Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1927-2017 FICCI @90

22nd Asian Harmonization Working Party Annual Meeting

MAKE IN INDIA

MAKE IN INDIA

4-8 December, 2017 I New Delhi

Ministry of Health & Family Welfare
Government of India

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WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

AHWP WG1 UPDATES

December 2017

WG1 – Member Status

Chair

Mr. Essam Al Mohandis

Kingdom of Saudi Arabia FDA

Co-Chair

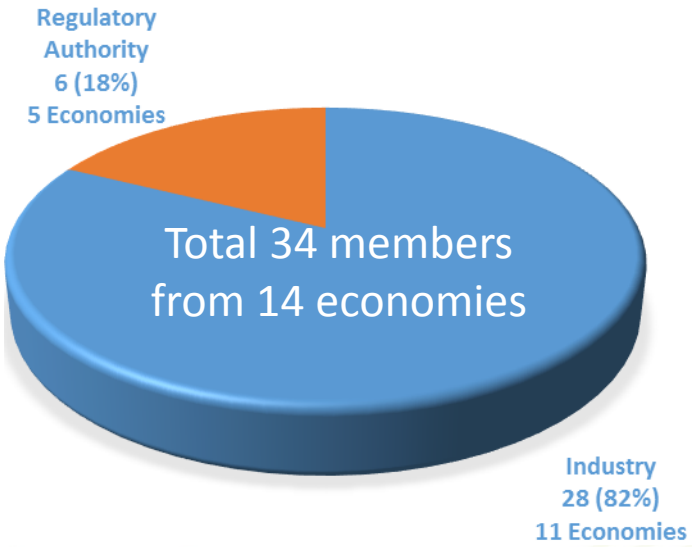
Ms. Kate HyeongJoo Kim

Johnson & Johnson Medical ASPAC

Secretary

Ms. Mandy MyoungShim Kim

Johnson & Johnson Medical Korea



WG1 – Activities in 2017

- 20 Feb. Group call – Reviewed eLabelling WI initiation
- 2-3 Mar. TC meeting in HK – Committed eLabelling WI & Received 3D Printed Device regulation WI
- 6 Apr. Group call – Discussed two WI plan
- 11 May. Group call – Training on Overview of 3D Printing of Medical Devices by Sung-In Baek, MFDS
- 5 July. Group call – Reviewed eLabelling Questionnaire
- 21 Nov. Group call – Reviewed two proposed documents
- 6 Dec. F2F meeting in Delhi, India

Proposed Work Plan (updated on May 11th)

No	Work Item	Deliverables	Timeline
1	1. e-Labeling/e-IFU as an alternate method for compliance to labeling requirement	Survey to investigate the current status in major AHWP member economy of accepting web-based manual and on-screen label as a mean of compliance to local labeling requirement and to investigate the current status of AHWP non-economy members i.e., IMDRF, TGA, FDA, EU (Collaborate with WG2!)	May 2017
		White paper endorsed at the Annual Meeting	Nov 2017
		Solutions proposed to overcome potential barriers posed by different stakeholders (regulators, users, or patients) • Enact New Regulations • Limit the applicability scope to selected MD types, e.g. professional users, not consumer	2018
2	2. Regulation on 3D Printed Medical Device	Information/training session for 3D printers was provided on 5/11 through the teleconference. If agreed among WG1 members, we will start preparing a guidance document for 3D printer to be endorsed at the end of this year as an AHWP guidance document	Nov 2017

Proposed Work Items for Endorsement

Handbook for Approval of Patient-matched Medical Devices Using 3D Printers

Regulation and treatment of e-IFU and e-Label of Medical Devices

- Review of International Practice

(WG1 & WG2)

Proposed Work Items for Endorsement

Handbook for Approval
of Patient-matched
Medical Devices
Using 3D Printers

Regulation and treatment
of e-IFU and e-Label
of Medical Devices
- Review of International Practice
(WG1 & WG2)

