the 11th of June (6 weeks).

This data collection covers four of the regulatory authorities (Australian TGA, Health Canada, US FDA, Saudi Arabian SFDA) included in the analysis under chapter 3 of this report mainly due to the fact that they provide information in English.

The data collected regard the type of safety measures (alert or recall), the specific device concerned (trade product name), and the related manufacturer, the description of the background/reason and of the actions recommended.

Information about the worldwide distribution of products, which is particularly important in order to appreciate whether a safety issue concerns the Union territory, is provided only by the US FDA.

This information is not provided by any other regulatory authority, therefore, in order to check if an extra EU safety measure affects the Union territory, EUDAMED appears to be the most appropriate means.

However, due to the gaps and shortcomings of the current EUDAMED (See EUDAMED Evaluation Report²²), this would be really effective only once the future European centralised databank will be fully operational.

In this respect, a manual searching test conducted by JRC in 2013 (See paragraph 3.3) showed that, in spite of the workload needed to search information into the current EUDAMED, the results obtained were not fully satisfactory mainly due to lack of information.

For this reason, the Annex does not contain data related to EUDAMED research although this option is reflected, through an empty column, for consideration by the EU CAs.

²² <http://ec.europa.eu/DocsRoom/documents/12981/attachments/1/translations>.

5 Conclusions

This report provides key information on additional data sources on alerts, recalls and other safety relevant information which have not been systematically used until now.

The appropriate management of this information would therefore be crucial for effective signal detection by regulators, both in the EU and worldwide.

To this aim, starting from the review of the existing sources of information, the document gives input and suggestions towards:

- (1) Improved **data set**,
- (2) Appropriate **technical tools**,
- (3) Automated ways for **EU relevance verification** and
- (4) Practical **working procedure** for management of the information collected.

i) Data sets and terminology

The report shows that a large amount of extra EU data on alerts and recalls and other relevant safety information is available.

Although very promising in view of the data richness, the possible systematic collection and use of this information is hampered by variations in terminology used by the different regulators.

In particular, it has been noted that terms are not always used to identify the same concepts (e.g. "alert" is used also to identify a "recall" and vice versa).

Alignment and harmonisation of this terminology would be supportive of the collection of this information but also its exchange and joint analysis by various regulators.

Moreover, the way how data are presented is very heterogeneous and fragmented, ranging from ad hoc and complete databases (e.g. on alerts, recalls or other safety communications) to simple lists of information of different nature (e.g. alerts, recalls, safety notices, etc...).

These divergences could represent an obstacle for effective automated collection and analysis of data.

Recommendations:

- (1) *We recommend exploring the opportunity for an international clarification and harmonisation of the terminology relating to safety information on medical devices.*
- (2) *For this purpose, the issue could be brought to the attention of the IMDRF.*

ii) Technical tools

The report outlines the main technical tools that would need to be developed in support of an effective management of the existing safety information.

Indeed, the nature, amount and way how the safety information is daily published and displayed through the analysed extra EU websites pose a series of technical issues.

In this respect, the report suggests a potential IT infrastructure for automated collection and analysis of data which highlights the main tools and solutions to be set up for identifying, collecting, checking, translating and displaying the relevant information.

Recommendations:

- *We recommend developing an integrated IT infrastructure supporting automated collection and preliminary analysis of data.*
- *This should mainly include IT programmes allowing for entity check and data mining, a webpage for displaying information and a translation tool.*

iii) EU relevance verification

A - The report shows that, in order to ensure effective signal detection, it will be important to set a process able to rapidly determine whether a recall or alert occurred outside the EU is relevant for the Union market.

B - In addition, it is important to highlight that relevance does not necessarily imply presence of the concerned product on the Union territory. Indeed, safety actions regarding products not on the EU market could also reveal risks and support early vigilance "pattern recognition" (i.e. correlations between use of devices and adverse health effects), they also need to be systematically identified and analysed.

Recommendations:

- (1) We recommend using the future EUDAMED as the key tool to provide information about the presence of the product on the EU.*
- (2) We recommend establishing a structured dialogue between all stakeholders and CAs for the early detection of potential risks relating to products not placed on the EU.*

iv) Working procedure

An effective management of the existing extra EU safety information would require a coordinated approach at European level to ensure full share and coordinated treatment of the available data.

