HEALTH MINISTRY OF LATVIA HEALTH STATISTICS AND MEDICAL TECHNOLOGIES STATE AGENCY

MEDICAL DEVICES MARKET SURVEILLANCE AND VIGILANCE SYSTEM (LV/2003/IB/EC-02 FINAL REPORT)

IMPLAMENTATION AND FULFILMENT OF THE TWINNING PROJECT

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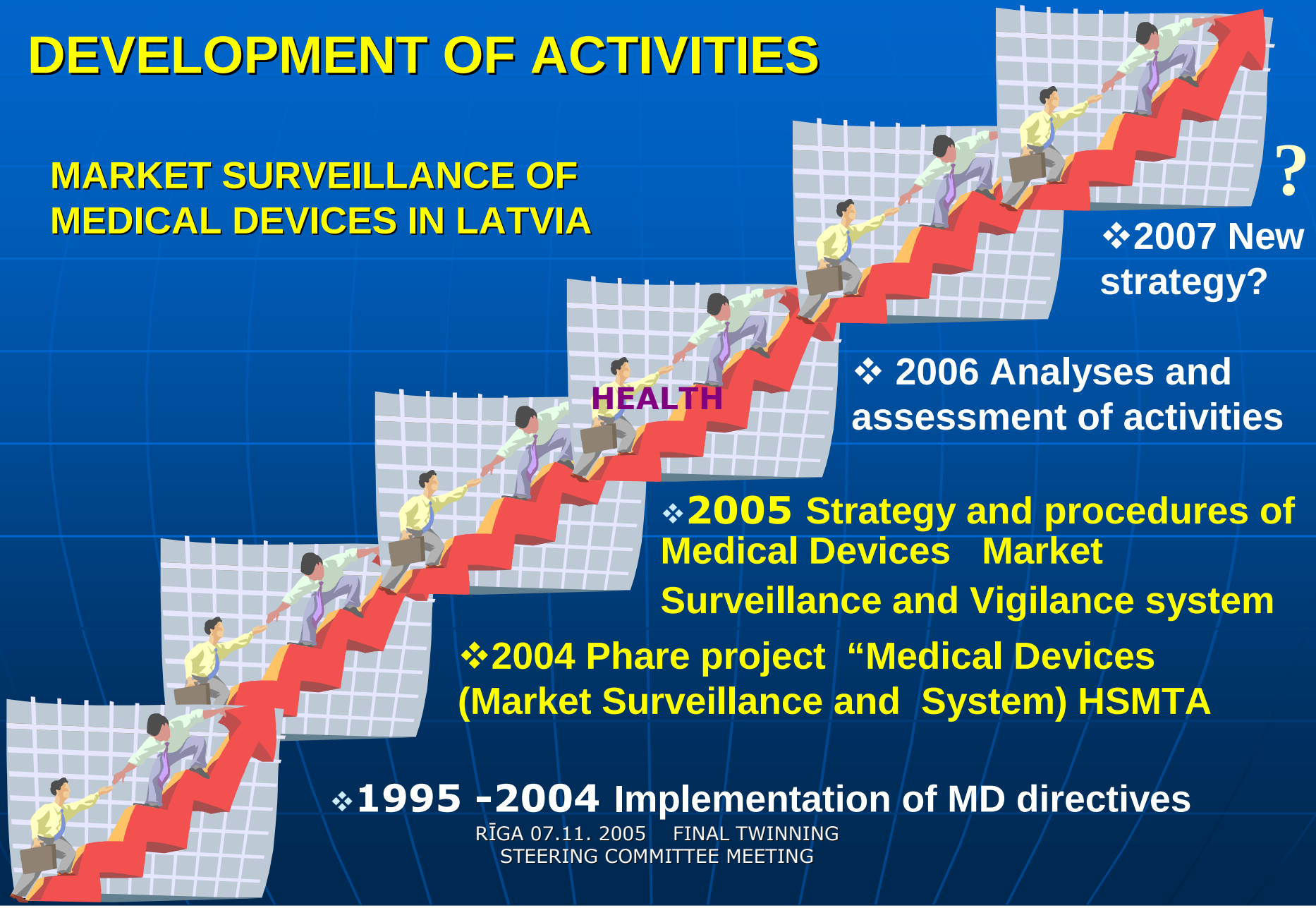
ALNIS DAMBERGS – HEAD OF MEDICAL TECHNOLOGIES AND STANDARDS SECTION, HSMTA

RĪGA 07.11. 2005 FINAL TWINNING STEERING COMMITTEE MEETING

MINISTRY OF HEALTH OF LATVIA HEALTH STATISTICS AND MEDICAL TECHNOLOGIES STATE AGENCY

DEVELOPMENT OF ACTIVITIES

MARKET SURVEILLANCE OF MEDICAL DEVICES IN LATVIA



❖2007 New strategy?

?