Handbook – Approval of Patient-matched MD Using 3D Printers

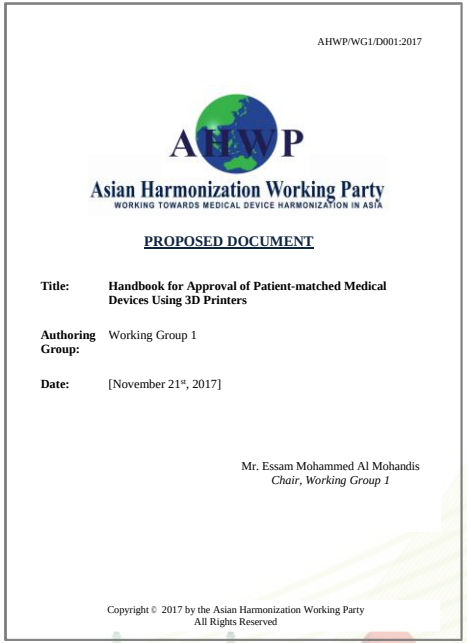
- intended to specify requirements that are related to approval process and procedures for patient-matched medical devices using 3D printers.
- intended to be revised to harmonize terms and definitions with other regulatory authorities and IMDRF in the future.
- explain the basic regulatory requirements that regulators need to review in order to increase the levels of understanding in evaluation when approving patient-matched medical devices using 3D printers.

Handbook – Approval of Patient-matched MD Using 3D Printers

- Scope of Approval
  - In scope: Patient-matched medical devices using 3D printers
  - Out of scope: Mold, manufactured by 3D printers, for shaping medical devices in order to produce patient-matched devices
- Elements of Application
  - Model Name, Appearance, Size and weight
  - Operational Principle
    - Manufacturing process of modelling, printing, and post processing
    - Manufacturing method per material type
  - Intended use, Instructions for use

Handbook – Approval of Patient-matched MD Using 3D Printers

- Considerations for Technical Document Review
  - Documents for Intended Use
  - Documents for Operational Principles
  - Documents for Biological Safety
  - Documents for Performance
  - Documents for Physiochemical Properties



AHWP/WG1/D001:2017

Asian Harmonization Working Party
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PROPOSED DOCUMENT

Title: **Handbook for Approval of Patient-matched Medical Devices Using 3D Printers**

Authoring Group: Working Group 1

Date: [November 21st, 2017]

Mr. Essam Mohammed Al Mohandis
Chair, Working Group 1

Proposed Work Items for Endorsement

Handbook for Approval of Patient-matched Medical Devices Using 3D Printers

Regulation and treatment of e-IFU and e-Label of Medical Devices

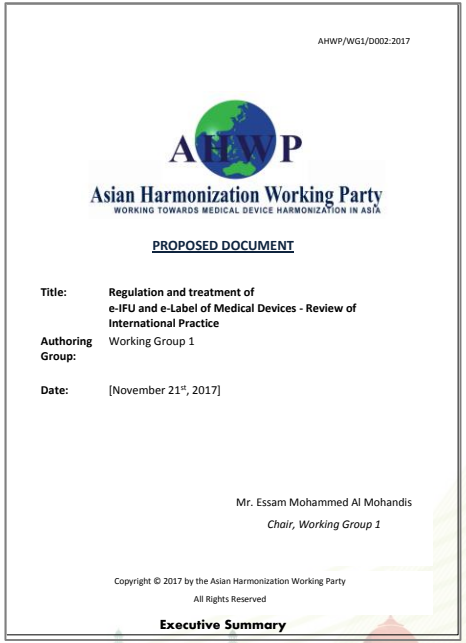
- Review of International Practice

(WG1 & WG2)

Whitepaper on e-Label/e-IFU

- Presents a summary of current international practices for regulation of e-labels and e-IFUs in a selection of representative jurisdictions.

