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Preface

The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory authorities and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

1.0 Introduction

The objective of the Global Harmonization Task Force (GHTF) is to encourage convergence at the global level in the evolution of regulatory systems for medical devices in order to facilitate trade whilst preserving the right of participating members to address the protection of public health by regulatory means considered the most suitable.

The primary way in which the GHTF achieves its goals is through the production of a series of guidance documents that together describe a global regulatory model for medical devices. The purpose of such guidance is to harmonize the documentation and procedures that are used to assess whether a medical device and its manufacturer conform to the regulations that apply in each jurisdiction. Eliminating differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

This document has been developed to encourage and support global convergence of regulatory systems. It offers:

- recommendations for the preparation and maintenance of registration and medical device listing databases by the Regulatory Authority;
- a harmonized definition of, and recommendations for, registration of medical device manufacturers and/or other parties in the supply chain; and
- a harmonized definition of, and recommendations for, the listing with a Regulatory Authority of all medical devices placed on the market by those parties.

This document is intended for use by Regulatory Authorities (RAs) and the parties responsible for providing registration and listing information to such authorities, and will provide benefits in establishing, in a consistent way, an economic and effective approach to the control of medical devices in the interest of public health. It seeks to strike a balance between the responsibilities of RAs to safeguard the health of their citizens and their obligations to avoid placing unnecessary burdens upon the industry.

The GHTF supports and encourages regulatory harmonization but recognises that some RAs may have to reflect different local needs when considering the recommendations in this guidance document. However, RAs that are developing registration and listing procedures or amending existing ones are encouraged to consider the adoption of the recommendations described in this document, as this will help to reduce the diversity of practices worldwide and facilitate the process of harmonization.

Where another GHTF guidance document is referenced within this text, its title is italicised for clarity.

Comments or questions about this document should be directed to the Chair or Secretary of the GHTF Study Group 1 whose contact details may be found on the GHTF web page[1].

2.0 Rationale, Purpose and Scope

2.1 Rationale

In many jurisdictions where regulations for medical devices are introduced for the first time, the initial step in the process is often the collection by the RA of information relating to:

- the types of medical devices supplied to the market,
- the manufacturers of these devices, and
- other parties responsible for supplying them to the market in that jurisdiction.

Having established databases that contain such information, the information is updated in response to changes in the medical devices being placed on the market, changes to parties in the supply chain and any other changes to the information provided in the first instance.

The collection and retention of this information on manufacturers, authorised representatives, importers and distributors (hereafter referred to as 'registration') and the medical devices supplied to the market by those parties (hereafter referred to as 'listing') are fundamental elements of regulatory control[2]. Where available resources are limited, registration and listing may be the only, or primary, regulatory control that exists within a jurisdiction.

Many regulators of medical devices have incorporated registration and listing requirements into their medical device regulations. The information held is useful in facilitating regulatory actions such as compliance audits and field safety corrective actions. It may also be used for law enforcement purposes. To date, these registration and listing systems are not harmonized.

When registration and listing information, in whole or part, is publicly accessible, it allows device purchasers or users of medical devices to identify products available to them and determine the identity and location of their manufacturers and/or distributors and/or importers.

2.2 Purpose

This guideline offers definitions for the terms 'registration' and 'listing'. It clarifies the roles and responsibilities of those entities involved in supplying a medical device to the

[1] www.ghtf.org
[2] See GHTF/SG1/N40:2006 *Principles of Conformity Assessment for Medical Devices*

market, such as the manufacturer, authorised representative, distributor and importer[3], with respect to registration and listing. It also provides guidance on the data content for registration and listing.

This document will have as its audience RAs and those parties involved in supplying medical devices to the market. It should assist jurisdictions introducing medical device regulations for the first time and those revising existing registration and listing regulations. In addition, this guidance is expected to improve the clarity of other GHTF harmonized guidance documents[4] with respect to registration and listing.