❖ 2006 Analyses and assessment of activities

❖2005 Strategy and procedures of Medical Devices Market Surveillance and Vigilance system

❖2004 Phare project "Medical Devices (Market Surveillance and System) HSMTA

❖1995 -2004 Implementation of MD directives

Adoption and implementation of the *acquis*

- Progressive alignment of framework laws.
- Progressive alignment of sectorial laws with the MDDs and other directives.
- Development of technical infrastructures in order to ensure the technical competence of the bodies involved in the conformity assessment procedures is at the level required by EU.
- Setting up the necessary structures for the correct enforcement of the *acquis*.
- Define the procedures and means for correctly carrying out vigilance and market surveillance.

Phasing in

- **Transposition of all technical regulations and European technical acts into the national legislation of Latvia.**
- **Establish and implementation of common European regulatory standards including those ones harmonised within the framework of EU.**
- **Early exchange of scientific and technical expertise and legal regulatory affairs information.**
- **Implementation of operational aspects of efficient regulatory authorities.**

- Building up of **mutual confidence** in order to strengthen the process work, quality management systems, handling of review and the development of methods to implement scientific and technical advances.
- Obtain **feedback on the implementation** activities undertaken in the area of the regulation of Medical Devices.
- Contribute to **informing Latvian stakeholders** of their obligations pre- and post- accession.
- Obtain feedback on **progress made by Latvian stakeholders** towards meeting their post-accession obligations.

6. **EC Directive 2003/12/EC ON THE RECLASSIFICATION OF BREAST IMPLANTS IN THE FRAMAWORK OF DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES 03.02.2003**

7. **EC Directive 85/374/EEC ON PRODUCT COMPLIANCE.**

8. **EC Directive 2002/96/EC ON WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT 27.01.2003 (WEEE)**

9. **EC Directive 2002/95/EC ON RESTRICTION OF USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT 27.01.2003 (RoHS)**

MEDICAL TREATMENT LAW 26.02.1998; 14.06.2000; 20.06.2001;

Medical Device Market Indirect Supervision

1. **Medical devices and goods registration (notification) as well as market indirect supervision was initiated in 1998;**
2. **National Register of medical devices and goods import was established in 1998;**
3. **Validity of Licenses for medical devices import and distribution 1 to 5 years;**
4. **EU standard LVS EN ISO 15225:2000 are used from January 1, 2003 in medical devices and goods registration;**
5. **First safety group medical device registration simultaneously with supply legality control beginning from June 19, 2002.**

BEFORE:

MEDICAL DEVICE MARKET SUPERVISION, LEGISLATION

1. **Regulation of medical device and product registration, trade and distribution / MC Regulations, March 6, 2001/**

2. **Regulation on Medical devices and goods exploitation and technical supervision / MC Regulations, February 19, 2002/.**

3. **???**

AFTER:

MEDICAL DEVICE MARKET SUPERVISION, LEGISLATION

1. **Regulation of medical device and product registration, trade and distribution / MC Regulations, March 6, 2001/**

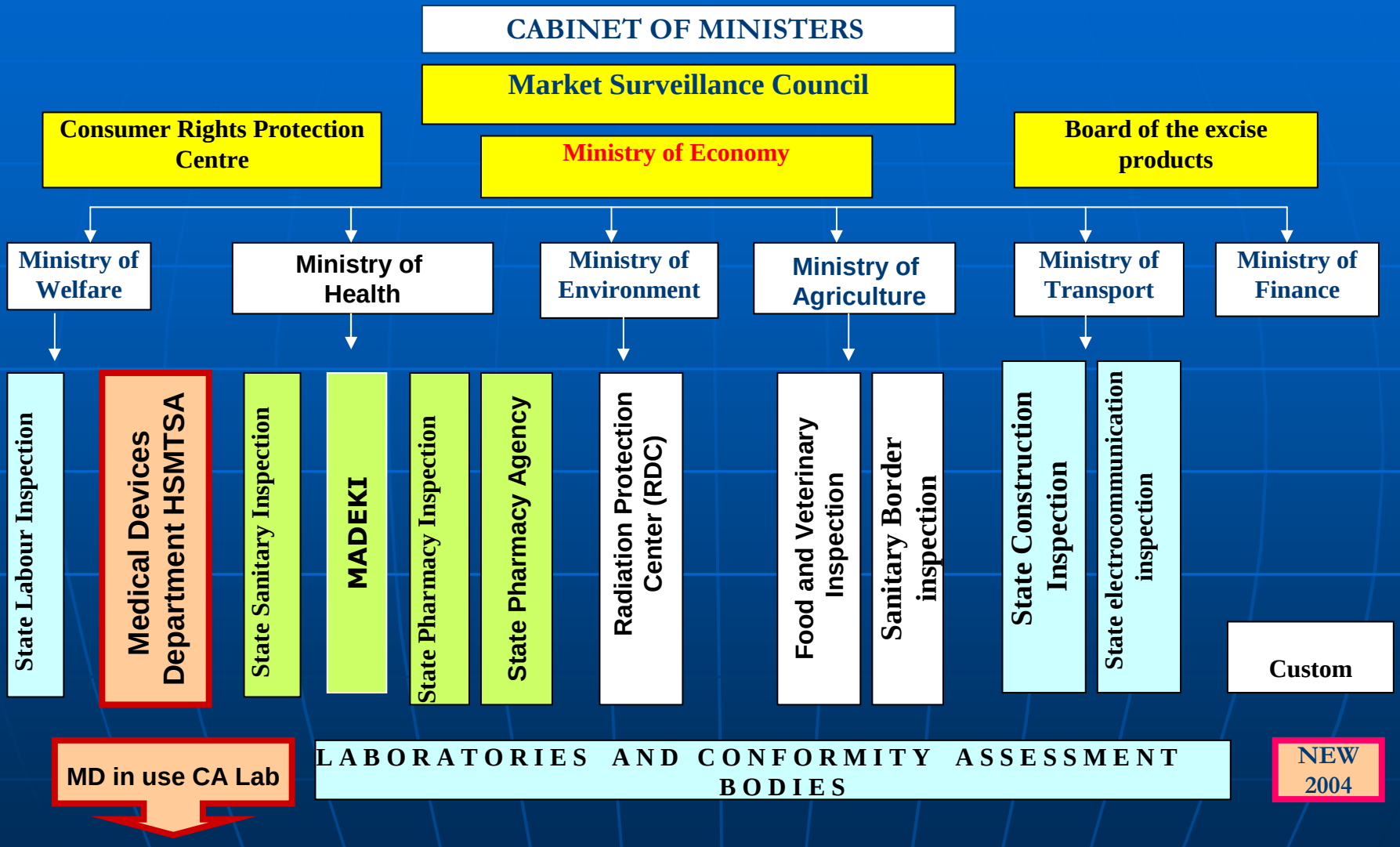
2. **Regulation on Medical devices and goods exploitation and technical supervision / MC Regulations, February 19, 2002/.**

