Resolutions towards Endorsement

20th AHWP Meeting
2-6 Nov 2015, Bangkok, Thailand

Mr. Bryan So
Executive Deputy Secretary General, AHWP

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Resolution towards Endorsement

AHWP new member economy applications

1) Mongolia
2) Republic of Kazakhstan

WG documents

1) Guidance for Preparation of a Common Submission Dossier Template Dossier for General Medical Device Product Submission
2) White Paper on Regulation of Combination Products – a Review of International Practice
3) Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device"
4) Guidance document on Qualification of Medical Device Software
5) Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative

Resolution towards Endorsement

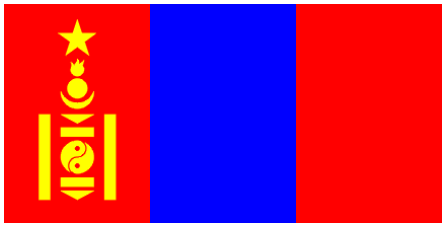
- ***WG documents (Cont.)***

6) Clinical Evaluation
7) Clinical Evidence for Medical Device – Key Definitions and Concepts
8) Clinical Evidence for IVD Medical Device – Key Definitions and Concept
9) Clinical Evidence for IVD Medical Device – Scientific Validity Determination and Performance Evaluation
10) Distributor Auditing Checklist
11) Guidance on Regulatory Auditing of Quality Management System of Medical Device Distributions: Auditing Strategies
12) Regulatory Audit Report Guidance Document
13) Guidance for Medical Device Naming Rule

AHWP New Member Economy Application

Mongolia

Application for AHWP member economy was received from Ministry of Health and Sports, Mongolia:



- ✓ Official letter for application
- ✓ Application Form with Nominated Representatives:
  - – Primary (Regulatory Authority) – Mr Bayarjargal. S
  - – Secondary (Regulatory Authority) – Mr Ganbaatar. Ts
  - – Primary (Industry) – Ms Enkhjargal Biziya

Endorsement

Yes / No?

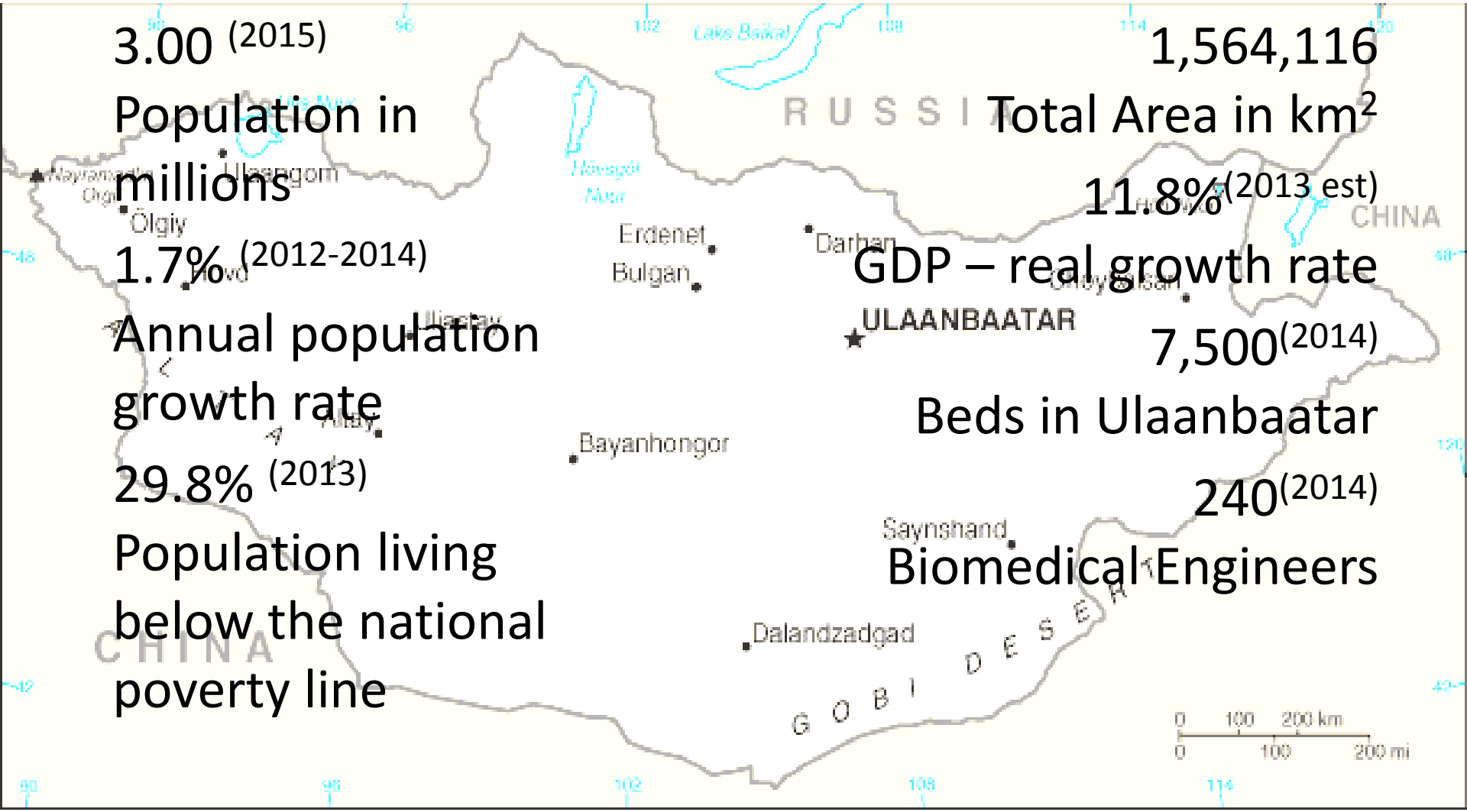
(Short speech by Ms Biziya, Ministrial Advisor, MOH and Sports)