2.3 Scope

This guidance applies to all products that fall within the GHTF definition of a medical device that appears within the GHTF document *Information Document Concerning the Definition of the Term "Medical Device"*, including those used for the in vitro diagnostic examination of specimens derived from the human body.

3.0 References[5]

GHTF/SG1/N029:2005 *Information Document Concerning the Definition of the Term "Medical Device".*

GHFT/SG1/N055:2009 *Definition of the Terms "Manufacturer", "Authorised Representative", "Distributor" and "Importer".*

4.0 Definitions

1. **Contact details:** means a postal address in a format that allows physical location to be established together with a telephone number and e-mail address.

2. **Listing:** the process whereby a party submits information to the Regulatory Authority in a jurisdiction, regarding the identification of a medical device(s) that is or will be supplied to the market in that jurisdiction.

3. **Supply(ing) to the market**: the making available, in return for payment or free of charge, of a device, other than a device intended for clinical or performance evaluation, with a view to distribution and/or use on the market.

4. **Registration:** the process by which a party submits information to the Regulatory Authority in a jurisdiction, regarding the identification and establishment location(s) of

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[3] See GHFT/SG1/N055:2009 *Definition of the Terms "Manufacturer", "Authorised Representative", "Distributor" and "Importer".*

[4] GHTF/SG1/N040:2006 Principles of Conformity Assessment for Medical Devices and GHTF/SG1/N046:2008 Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices

[5] The listed documents are subject to periodic review and may be superseded by later documents. The reader is encouraged to refer to the GHTF website, www.ghtf.org, to confirm whether the referenced documents remain current.

the manufacturer and other parties, responsible for supplying a medical device(s) to the market in that jurisdiction.

5.0 Registration

5.1 General

5.1.1 Registration provides information on the parties that are or will be, supplying medical devices to the market that is within the RA's jurisdiction.

5.1.2 The RA should identify unambiguously which parties are required to provide it with registration information.

5.1.3 Providing registration information to the RA does not remove from that party (i.e. the registering party) its obligation to comply fully with other regulatory requirements that apply to it within the jurisdiction.

5.2 Parties subject to registration

5.2.1 Medical device manufacturers, authorised representatives, importers and distributors may be subject to registration requirements.

Note: The benefit of registering distributors may depend on both the RA's existing knowledge of the supply chain and the kind of medical device the distributor will supply to the market When specifying which distributors, if any, are subject to registration requirements, the RA should take account, for example, of:

- the purpose of collecting registration information;
- whether registration should be restricted to distributors supplying high risk devices;
- whether registration of distributors is necessary only where the medical device is imported into the RA's jurisdiction;
- whether it is necessary to register those distributors involved only in the supply of consumer products to the end user, e.g. domestic retail pharmacies;
- the likely size, complexity and maintenance of the resulting database.

5.2.2 While retaining responsibility, any party required to register with the RA may contract another party to complete the registration process on its behalf.

5.3 Timing of registration

A registering party should submit all necessary information to the RA before it is involved in the supply of any medical device to the market for the first time.

Note: When the registration database is first established, some of the parties subject to registration will already be supplying medical devices to the market. Such parties should be allowed a reasonable period of time to comply with the new registration requirements.

5.4 Information to be submitted for registration purposes

For the purposes of registration, and irrespective of device classification, each registering party should submit the following information to the RA.

1. An indication of whether the registering party is a manufacturer, an authorised representative, an importer or a distributor of medical devices supplied to the market of the jurisdiction where the information is being collected. Some registering parties will fall into more than one of these categories.

2. Name and contact details of the place of business of the registering party, together with the name and post held of the person within that organisation responsible for the registration.

3. Where the registering party has contracted another party to complete the registration process on its behalf (see 5.2.2), the name and contact details of the place of business of that other party, together with the name and post held of the person providing the required information.

4. An indication that the information provided is either a new entry or an update of previously submitted information. If the second situation applies, the registration code previously allocated to the registered party (see Section 5.5 bullet 8) should be provided.