Recommendations:

- (1) We recommend setting up a practical procedure for the systematic management of alerts, recalls and other relevant safety information.*
- (2) This procedure should allow for prompt analysis and coordinated reaction to safety problems affecting the EU territory and could be put in place by MS CAs and EC in the framework of the EU Vigilance Medical Device Expert Group (MDEG), e.g. through its regular teleconferences.*

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List of abbreviations and definitions

| | |
|----------|---|
| ANMAT | National Administration of Drugs, Foods and Medical Devices (AR) |
| ANVISA | Health Surveillance Agency (BR) |
| ARTG | Australian Register for Therapeutic Goods |
| AT | Austria |
| BE | Belgium |
| BfArM | Federal Institute for Drugs and Medical Devices (DE) |
| BU | Bulgaria |
| CA | Competent Authority |
| CDRH | Center for Devices and Radiological Health (US) |
| CE | Conformité Européenne |
| CFDA | China Food and Drug Administration |
| CH | Switzerland |
| COFEPRIS | Federal Commission for the Protection against Sanitary Risks (MX) |
| CY | Cyprus |
| CZ | Czech Republic |
| DAEN | Database of Adverse Event Notifications (US) |
| DE | Germany |
| DG | Directorate-General |
| DK | Denmark |
| DVC | Device |
| EMM | Europe Media Monitor |
| EC | European Commission |
| ES | Spain |
| EU | European Union |
| EUDAMED | European Databank on Medical Devices |
| FDA | Food and Drug Administration (US) |
| FI | Finland |
| FR | France |
| FOIA | Freedom of Information Act (US) |
| FSN | Field Safety Notice |
| FSSHSD | Federal Service on Surveillance in Healthcare and Social Development (RU) |
| GHTF | Global Harmonisation Task Force |
| GR | Greece |
| GROW | Directorate-General Internal Market, Industry, Entrepreneurship and SMEs |
| HPRA | Health Products Regulatory Authority (IE) |
| HSA | Health Sciences Authority (SG) |
| HU | Hungary |
| IE | Ireland |
| IFU | Instructions for Use |
| IMDRF | International Medical Device Regulators Forum |
| IRIS | Incident Reporting and Investigation Scheme (US) |
| IT | Italy |
| IVD | <i>In Vitro</i> Diagnostic |
| JRC | Joint Research Centre |
| KR | Croatia |
| LV | Latvia |
| LI | Lithuania |
| MAUDE | Manufacturer and User Facility Device Experience (US) |
| MDCO | Medical Device Control Office (HK) |
| MDEG | Medical Devices Expert Group |
| MDR | Medical Device Report |
| MedSun | Medical Product Safety Network (US) |
| MHLW | Ministry of Health, Labour and Welfare (JP) |
| MHPD | Marketed Health Products Directorate (CA) |
| MHRA | Medicines and Healthcare Products Regulatory Agency (UK) |

| | |
|----------|---|
| MOSES | Major Open Systems Environment Standards |
| MS | Member State |
| MT | Malta |
| NAFDAC | National Agency for Food and Drug Administration and Control (NG) |
| NCAR | National Competent Authority Report |
| NCMDR | National Centre for Medical Devices Reporting (SA) |
| NL | Netherlands |
| NO | Norway |
| NOTIVISA | Sistema de Notificações em Vigilância (BR) |
| ONTS | Optima News Translation System |
| PMDA | Pharmaceuticals and Medical Devices Agency (JP) |
| PL | Poland |
| PT | Portugal |
| RO | Romania |
| SARA | System for Australian Recall Actions (AU) |
| SBD | Summary Basis of Decision (CA) |
| SE | Sweden |
| SFDA | Saudi Food and Drug Authority |
| SK | Slovakia |
| SL | Slovenia |
| SMDR | Singapore Medical Device Register |
| SMEs | Small and medium-sized enterprises |
| TGA | Therapeutic Goods Administration (AU) |
| TPD | Therapeutic Products Directorate (CA) |
| TU | Turkey |
| UK | United Kingdom |
| US | United States |

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