



THE VOICE OF HIGH MEDICAL TECHNOLOGY INDUSTRY IN RUSSIA



IMEDA

International Medical Device Manufacturers Association

October 4, 2011

Mission



Be the advocate for a legal, regulatory and economic climate that advances public health care by assuring patient access to the benefits of medical technology and ensures equal opportunities for national and international industry.



Promote and encourage ethical business principles and practices among its members and the industry in general.



Co-operate with and represent the interests of the medical technology industry and co-operate with the Parliament, Ministries and other appropriate government organs.



Encourage the development of new and innovative technologies and ensure that these are accessible to patients.

Strategic

Objectives 2011

IMEDA AND THE AUTHORITIES

Consolidates

the voice of the major market players

Moderates

the dialogue between the industry and the state

Initiates

ideas on how to modernize the Russian medical devices industry and make the state-of-the-art technologies available for the Russian population

IMEDA AND THE MEMBERS

- Provides** a reliable source of the information on the new regulations (actual and upcoming) and helps to understand their impact on the business and future of the industry
- Helps** to understand the main trends of the market place and the Russian statutory environment
- Provides** with valuable business tools: surveys, snapshots, reports, updates, etc.
- Helps** to establish contacts within industry and outside

IMEDA AND THE SOCIETY

Informs and educates Russian population about the hottest new technologies available in the healthcare

Supplies the Russian society with the products of highest quality and takes full responsibility for their use in Russia

Guarantees the Russian society access to the modern advancements of the world healthcare industry

Key industry challenges 2011

- No clear **legislation** on Medical devices
 - New regulatory initiatives are controversial and not connected between themselves (technical regulations of Customs Union, Law on medical devices, Medical devices state procurement ammendments, Bill on nation's health protection)
- No **definition** of Medical devices and their specific attributes/characteristics
- No good **expertise** of the industry specifics at the government level
 - “pharma” orientation of the officials
 - Limited exposure to the whole range of MDs (mostly “heavy diagnostic equipment”)
- No clear industry **image** nor understanding of the MDs industry **value proposition** and importance for the society and the government

LEGISLATION AND REGULATIONS: HAVES AND HAVE-NOTS

HAVES?

FZ 94
State procurement

Bill on Nation's Health protection?

FZ 326
Medical insurance

HAVE-NOTS

RUSSIA:
Medical devices circulation?
Technical regulation?

Customs Union?
Harmonization of requirements?
Harmonization of technical
regulation?

Harmonization with EU?
Harmonization with GHTF
recommendations (Global
harmonization task force)?

CUSTOMS UNION REGULATION

Q1 2010

Decision on development of the Technical regulation on safety of medical devices by the Customs Union Commission. Russian delegation in charge of the draft regulation

December 8, 2010

Change of responsibilities: Belarus nominated as responsible for the Technical regulation draft. Draft submission deadline – March 2011. Final submission for enforcement – June 2011.

January 25-26, 2011

Customs Union Commission decides to suspend the technical regulation development due to the substantial differences in regulation on medical devices of the 3 countries. Recommendation to the 3 countries to harmonize regulations first.

May 18, 2011

Meeting of the Customs Union Coordination committee for technical regulation, sanitary, veterinary and phyto-sanitary measures. Decision to create a new task force on harmonization. Draft submission deadline changed – August 2011.