5. The date when the information is submitted.

5.5 Role of the Regulatory Authority

The RA is responsible for:

- identifying which of the parties listed in Section 5.2.1 is required to provide information to it;
- specifying the information it requires from each registering party (see Section 5.4);

- specifying the format, mechanism and frequency with which the registration information is to be provided;

  Note: RAs are encouraged to establish an internet-based system for collection of registration information.

- designating the language(s) requirements for the submitted registration information;
- providing a mechanism that allows incorporation of either a new entry or updated information, into a searchable database, and ensuring such entries are incorporated within 30 days of the information being provided;
- the development, maintenance and security of the database containing the entrusted data;
- ensuring the recorded data reflects accurately the information provided by the registering party;
- assigning, for internal data management purposes, a unique registration code to each registering party;
- acknowledging to the registering party that the information has been received and whether it is acceptable or not;
- specifying whether only itself and the registering party has access to the registration information, or whether some or all of the information held may be accessed by others, e.g. purchasers of medical devices, while taking care to safeguard commercially sensitive information.
- on a periodic basis, not more frequent than annually, requesting each registering party to confirm that the information provided for registration purposes continues to be accurate.

5.6 Role of the Registering Party

The registering party is required to:

- provide the RA with the registration information specified in Section 5.4;
- attest to its accuracy;
- update the information provided within 30 calendar days of the occurrence of any change, or when requested to do so by the RA, in order to maintain the accuracy of the registration information;
- respond to the RA's request to confirm that the information provided for registration purposes continues to be accurate.

6.0 Medical Device Listing

6.1 General

6.1.1 Listing provides information on medical devices that are or will be, supplied to the market that is within the RA's jurisdiction.

6.1.2 The RA should identify unambiguously which parties are required to provide it with listing information.

6.1.3 Providing listing information to the RA does not remove from the party providing such information (i.e. the listing party) its obligation to comply fully with all the other regulatory requirements that apply to it within the jurisdiction.

6.2 Parties subject to listing requirements

6.2.1 Medical device manufacturers, authorised representatives, importers and distributors may be subject to listing requirements.

6.2.2 The listing party should be registered with the RA according to the provisions of Section 5 of this document.

6.2.3 While retaining responsibility, any party required to provide listing information may contract another party to complete the listing process on its behalf.

6.3 Timing of listing

A listing party providing information to an existing database should submit all necessary information to the RA when it supplies the device to the market for the first time.

Note: When the medical device listing database is first established, some of the devices subject to listing requirements will already be on the market. In this situation, the party providing listing information should be allowed a reasonable period of time to comply with the new listing requirements.

6.4 Information to be submitted for listing purposes

For the purposes of listing, the listing party should provide the following:

1. An indication of whether the listing party is a manufacturer, an authorised representative, an importer, or a distributor of medical devices supplied to the market of the jurisdiction where the information is being collected, together with the unique registration code allocated to it when it registered with the RA.

2. Name and contact details of the registered place of business of the listing party together with the name and post held of the person within that organisation responsible for the provision of listing information.

3. Where the listing party is an authorised representative, an importer or a distributor of medical devices it should provide the name and contact details of the registered place of business of the manufacturer(s) of the medical device(s) for which it is providing listing information together with the name and post held of the person responsible for the provision of listing information within the manufacturer's organisation.

4. Where the listing party has contracted another party to complete the listing process on its behalf (see 6.2.3), the name and contact details of the place of business of that other party, together with the name and post held of the person providing the required information.

5. Information sufficient to identify each medical device for which listing information is required.

6. A device code, allocated through an internationally recognised coding system[6], for each medical device for which listing information is required.

7. An indication that the information provided is either a new entry or an update of previously submitted information. If the second situation applies, the listing code previously allocated to the medical device (see Section 6.5 bullet 8) should be provided.

   Note: the RA may retain an archive of medical devices that are no longer being supplied to the market.

