Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

11th ASIAN HARMONIZATION WORKING PARTY (AHWP) MEETING
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ANNEX 4: POST-MARKET ALERT SYSTEM

DRAFT
PAPER FOR DISCUSSION

SUBJECT: FORMALIZATION OF A POST MARKET ALERTS DISSEMINATION FRAMEWORK AMONG AHWP MEMBER ECONOMIES

BACKGROUND

1 The nature of medical devices, and the context in which they are used, set them apart from common consumer goods. Owing to the risks and potential problems associated with the use of medical devices, it is generally accepted in advanced countries that there should be at least some degree of regulatory oversight and control over devices in the pre-market and post-market phases. The post market surveillance phase for a medical device is as important as all of the pre-market conformity assessment activities.

2 The regulation of medical devices involves a balance between pre-market assessment activities and post-market monitoring and surveillance. The objective of the pre-market control is to ensure that when available for supply, the device products are safe for their intended use, are of appropriate quality and performance, and are truthfully and adequately labelled for use. It is, however, not possible to assure the complete safety of a product before it is marketed.

3 The post-market control, therefore, serves as a critical element in mitigating risks associated with their use downstream in the regulatory cycle especially:

- in checking that the product continues to be of acceptable quality, safety and performance and is being supplied in accordance to the approved conditions; and

- as a means for the identification of unsafe or potentially unsafe products.

Examples of post-market surveillance programme include market intelligence and surveillance, and adverse event monitoring.

4 Presently, there is no inter-AHWP member economies adverse event reporting and product recall systems to alert healthcare practitioners and patients when an adverse event involving defects are detected. This may result in delays in corrective actions, unnecessary exposure of users of medical devices to an unacceptable level of risk, as well as exposure of the healthcare sector to the costs of remedial actions when products fail.

Submitted by: Alfred Kwek, Regulatory Scientist, Centre for Medical Device Regulation, Health Sciences Authority, Singapore
Wong Yew Sin, Director, Centre for Medical Device Regulation, Health Sciences Authority, Singapore

5 In addition, in the event of an adverse event occurring, there is heavy reliance on information and literature provided by manufacturer [1]. Local independent authoritative information may be lacking for the public to make informed choices on the safe use of medical devices.

6 Moreover, because of the absence of medical device regulation in some AHWP member economies, the reporting of adverse event and product recall by manufacturers is not mandatory. For having placed their products on the markets which though are unregulated, the manufacturers do have obligations to report to these authorities as well.

DEVELOPING THE POST MARKET ALERTS DISSEMINATION FRAMEWORK

7 Singapore has been tasked to propose to AHWP a framework for sharing of adverse event information amongst AHWP member economies relating to the issue of an alert on unsafe medical devices in one market.

8 In drawing up the proposed framework, Singapore has explored two options:-

- Option 1 looks at a "central clearing-house" approach whereby information is collected by and disseminated from a centralised body. This was rejected, as it requires elaborate infrastructure set-up and huge resources for maintenance of the system.

- Option 2 looks at a "nodal distribution system" approach whereby information is disseminated by any AHWP member economy. Any AHWP member economy can be the first node of information[2] dissemination

9 Singapore is proposing that the scope of information sharing among AHWP member economies be limited to device products that warrant corrective action(s) in the domestic market. Please see Figure 1 for a detailed illustration of the proposed framework.

10 The proposed framework in cascading steps, as illustrated in Figure 1, can be summarized as:

a) <u>Step 1</u>

A "reportable adverse event" [3] has occurred and the manufacturer is obligated to report it to all Regulatory Authorities of the markets it has placed its devices in.

b) <u>Step 2</u>

[1] "manufacturer" must be understood as including the legal manufacturer, its authorized representative or any other person who is responsible for placing the device on the market.

[2] Only information meeting agreed criteria (to be discussed) would be disseminated.

[3] To be harmonised and defined.

Regulatory Authority A decides that this adverse event warrants the issuance of a domestic safety alert to its users. At the same time, it transmits details relating to this adverse event to all AHWP member economies.

c)

Step 3

Upon receipt of the safety alert information transmitted from Regulatory Authority A, Regulatory Authority B makes an informed decision to issue its own safety alert to its domestic users. However, Regulatory Authority C does not deem this safety alert to be applicable to its domestic users and hence no action was taken.

11 The operation of the proposed framework has the following features:

(i) Independent Jurisdiction over Domestic Markets

To ensure that the proposed framework that is eventually developed is customized and appropriate to the local context, it is important that individual AHWP member economy has independent jurisdiction over its decision to say, a recall or non-recall of an affected device product.

(ii) Limited Scope of Shared Information

It is proposed that information shared among AHWP member economies countries be limited to adverse events mandating corrective actions it has taken in its domestic markets only. It is envisaged that such information will most likely be non-proprietary information already available in the public domain.

(iii) No Centralized Infrastructure Needed to Set Up

It is proposed that information for sharing be disseminated to all AHWP member economies by the initiating Regulatory Authority raising an alert in their domestic market. There is no need for a centralized clearing house to manage and communicate the information and which may be costly to set up as an infrastructure.

(iv) Status Quo for Manufacturers' Obligations to Report Adverse Events to Individual AHWP Member Economies

In the proposed framework, status quo remains whereby the manufacturers' obligations to report adverse events stays. The proposed framework does not obviate or remove from the manufacturers their obligations, statutorily or otherwise, to report adverse events to the individual Regulatory Authority for devices placed in their markets.

ENSURING SUCCCESS OF THE PROPOSED FRAMEWORK

12 To ensure success of the framework, device manufacturers and regulators must work together. This proposal can succeed if manufacturers and regulators alike agree and recognise that a good reporting culture, nationally as well as among AHWP member economies, can only be achieved through confidence between all parties concerned.

13 The obligation to report differs between countries. Reporting systems may either be voluntary or compulsory, and the scope of the system may also vary. The common factor seems to be an obligation for the manufacturer to report incidents he is aware of, and which involves his devices. For manufacturers, besides issues such as confidentiality of information reported and discrete handling and treatment of data, more importantly will be the way conclusions are drawn. What information will be released and used, and how will this be done. *Note: patient identification will not be disclosed in this proposed framework.*

FORMALISING THE REPORTING FRAMEWORK

14 Moving forward, the proposal will require AHWP member economies to work together to:

- harmonise the definition of “adverse events”;
- define the scope of inter-AHWP member economies “reportable events”;
- define the scope of applicable “reporting exemption rules”;
- harmonise the timeframe for transmission of inter-AHWP member economies adverse event reports; and
- harmonise the details to be included in the adverse event reports.

FOR CONSIDERATION

15 Submitted for discussion and consideration by all AHWP member economies.

REFERENCE

GHTF-SG2-N008R4, Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices

Figure 1: Cascading Steps – Illustration of the proposed framework for sharing of adverse events information among AHWP member economies