3. **??? "Requirements for placing on the market and putting into service, distribution, operation and technical supervision of medical devices" MC Regulations, August 2nd 2005**

MINISTRY OF HEALTH OF LATVIA

HEALTH STATISTICS AND MEDICAL TECHNOLOGIES STATE AGENCY

MARKET SURVEILLANCE SYSTEM IN LATVIA



NATIONAL EXPERIENCE

HEALTH MINISTRY (2003):

- LEGISLATION
- IMPLEMENTATION
- DESIGNATION OF COMPETENT AUTHORITY – HEALTH STATISTICS AND MEDICAL TECHNOLOGIES STATE AGENCY (09.03.2003)
- ENFORCEMENT OF THE MDD&NATIONAL LEGISLATION
- REGISTRATION OF MANUFACTURERS/ AUTHORIZED REPRESENTATIVES/ VENDORS
- ?? MD IN USE TECHNICAL SURVEILLANCE (BENEFIT OF PATIENT?)

HSMTSA TASKS AND TOPICS

- Aspects of Public Health and Internal Market
- Post-accession Common Decision Making
- Availability of Medical Devices and Implications for Member States and Industries
- Import from Third Countries
- **The Developing of EU Regulatory System**

HEALTH STATISTICS AND MEDICAL TECHNOLOGIES STATE AGENCY HEALTH MINISTRY OF LATVIA

MEDICAL DEVICES BOARD FOR LATVIA

BEFORE:

DIRECTOR (HSMTSA)
Mr. EGILS LAVENDELIS

MD REGULATORY PROJECTS COORDINATOR

DEPUTY DIRECTOR ON MT AND MD

MEDICAL DEVICES DEPARTMENT*

MD TECHNICAL CONFORMITY ASSESMENT AND SURVEILLANCE SECTION

TECHNICAL SURVEILLANCE EXPERTS SECTION

LABORATORY

IT SUPPORT (LATMED)

MD MARKET SURVEILLANCE UNIT

MD VIGILANCE SYSTEM SECTION
Mrs. NELLIJA KANGARE

MD MARKET SURVEILLANCE SECTION
Mr. JANIS BEBRIS

1ST SAFETY GROUP MD STATE REGISTER

MD MANUFACTURING AND EXPLOITATION INSPECTION GROUP

MD COMPETENT AUTHORITY FROM SEPTEMBER 2003

HEALTH STATISTICS AND MEDICAL TECHNOLOGIES STATE AGENCY HEALTH MINISTRY OF LATVIA

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AFTER:

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FUTURE:

