



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED FINAL DOCUMENT

Title: Guidance for Medical Device Naming Rule

Authoring Group: Special Task Group on UDI & Nomenclature

Date: 1 Nov 2015

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1. INTRODUCTION

1.1. Purpose

The document is intended to provide guidance for a scientific based medical device nomenclature system used by both regulatory authorities and industry, where is based on the discussion around nomenclature in some STG member economy, where the methodology could be used as reference.

The adoption of this guidance document in AHWP member economies will promote the use of generic names of medical device for both pre-market applications and post-market surveillance and tracking purposes with different regulatory authorities.

1.2. Scope

This guidance document describes the principle, application scope, structural composition, prohibited content of the Medical Device Naming Rules.

This document applies to all products that fall within the definition of a medical device (See section 1.3), except for in-vitro diagnostic medical devices.

1.3. Definitions

Medical Device - 'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

In Vitro Diagnostic (IVD) Medical Device - 'In Vitro Diagnostic (IVD) medical device' means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

Note 1: IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.

Note2: In some jurisdictions, certain IVD medical devices may be covered by other regulations.

Instructions for use: information provided by the manufacturer to inform the device user of the medical device's intended purpose and proper use and of any precautions to be taken.

Intended use / purpose: The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

User: the person, either professional or lay, who uses a medical device. The patient may be the user.

Manufacturer (or legal manufacturer or known as “product owner” in some countries): for the purposes of this guidance document, means a person who sells a medical device under his own name, or under a trade- mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for one or more of the following activities:- designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on his behalf.

2. GUIDANCE

Guidance for Medical Device Naming Rule (Draft for AHWP STG Discussion)

Article 1 The Rules are hereby formulated to strengthening supervision and administration of medical devices and ensuring scientific and standardized naming of medical devices.

Article 2 The generic naming of all medical devices sold and used within AHWP member economies shall conform to the Rules.

Article 3 The generic naming of medical devices shall also conform to the related provisions of relevant laws and regulations of the AHWP member economies where applicable, as well as be consistent with the product properties, and be scientific, clear and brief. Shall not mislead and deceive users.

Article 4 The generic naming of medical device shall be in AHWP member economies' official language and meet common national language and words rules.

Article 5 The same kind of medical devices shall use same generic name. The generic name consists of one core word and no more than three feature words in common occasions.

Article 6 Core word is the most general presentation of medical devices that have the same or similar technical principle, structural composition, performance indices and intended use.

Article 7 Feature word is the description of main features of medical devices including applied parts, structural features, technical features, material composition and specific properties.

Applied parts refer to the action object or action point of main function of products, which may be the whole or part of human body, tissues, structures and organs.

Structural features refer to the description of different structure, appearance.

Technical features refer to instruction or limit of the special action principle or mechanism of products.

Material composition refers to the description of host material of products.

Specific properties refer to definitive description of certain special properties involving product.

Article 8 The name of medical devices shall not contain the following contents:

1. Model or specification;
2. Signs like pattern or symbol
3. Personal name, corporation name, brand name, trade name or other similar names;
4. Other absolute or exclusive words such as “The best”, “The newest”, “unique”, “accurate” and “quick-acting”, etc.;
5. Words expressing or implicating the treatment of a disease, or containing assertion or guarantee of efficacy, effective rate and curative rate;
6. Contents expressing or implicating that curing all diseases, applicable to all symptoms or exaggerating indications, or containing the tendentious contents such as “beauty”, “healthcare”, etc.;
7. Conceptual names which are empty, hypothetical or not proved by scientific findings or clinical results;
8. Other contents prohibited by member economies’ national laws and regulations.

Article 9 Generic name of medical devices shall not be used for trademark registration.

Article 10 The generic naming rules for in vitro diagnostic reagents managed as medical devices shall be implemented in accordance with relevant provisions on in vitro diagnostic reagents.

3. REFERENCE:

- **GHTF - SG1 N071:2012** Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'
- **GHTF - SG1 N70:2011** Label and Instructions for Use for Medical Devices
- **CFDA** – Medical Device Naming Rules (Interim) (Call for Comments version)