No	Countries	Interviewer	Interviewee	Remark
1	China	Victoria Qu	Regulatory Authority	WG1
2	Korea	Young Soon	Regulatory Authority	WG1
3	Saudi Arabia	Essam	Regulatory Authority	WG1
4	India	Pavan	Regulatory Authority	WG1
5	Singapore	Yusyanti	Regulatory Authority	WG1
6	Philippines	Wen-Wei	Regulatory Authority	WG2
7	Tanzania	Christopher	Regulatory Authority	WG2
8	Chinese Taipei	Christopher	Regulatory Authority	WG2
9	Kazakhstan	Christopher	Regulatory Authority	WG2
10	HongKong	Swee Choong	Industries	WG1
11	Japan	Ozawa	Regulatory Authority	WG1, Non-AHWP



AHWP/WG1/D002:2017

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED DOCUMENT

Title: Regulation and treatment of e-IFU and e-Label of Medical Devices - Review of International Practice

Authoring Group: Working Group 1

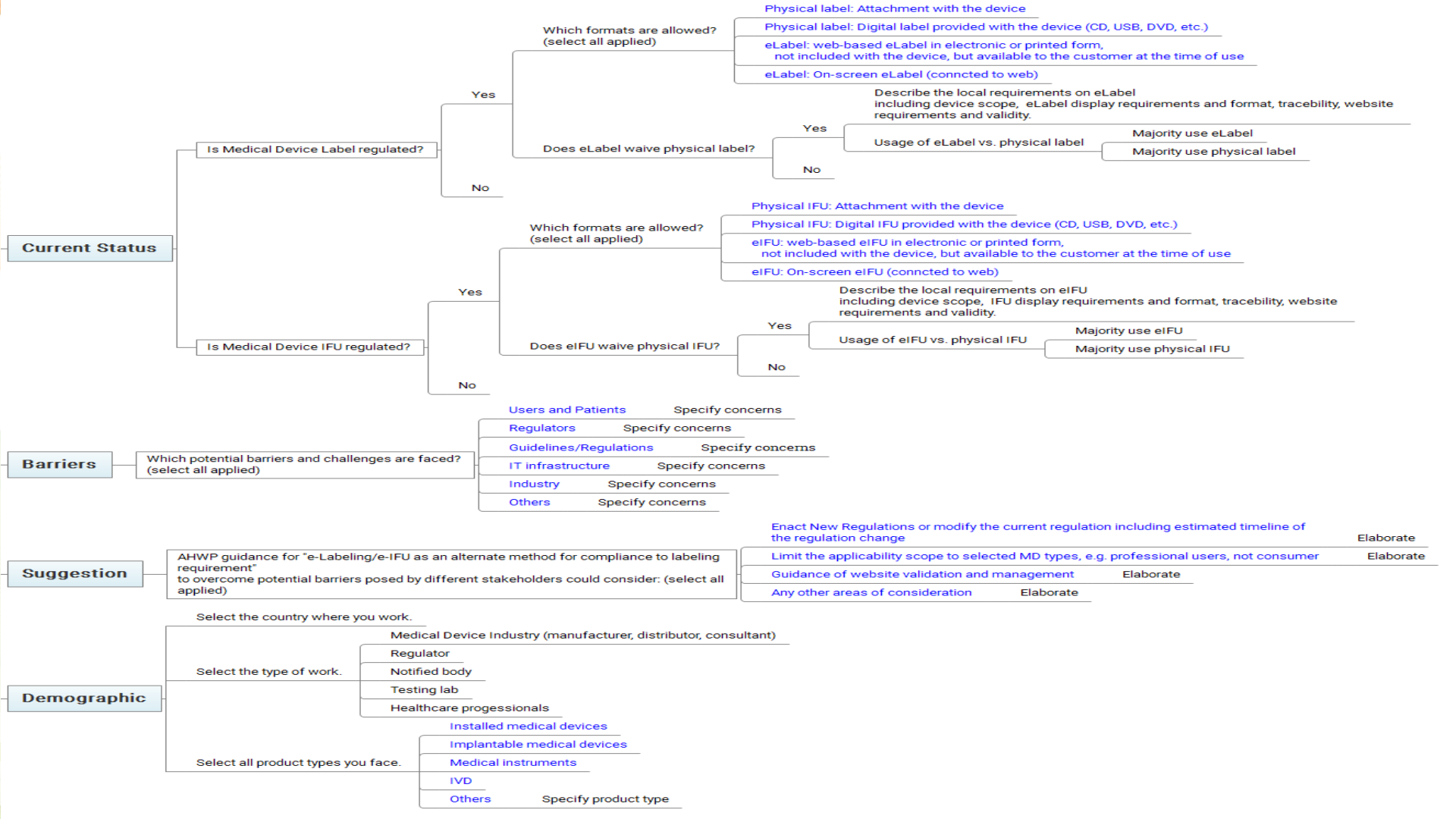
Date: [November 21st, 2017]