MEDICAL DEVICES DEPARTMENT*

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MD MARKET SURVEILLANCE UNIT

TECHNICAL SURVEILLANCE EXPERTS SECTION

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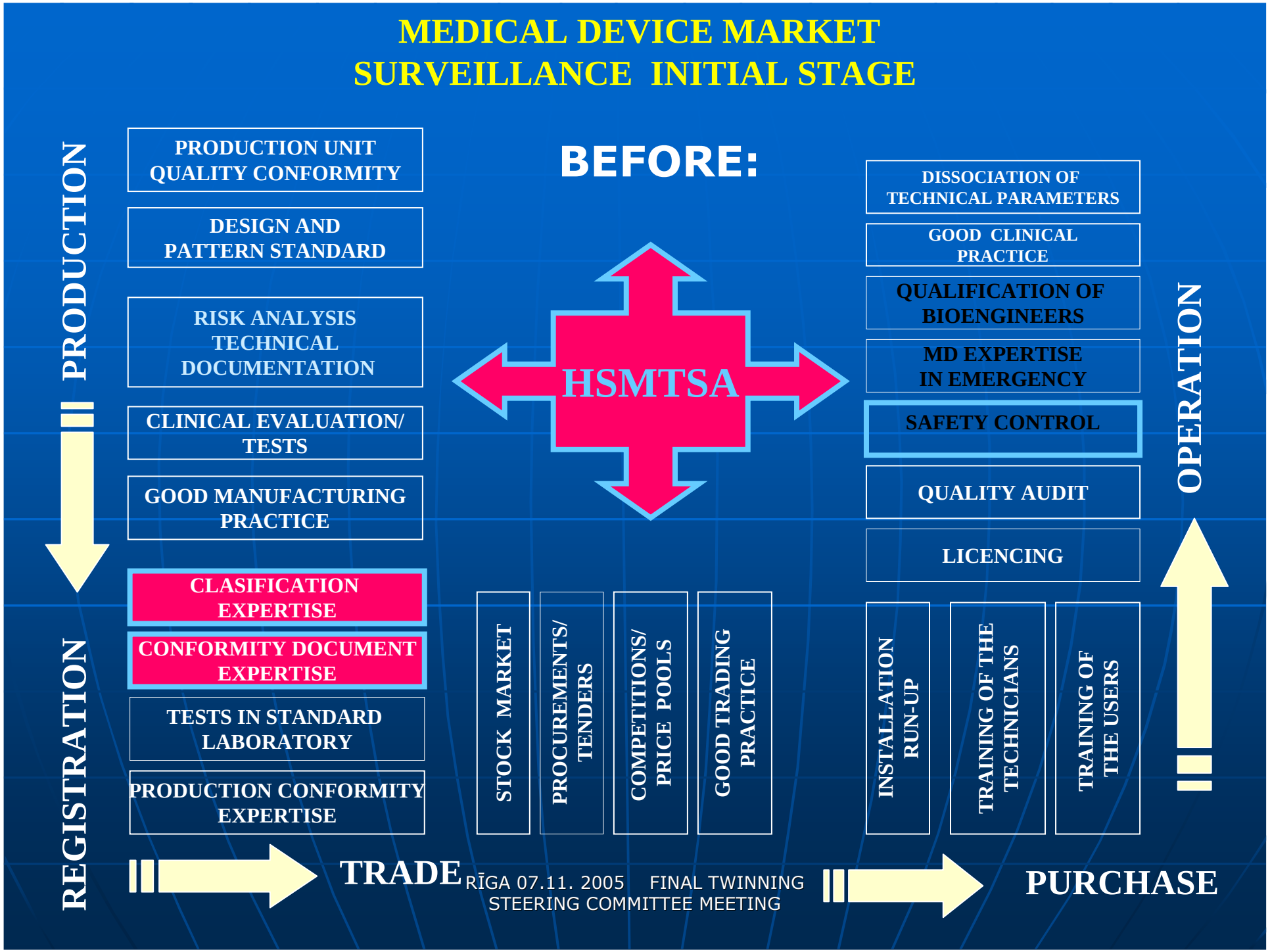
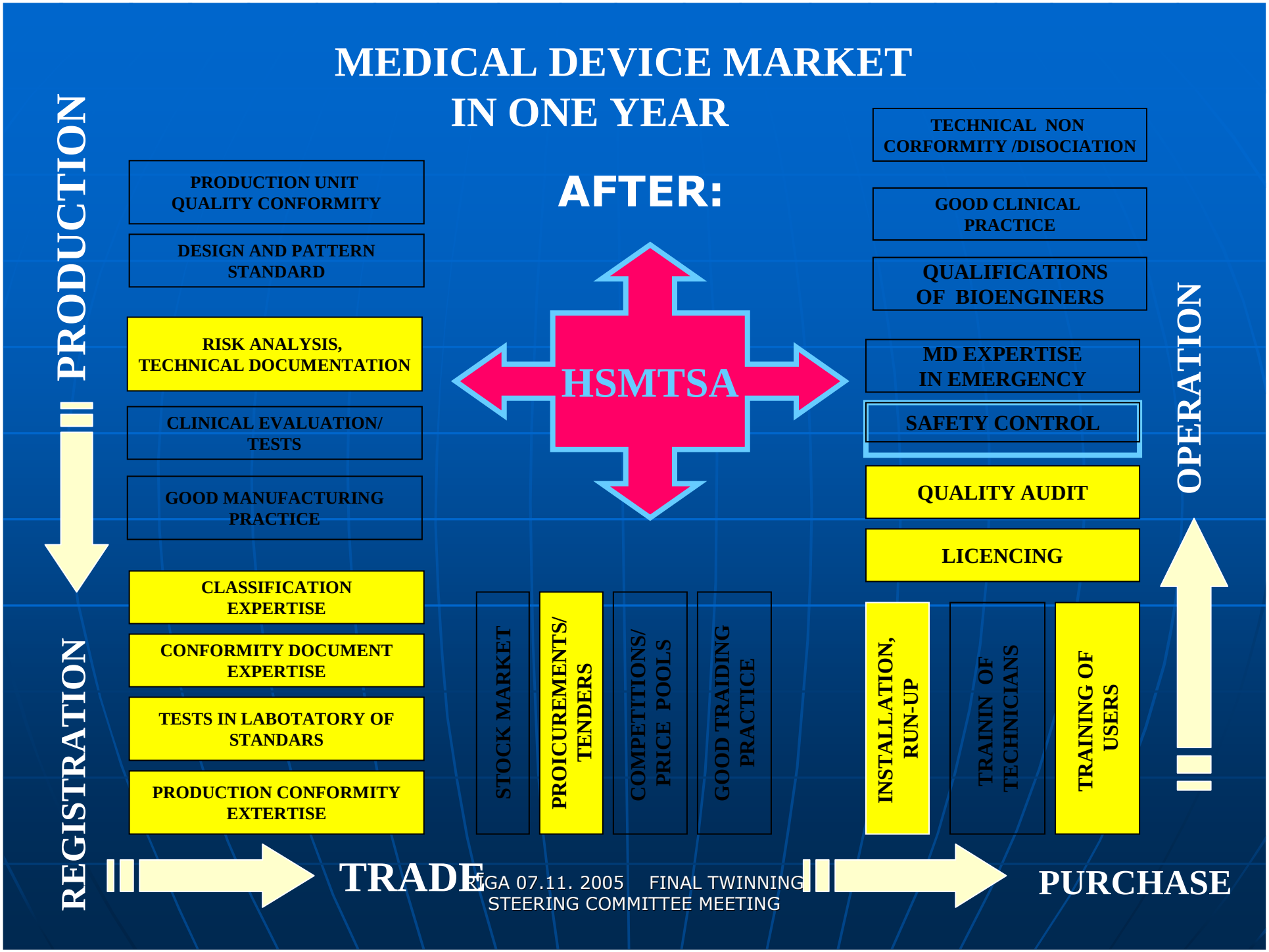
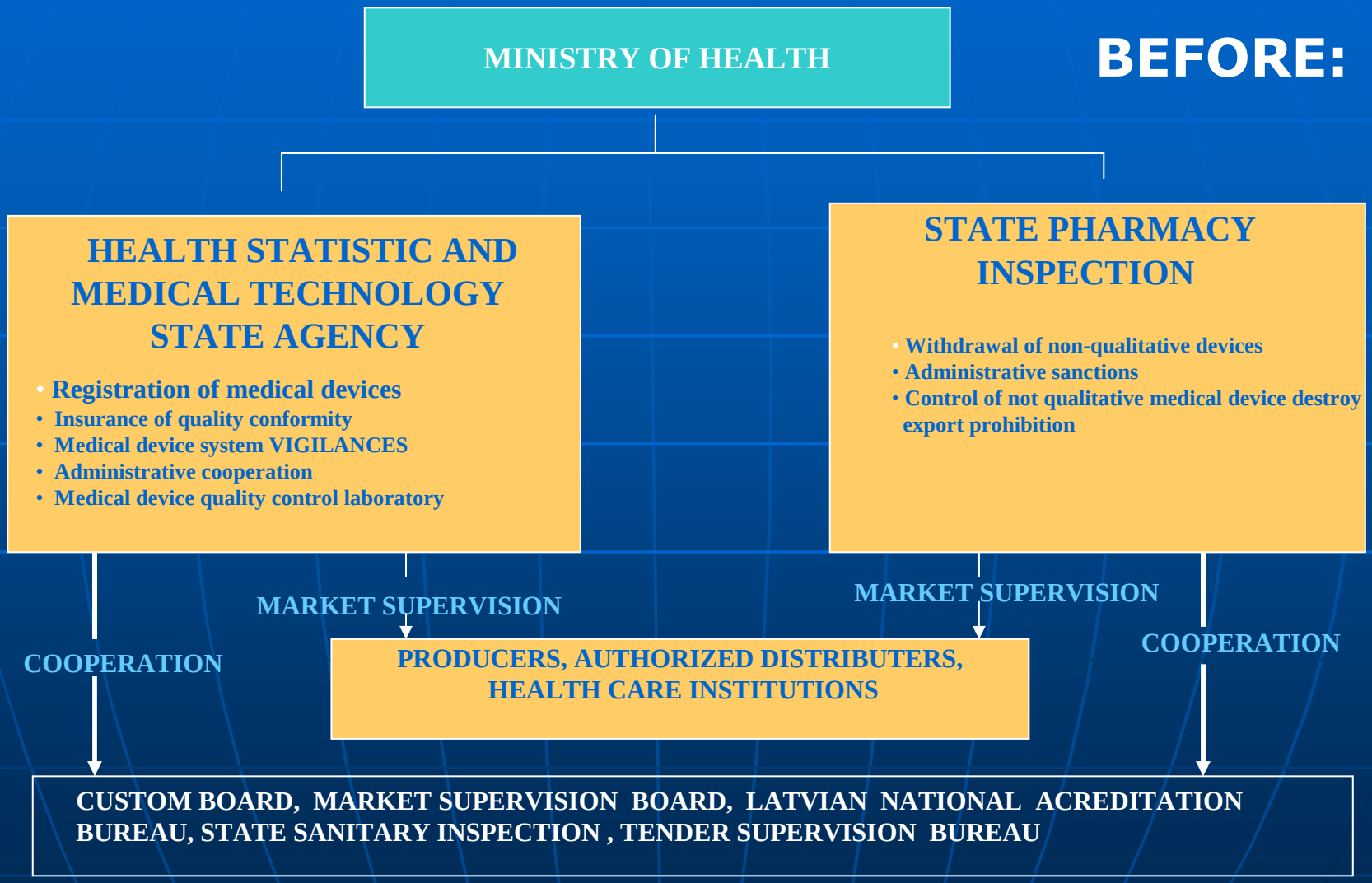
MEDICAL DEVICE MARKET
SURVEILLANCE INITIAL STAGE