8. The date when the listing information is submitted.

6.5 Role of the Regulatory Authority

The RA is responsible for:

- identifying which of the parties listed in Section 6.2.1 is required to provide information to it;
- specifying the information it requires from the listing party[7] (see Section 6.4);

[6] The Global Medical Device Nomenclature (GMDN) provides the use of generic descriptors for the identification of medical devices and other healthcare related products. The nomenclature system is managed by the GMDN Agency. The code is based on the international standard EN ISO 15225.

[7] RAs may seek to collect information on the contact details of the facilities where a medical device is made. This information may be available to the RA through a variety of means (e.g. quality management system documentation and/or the STED). Where this information is collected by the RA by such means, there should be no need to duplicate the information through the registration and listing process.

- specifying the format, mechanism and frequency with which the listing information is to be provided;

  Note: RAs are encouraged to establish an internet-based system for collection of listing information.

- designating the language(s) requirements for the listing information to be provided;
- providing a mechanism that allows incorporation of either a new entry or updated information, into a searchable database, and ensuring such entries are incorporated within 30 days of the information being provided;
- the development, maintenance and security of the database containing the entrusted data;
- ensuring the recorded data reflects accurately the information provided by the listing party;
- assigning, for internal data management purposes, a unique listing code to each medical device that is listed in the database;
- acknowledging to the listing party that the required information has been received and is acceptable;
- specifying whether only itself and the listing party may have access to the listing information and whether some or all of the information held may be accessed by others, e.g. purchasers of medical devices, while taking care to safeguard commercially sensitive information;
- on a periodic basis, not more frequent than annually, requesting each listing party to confirm that the information provided for listing purposes continues to be accurate.

6.6 Role of the listing party

The listing party is required to:

- provide the RA with the listing information specified in Section 6.4;
- attest to its accuracy;
- update the information provided within 30 calendar days of becoming aware of the occurrence of any change, or when requested to do so by the RA, in order to maintain the accuracy of the listing database;
- respond to the RA's request to confirm that the information provided for device listing purposes continues to be accurate.

参考2

関連法令

１．承認台帳について

薬事法施行令
（昭和三十六年一月二十六日政令第十一号）

（医薬品等の承認台帳）
第十九条　厚生労働大臣は、法第十四条第一項 及び第九項 （法第十九条の二第五項 において準用する場合を含む。）並びに法第十九条の二第一項 の規定による承認に関する台帳を備え、厚生労働省令の定めるところにより、必要な事項を記載するものとする。
２　第八十条第一項（第一号に係る部分に限る。）又は第二項（第五号に係る部分に限る。）の規定により都道府県知事が前項の承認を行うこととされている場合における同項の規定の適用については、同項中「厚生労働大臣」とあるのは、「都道府県知事」とする。

薬事法施行規則
（昭和三十六年二月一日厚生省令第一号）
第四十九条
令第十九条に規定する法第十四条第一項又は第九項の規定による承認に関する台帳に記載する事項は、次のとおりとする。
一　承認番号及び承認年月日
二　承認を受けた者の氏名及び住所
三　承認を受けた者の製造販売業の許可の種類及び許可番号
四　当該品目の製造業者又は外国製造業者の氏名及び住所
五　当該品目の製造業者の許可区分及び許可番号又は外国製造業者の認定区分及び認定番号
六　当該品目の名称
七　当該品目の成分及び分量又は形状、構造及び原理
八　当該品目の効能、効果又は使用目的
九　当該品目の用法及び用量又は操作方法若しくは使用方法
十　当該品目の規格及び試験方法

２．医療機器の認証と報告書について

薬事法（昭和三十五年八月十日法律第百四十五号）

第二十三条の五　登録認証機関は、第二十三条の二第一項若しくは第四項の規定により認証を与え、若しくは同条第五項の届出を受けたとき、又は前条の規定により認証を取り消したときは、厚生労働省令で定めるところにより、報告書を作成し、厚生労働大臣に提出しなければならない。