Mr. Essam Mohammed Al Mohandis
Chair, Working Group 1

Executive Summary

Whitepaper on e-Label/e-IFU

- Addresses the current and potential application of E-Labelling and E-IFUs in the healthcare industry and the attitudes and concerns surrounding it.
- Shows that there are areas of consensus and similarities of practice in the regulation of e-labelling and e-IFUs, but there are also areas of substantial difference between regulators. Key findings were:
  - Most agencies do not accept electronic labels or IFUs.
  - The majority of agencies regulate IFUs and Labels for medical devices.
  - The greatest concern for most agencies was the accessibility issue for patients and health care professionals alike, particularly in rural regions.
  - There is a similarity in application of manufacturing.
  - The definition of IFU and Label were almost identical across the agencies.
  - Most agencies required approval for any update/changes to content for labels and IFU's.


Current Status
Is Medical Device Label regulated?
Yes
Which formats are allowed? (select all applied)
Physical label: Attachment with the device
Physical label: Digital label provided with the device (CD, USB, DVD, etc.)
eLabel: web-based eLabel in electronic or printed form, not included with the device, but available to the customer at the time of use
eLabel: On-screen eLabel (conncted to web)
Does eLabel waive physical label?
Yes
Describe the local requirements on eLabel including device scope, eLabel display requirements and format, tracebility, website requirements and validity.
Usage of eLabel vs. physical label
Majority use eLabel
Majority use physical label
No
No
Is Medical Device IFU regulated?
Yes
Which formats are allowed? (select all applied)
Physical IFU: Attachment with the device
Physical IFU: Digital IFU provided with the device (CD, USB, DVD, etc.)
eIFU: web-based eIFU in electronic or printed form, not included with the device, but available to the customer at the time of use
eIFU: On-screen eIFU (conncted to web)
Does eIFU waive physical IFU?
Yes
Describe the local requirements on eIFU including device scope, IFU display requirements and format, tracebility, website requirements and validity.
Usage of eIFU vs. physical IFU
Majority use eIFU
Majority use physical IFU
No
No
Barriers
Which potential barriers and challenges are faced? (select all applied)
Users and Patients
Specify concerns
Regulators
Specify concerns
Guidelines/Regulations
Specify concerns
IT infrastructure
Specify concerns
Industry
Specify concerns
Others
Specify concerns
Suggestion
AHWP guidance for "e-Labeling/e-IFU as an alternate method for compliance to labeling requirement"
to overcome potential barriers posed by different stakeholders could consider: (select all applied)
Enact New Regulations or modify the current regulation including estimated timeline of the regulation change
Elaborate
Limit the applicability scope to selected MD types, e.g. professional users, not consumer
Elaborate
Guidance of website validation and management
Elaborate
Any other areas of consideration
Elaborate
Demographic
Select the country where you work.
Select the type of work.
Medical Device Industry (manufacturer, distributor, consultant)
Regulator
Notified body
Testing lab
Healthcare progessionals
Select all product types you face.
Installed medical devices
Implantable medical devices
Medical instruments
IVD
Others
Specify product type

Proposal of Work Items

No.	Work Item	Deliverables	Timeline
1	e-Label/e-IFU as an alternate method for compliance to labeling requirement	Solutions proposed to overcome potential barriers posed by different stakeholders (regulators, users, or patients) • Enact New Regulations • Limit the applicability scope to selected MD types, e.g. professional users, not consumer	2018 onward
2	Regulation on 3D Printed Medical Device	Guidance aligned with IMDRF work item	2018 onward

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THANK YOU!