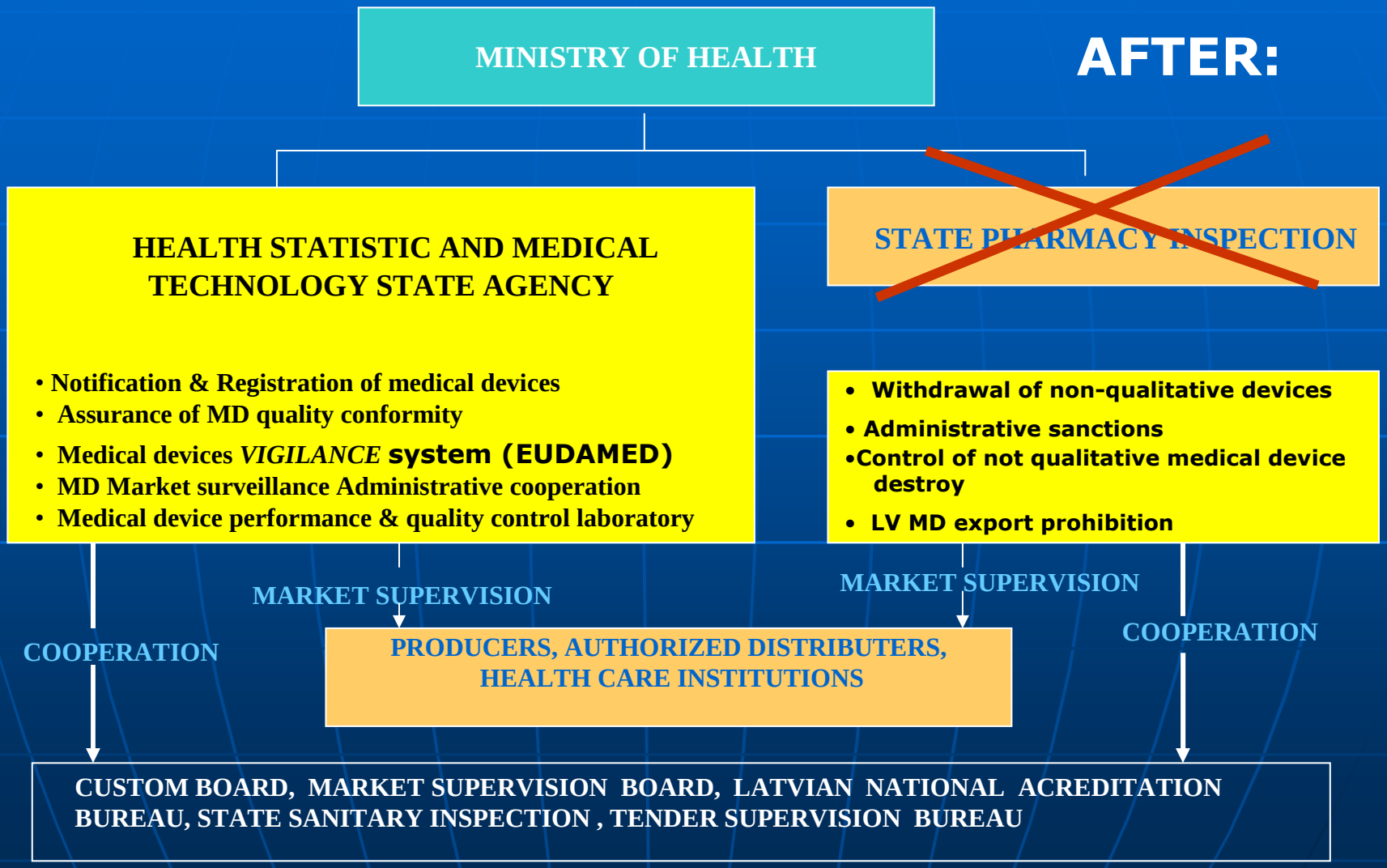



MEDICAL DEVICE MARKET
IN ONE YEAR
AFTER:
PRODUCTION
REGISTRATION
OPERATION
TRADE
PURCHASE
HSMTSA
PRODUCTION UNIT QUALITY CONFORMITY
DESIGN AND PATTERN STANDARD
RISK ANALYSIS, TECHNICAL DOCUMENTATION
CLINICAL EVALUATION/ TESTS
GOOD MANUFACTURING PRACTICE
CLASSIFICATION EXPERTISE
CONFORMITY DOCUMENT EXPERTISE
TESTS IN LABOTATORY OF STANDARS
PRODUCTION CONFORMITY EXTERTISE
TECHNICAL NON CORFORMITY /DISOCIATION
GOOD CLINICAL PRACTICE
QUALIFICATIONS OF BIOENGINERS
MD EXPERTISE IN EMERGENCY
SAFETY CONTROL
QUALITY AUDIT
LICENCING
STOCK MARKET
PROICUREMENTS/ TENDERS
COMPETITIONS/ PRICE POOLS
GOOD TRAIDING PRACTICE
INSTALLATION, RUN-UP
TRAININ OF TECHNICIANS
TRAINING OF USERS