２　厚生労働大臣が、第十四条の二第一項の規定により機構に審査を行わせることとしたときは、指定管理医療機器等（専ら動物のために使用されることが目的とされているものを除く。）に係る認証についての前項の規定による報告書の提出をしようとする者は、同項の規定にかかわらず、厚生労働省令で定めるところにより、機構に提出をしなければならない。この場合において、機構が当該報告書を受理したときは、厚生労働省令で定めるところにより、厚生労働大臣にその旨を通知しなければならない。

薬事法施行規則

（昭和三十六年二月一日厚生省令第一号）

（登録認証機関の報告書）

第百十九条　法第二十三条の五第一項 に規定する報告書は、毎月、次に掲げる事項を記載し、その翌月末日までに厚生労働大臣に提出するものとする。

一　当該月に与えた基準適合性認証又は当該月に受けた法第二十三条の二第五項 の届出（以下この項において「認証等」という。）に係る製造販売業者又は外国指定管理医療機器製造等事業者の氏名及び住所

二　外国指定管理医療機器製造等事業者にあつては、その選任した選任製造販売業者の氏名及び住所

三　当該製造販売業者又は選任製造販売業者が受けている製造販売業の許可番号

四　認証等に係る品目の製造所の名称、所在地及び製造工程の概要

五　認証等に係る品目の名称及びその認証番号

六　認証年月日又は届出を受けた年月日

七　基準適合性認証の申請時又は法第二十三条の二第五項 の届出時における同条第三項の規定による調査の実施年月日及び当該調査結果の概要

八　認証等に係る第百二十八条に規定する基準に基づく監査の実施年月日及び当該監査結果の概要

九　認証等に係る品目の添付文書

十　認証等に係る変更（軽微な変更を含む。）をした場合又は基準適合性認証の取消しをした場合は、その旨

2　厚生労働大臣が、法第十四条の二第一項 の規定により機構に審査を行わせることとした場合における前項の規定の適用については、同項中「厚生労働大臣」とあるのは「機構」と、前項中「厚生労働省」とあるのは「機構」とする。

事　務　連　絡
平成21年 11 月 4 日

独立行政法人医薬品医療機器総合機構　御中

厚生労働省医薬食品局
審査管理課医療機器審査管理室

認証品目リストの公表について（依頼）

標記については、平成20年4月21日付け事務連絡により、薬事法第２３条の５第１項の規定に基づく報告書の提出に併せ、認証品目リストについても貴機構あて提出するよう登録認証機関あて依頼しているところですが、情報公開の推進並びに事業の透明化確保と国民に対するサービスの向上を図る観点から、今後、登録認証機関から提出のあった認証品目リストを公表することとしましたので、貴機構ホームページ（http://www.pmda.go.jp/）に掲載いただくようお願いします。

なお、当該リストは月一回を目途に更新いただくよう、よろしくお取り計らい願います。

資料リスト

野村総合研究所 NRI 未来創発
Dream up the future.

『医療機器の国際的な情報交換のため
基盤整備に関する調査』

医療機器データベース要件定義書

第1.0版

平成24年2月27日

株式会社 野村総合研究所

NRI Innovation!

『医療機器の国際的な情報交換のための基盤整備に関する調査』
要件定義書

1. はじめに
2. スケジュール要件
3. システム機能要件
4. システム方式要件
5. データ要件
6. ユーザインタフェース要件
7. セキュリティ要件
8. 設計・開発要件
9. テスト要件
10. 移行要件

1. はじめに

アジアを含む各国との間で、一般的名称及び品目情報を関連付けし、アジア各国との輸出入や、不具合や回収発生時の国際的な情報交換を円滑化することが望まれている。

そこで、米国が導入検討中のUDI(固有機器データベース)や欧州のEUDAMED(欧州データバンク)の施行にあわせて、日本の医療機器情報の承認番号、名称、使用目的・効能・効果等の基本情報について、日英両方の言語によるデータベース化や、安全対策情報交換の基盤となる各国データベース間の品目情報の関連付けを行うための基盤整備ついて調査研究を行ってきた。

本書は、上記の調査研究において検討を行った医療機器データベースについて、要件定義書として取りまとめたものである。