CUSTOMS UNION REGULATION

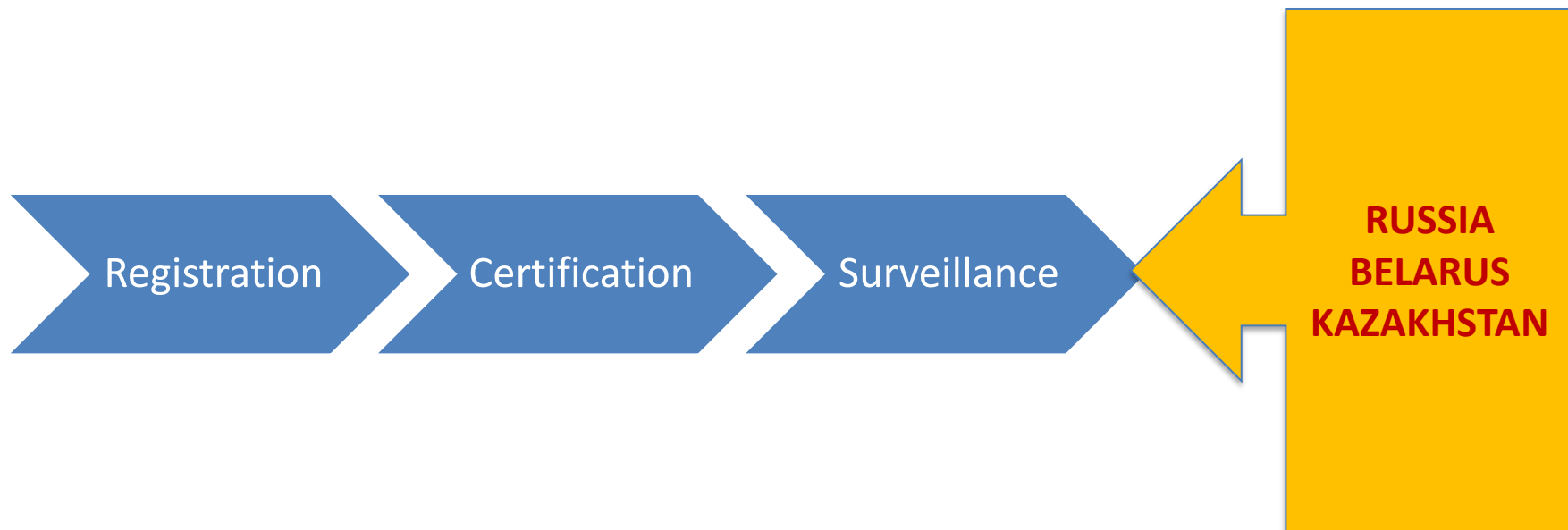
August 11-12, 2011

The meeting of the taskforce takes place. The 3 countries representatives of the Ministries of Health support the 2 main ideas:

- 1. The technical regulation for the medical devices is not necessary.** The countries should gradually harmonized their legislations instead. The results of their efforts should be the Agreement on harmonization of regulations.
- 2. The Agreement and the harmonized principles should cover ONLY the local manufacturers** of the Customs Union countries.