Perspective health care devices market supervision scheme

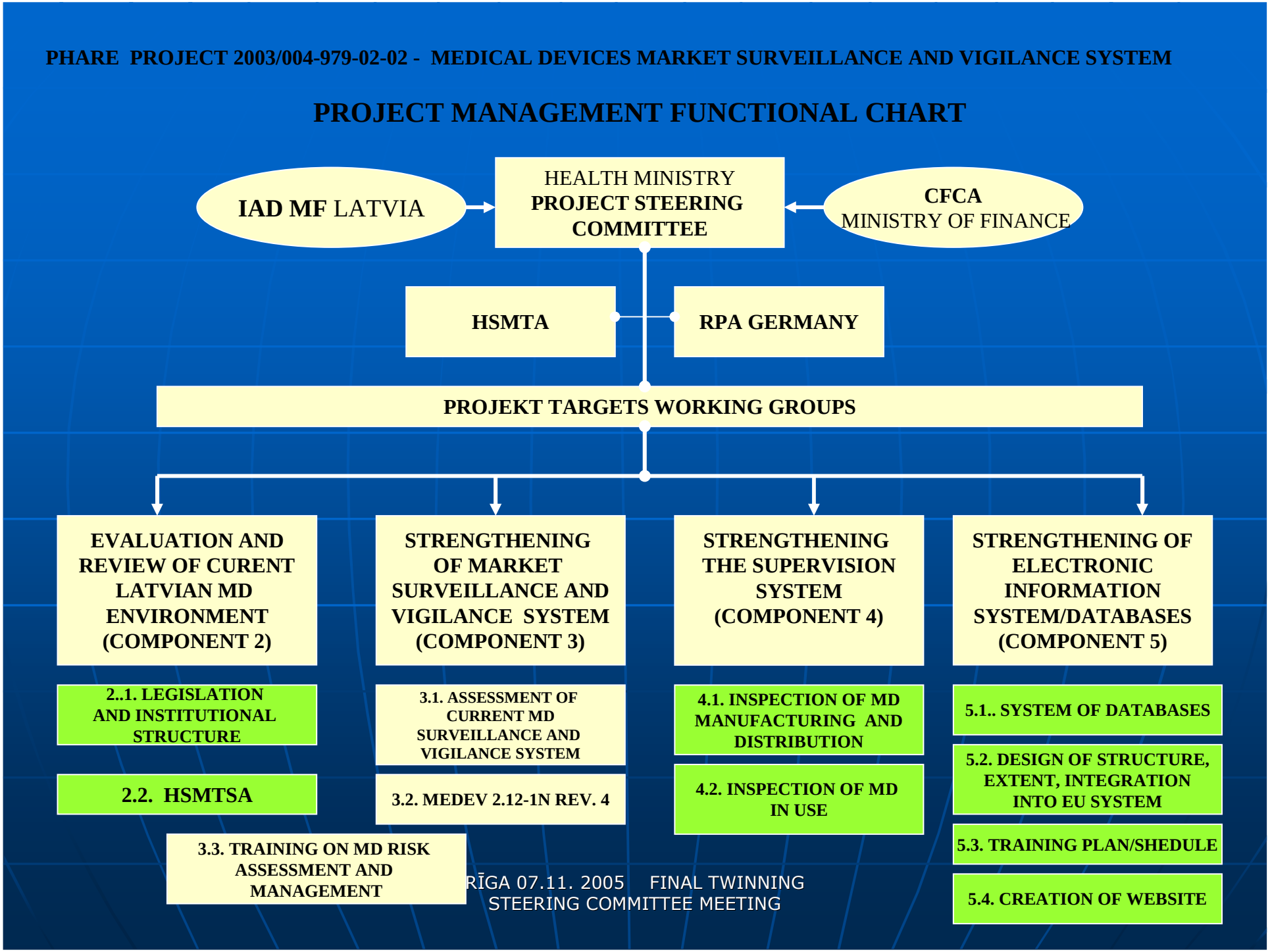


Perspective health care devices market supervision scheme



PHARE PROJECT 2003/004-979-02-02 - MEDICAL DEVICES MARKET SURVEILLANCE AND VIGILANCE SYSTEM

PROJECT MANAGEMENT FUNCTIONAL CHART



MEDICAL DEVICES TWINNING COVENANT COMPONENTS

2. COMPONENT

EVALUATION AND REVIEW OF CURRENT LATVIAN MD ENVIRONMENT

2.1. LEGISLATION AND INSTITUTIONAL STRUCTURE

2.1.1. REVIEW OF EXISTING AND DRAFTED LEGISLATION, STRUCTURE OF THE INSTITUTIONAL SYSTEM AND THE RELATED LEGAL PRACTICE;
2.1.2. APPROBATION OF APPROPRIATE STANDARDS;

•2.2. HEALTH STATISTICS AND MEDICAL TECHNOLOGIES STATE AGENCY

2.2.1. EVALUATION OF THE CURRENT STRUCTURE OF THE AGENCY;
2.2.2. EVALUATION AND REVIEW OF THE ENVIRONMENT OF THE AGENCY

LATVIAN EXPERTS TEAM: **ALNIS DAMBERGS (LEADER)**
MARIS IGNATOVIČS – LAWYER

SUPPORT: **MEDICAL CONSULTING SERVICE Ltd;**
DIRECTOR: DMITRIJS BABARIKINS
SUPPLY TENDER IS FINISHED;

MEDICAL DEVICES TWINNING COVENANT COMPONENTS

3. COMPONENT

STRENGTHENING OF MARKET SURVEILLANCE AND VIGILANCE SYSTEM

3.1. ASSEMENT OF CURRENT MD MARKET SURVEILLANCE AND VIGILANCE SYSTEM

3.2. INTEGRATION AND ALIGNMENT OF THE LATVIAN VIGILANCE SYSTEM ACCORDING TO GUIDELINE MEDDEV 2.12-1. REV 4;

3.3. ENCHANCEMENT OF SAFETY ACTIONS AND TRAINING ON RISK ASSESSMENT AND RISK MANAGEMENT AT EU LEVEL TO DIFFERENT PRODUCT GROUPS OF MD (ACTIVE IMD, MD, IVDMD)

LATVIAN EXPERTS TEAM:	**Ms. IVETA GAVARE (LEADER)** **Mr. JANIS BEBRIS** **Ms. NELLIJA KANGARE**