Mongolia Representative

Enkhjargal Biziya (Ph.D)
Chairman, MMDA, Mongolia
(Founder MMDA in Oct,2015)
Ministrial advisor MOHS
Director, Subsection for Biomedical engineering and medical device of Mongolian Ministry of Health and Sports
Professor Biomedical engineering dept, Mongolian University of Science and Technology
CEO, IMI Clinical engineering institute
President, Mongolian Society of Biomedical Engineering


RUSSIA
KAZAKHSTAN
UZBEKISTAN
MONGOLIA
JAPAN
IRAN
AFGHANISTAN
CHINA
PAKISTAN
INDIA
BURMA
THAILAND
PHILIPPINES
SRI LANKA
MALDIVES
Arabian Sea
Bay of Bengal
South China Sea
Philippine Sea

Mongolia – Fast Facts



3.00 (2015)
Population in millions

1.7% (2012-2014)
Annual population growth rate

29.8% (2013)
Population living below the national poverty line

1,564,116
Total Area in km^2

11.8% (2013 est)
GDP – real growth rate

7,500 (2014)
Beds in Ulaanbaatar

240 (2014)
Biomedical Engineers

AHWP New Member Economy Application

Republic of Kazakhstan

Application for AHWP member economy was received from Ministry of Health and Social Development, the Republic of Kazakhstan

- ✓ Official letter for application
- ✓ Application Form with Nominated Representatives:
  – Primary (Regulatory Authority) – Ms Gulmira Mukhamejanova

Endorsement

Yes / No?

(Short speech by Ms Gulmira, Deputy of Director General, MOH and Social Development)

RSE “National center for drugs and medical devices expertise”

REGISTRATION AND EXPERTISE OF MEDICAL DEVICES IN THE REPUBLIC OF KAZAKHSTAN

Mukhamedjanova G. –deputy general director of RSE “National center for drugs and medical devices expertise” MoHSD RoK

Bangkok, 2015


RUSSIA
KAZAKHSTAN
UZBEKISTAN
TURKMENISTAN
KYRGYZSTAN
TAJIKISTAN
AFGHANISTAN
PAKISTAN
INDIA
CHINA
IRAN
AZER.
MONG.
Caspian Sea
Aral Sea
Lake Balkhash
Astana
Tashkent
Bishkek
Dushanbe
Ashgabat
Kabul
Islamabad
Baku
Tehran

Resolution towards Endorsement

- ***AHWP new member economy applications***

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Guidance for Preparation of a Common Submission Dossier Template Dossier for General Medical Device Product Submission

FINAL DOCUMENT – GUIDANCE DOCUMENT

- ➢ Prepared by WG 1 – Pre-market: General MD
- ✓ Discussed in AHWP TC Leaders Meeting, Mar 2015
- ✓ Reviewed and commented by AHWP TC Leaders
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Posted on AHWP Website towards Endorsement

Endorsement

Yes / No?

Resolution towards Endorsement

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White Paper on Regulation of Combination Products – a Review of International Practice

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Definition of the Terms “Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device”

FINAL DOCUMENT – GUIDANCE DOCUMENT

- ➢ Prepared by WG 2 – Pre-market: IVDD
- ✓ Discussed in AHWP TC Leaders Meeting, Mar 2015
- ✓ Reviewed and commented by AHWP TC Leaders
- ✓ Posted on AHWP Website and for Calls for Comments

The endorsement of this document will be deferred for further discussion.

Resolution towards Endorsement

- ***AHWP new member economy applications***

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Guidance document on Qualification of Medical Device Software

FINAL DOCUMENT – GUIDANCE DOCUMENT

- ➢ Prepared by WG 3 – Pre-market: Software as a Medical Device
- ✓ Discussed in AHWP TC Leaders Meeting, Mar 2015
- ✓ Reviewed and commented by AHWP TC Leaders
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Posted on AHWP Website towards Endorsement

Endorsement

Yes / No?

Resolution towards Endorsement

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Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative

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- ➢ Prepared by WG 4 – Post-market
- ✓ Discussed in AHWP TC Leaders Meeting, Mar 2015
- ✓ Reviewed and commented by AHWP TC Leaders
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Posted on AHWP Website towards Endorsement

- Conditions:
  - ➢ For endorsement **under the condition** that the definition of "Adverse Event" (AE) will be further reviewed by WG and TC.

Conditional Endorsement

Yes / No?

Resolution towards Endorsement

- *WG documents (Cont.)*

6) Clinical Evaluation
7) Clinical Evidence for Medical Device – Key Definitions and Concepts
8) Clinical Evidence for IVD Medical Device – Key Definitions and Concept
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Clinical Evaluation

FINAL DOCUMENT – GUIDANCE DOCUMENT

- ➢ Prepared by WG 5 – Clinical Performance & Safety
- ✓ Discussed in AHWP TC Leaders Meeting, Mar 2015
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Clinical Evidence for Medical Device – Key Definitions and Concepts

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Endorsement

Yes / No?

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Clinical Evidence for IVD Medical Device – Key Definitions and Concept

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Clinical Evidence for IVD Medical Device – Scientific Validity Determination and Performance Evaluation

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Distributor Auditing Checklist

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- ➢ Prepared by WG 6 – Quality Management System: Audit & Assessment
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Regulatory Audit Report Guidance Document

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Guidance for Medical Device Naming Rule

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- ➢ Prepared by STG (U&N) – Special Task Group on UDI & Nomenclature
- ✓ Discussed in AHWP TC Leaders Meeting, Mar 2015
- ✓ Reviewed and commented by AHWP TC Leaders
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