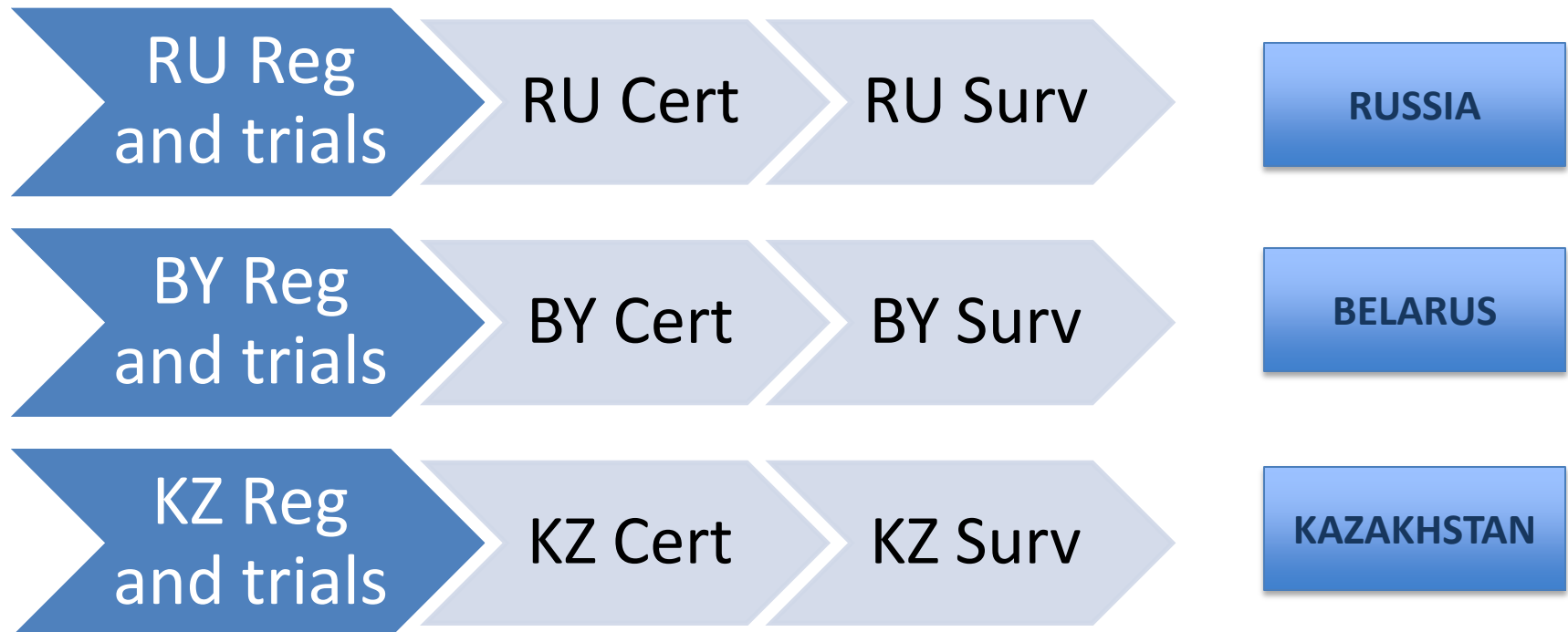
PROPOSED MARKET ACCESS PRINCIPLES FOR LOCAL AND FOREIGN MEDICAL DEVICES

**LOCAL MEDICAL DEVICES ENTER THE CUSTOMS UNION MARKET
IN ANY OF THE CU COUNTRIES WITH 1 SET OF RULES AND REGULATIONS
FOR REGISTRATION, MARKET ACCESS AND SURVEILLANCE**

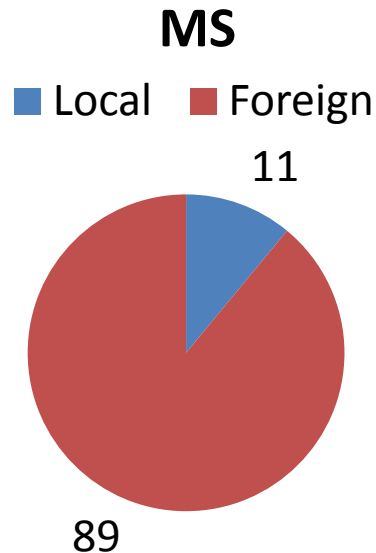


PROPOSED MARKET ACCESS PRINCIPLES FOR LOCAL AND FOREIGN MEDICAL DEVICES

FOREIGN MEDICAL DEVICES ENTER THE CUSTOMS UNION MARKET IN ANY OF THE CU COUNTRIES WITH 3 SETS OF RULES AND REGULATIONS FOR REGISTRATION, MARKET ACCESS AND SURVEILLANCE



ECONOMICAL AND REGULATORY IMPACT ON THE RUSSIAN BIOTECH MARKET



89% of the products on the CU market will go through

3 different regulatory systems with differences in:

- Safety requirements
- Quality management system requirements
- Risk classification variations
- 3 different products registers
- 3 different systems of market access: trials and tests
- 3 different surveillance systems
- Not subject to the Customs Union principles of free circulation of products on the market of the CU

11% of the products on the market will go through:

- Unified registration and market access procedure, recognized by the CU countries;
- Unified trials and tests: recognized by the CU countries;
- Unified surveillance system with inspections and controls recognized by the CU countries

IMEDA POSITION

- The Agreement on harmonization of medical devices legislations at the Customs Union will introduce discriminative practices towards 89% of the marketed products/manufacturers operating in the Customs Union. International manufacturers will be excluded from the direct access to the 3 Customs Union markets.
- The safety requirements to the medical devices should be aligned and equalized regardless of the country of origin but linked to the Risk class as it is common in all other countries of the world.
- The only working model to ensure the unification of safety requirements and at the same time free products circulation between the countries is the model which has not been completed and now seems to be disregarded: technical regulation for the common customs zone and national regulations in each country (EU model). The direction on harmonization of the regulation with the EU and GHTF recommendations should be maintained and implemented.
- The sense of the Agreement draft contradicts the goals and objectives of the Customs union.



CALL FOR ACTION!

We call upon you to help us to raise this question to the top political level, and to ensure that Russia will respect the rules and principles agreed in the GHTF and other international medical technology forums in any future legislation

2011

Partners
are welcome
to strengthen our voice!

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