SUPPORT:	**CONSULTING SERVICE COMPANY TENDER IS FINISHED (PILOT PROJECT)** **ISO/TS 20225:2001 TRANSLATION TENDER IS FINISHED;**

MEDICAL DEVICES TWINNING COVENANT COMPONENTS

4. COMPONENT

STRENGTHENING THE SUPERVISION SYSTEM

4.1. STRENGTHENING OF INSPECTION OF MD IN MANUFACTURING AND DISTRIBUTION

4.2. STRENGTHENING OF INSPECTION OF MD IN USE

LATVIAN EXPERTS TEAM: Ms. ELLA JOFFE (LEADER)
Mr. JANIS BEBRIS

SUPPORT: STUDY VISIT - 4.1. (3X5) – APRIL 2005;

ACTIVITIES: 21-22.12.2004
14-16.02.2005

MEDICAL DEVICES TWINNING COVENANT COMPONENTS

4. COMPONENT

STRENGTHENING THE SUPERVISION SYSTEM

4.1. STRENGTHENING OF AUDITS SYSTEM OF MD IN MANUFACTURING AND DISTRIBUTION ON VIGILANCE SYSTEM CASES

4.2. STRENGTHENING OF AUDITS SYSTEM OF MD IN USE

LATVIAN EXPERTS TEAM:

Mrs. ALNIS DAMBERGS (LEADER)
Mr. JANIS BEBRIS

MEDICAL DEVICES TWINNING COVENANT COMPONENTS

5. COMPONENT

STRENGTHENING OF ELECTRONIC INFORMATION SYSTEM/DATABASES

5.1. ASSEMENT OF CURRENT SYSTEM OF DATABASES

5.2. DESIGN OF STRUCTURE AND EXTENT, TECHNICAL SPECIFICATIONS AND LINKAGE TO/INTEGRATION INTO EU SYSTEMS;

5.3. SETTING UP TRAINING PLAN AND TRAINING OF AGENCY STAFF;

5.4. CREATION AND SERVICING OF WEBSITE.

LATVIAN EXPERTS TEAM:

Ms. ZITA ALTENBURGA (LEADER)
Mr. DAINIS JONĪTIS
Mr. AIVARS KURPNIEKS
Ms. NELLIJA KANGARE

SUPPORT:

THE FIRST MEETING WAS HELD ON 08.12.2004
IT REENGINEERING PROJECT AND SUPPLY TENDER WOULD BE FINISHED ON 15.11.2005


Thank you for your attention