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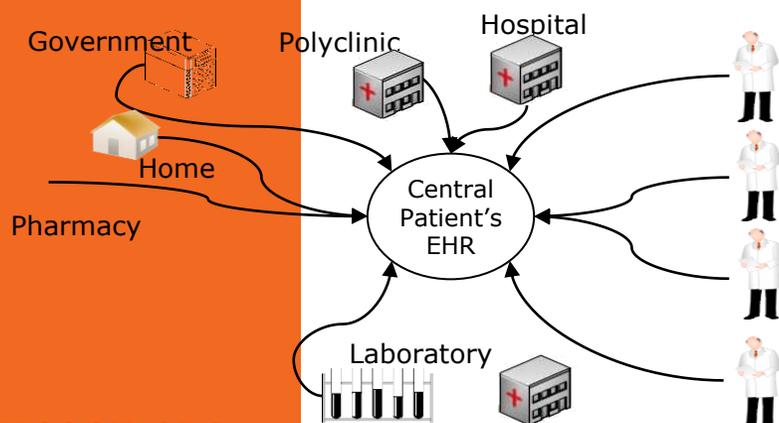
- Introduction to COCIR
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Introduction to COCIR



- COCIR is a non-profit trade association, founded in 1959 and having offices in Brussels and China, representing the medical technology industry in Europe
- COCIR covers 4 key industry sectors:
 - Medical Imaging
 - Radiotherapy
 - Health ICT
 - Electromedical
- Our Industry leads in state-of-art advanced technology and provides integrated solutions covering the complete care cycle





COCIR Membership

COCIR COMPANY MEMBERS:



NATIONAL TRADE ASSOCIATIONS MEMBERS:





COCIR at International Level



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION



1. Leadership role of Russian government at IMDRF level

- Russia as IMDRF chair 2019
 - Successful collaboration on standardization and Artificial Intelligence Workshops
- Focus needed on **implementation of IMDRF documents** in member jurisdictions and beyond

On regulatory framework, our vision is:

APPROVED ONCE, ACCEPTED EVERYWHERE



2. Regulatory framework and procurement challenges for our industries



Challenges in local registration of changes

- Even small changes lead to a re-registration in Russia with very long registration timelines
 - **1st proposal:** alignment between EU, United States and China by distinguishing between administrative, minor, and significant changes
 - **2nd proposal:** transition period for any changes including re-registration as the time of product modification rhythm is quicker than re-registration with all required tests
- All EU produced products made compliant to EU MDR may lead to required re-registration in Russia
 - **Proposal:** set up fast track re-registration or simplified re-registration process for this change



Eurasian Medical Device Regulations

- Welcome harmonization of regulation in Eurasian Economic Union
- Change from local registrations to Eurasian Economic Union medical device regulations
 - Deadline for re-registrations: 21 December 2026
 - Local registration of new products will be allowed until 31 December 2021 - then all new registration submissions must be made using the Eurasian process
- Questions about readiness of the system



Local Content Requirements in Public Procurement

- Russian government has introduced measure to restrict procurement of certain medical devices and favour local manufacturers and localized products
- Industry requires open procurement processes and fair competition rights conditions to ensure better access to innovative, safe, high-quality medical devices for Russian citizens
- **Proposal:** accession of Russian Federation to WTO Agreement on Government Procurement (GPA)



3. Industry initiatives on COVID-19 and importance of priority medical devices





COVID-19 Information Center on the public website **was launched in March to:**

- Ensure most recent public information from EU Institutions and Global Organizations such as WHO, The World Bank are centralized and disseminated publicly through our website
- To inform the general public on what the COCIR industries are doing to tackle COVID-19
- To post relevant COCIR public statements such as the MDR postponement



What are our industries doing?

- Dynamic involvement of our industries with re-organization to respond to demands
- Supply priority medical devices for COVID-19 patients
- Ensure manufacturing plants can work and re-adjust their production to respond to the demands from governments and hospitals
- Ensure engineers/workers have protective equipment and can move safely cross-border to ensure installation and well functioning of equipment in hospitals and at home



Industry Innovations

- Industries continue to innovate to provide priority medical devices
 - Ventilators
 - Imaging equipment (e.g. CT, X-Ray, Ultrasound)
 - Oxygen equipment
 - Etc
- In addition and because of the increasing importance of Digital Health, COCIR is communicating even more on the following strategic elements:
 - Cybersecurity (ensuring cybersecurity by design)
 - Artificial Intelligence (refer to concrete AI solutions available on the market)
 - Health Data Space
 - Need for implementation and scaling up of EHR solutions and ensure interoperability

| Artificial Intelligence in Healthcare



AI IN CHEST IMAGING



AI FOR PNEUMOTHORAX (PTX) DETECTION & IMPROVED WORKFLOW PRODUCTIVITY



AI IN PATIENT POSITIONING FOR COMPUTED TOMOGRAPHY IMAGING



AI WOMEN'S HEALTH ULTRASOUND



SNAKEBITE & SNAKE IDENTIFICATION VIA MOBILE DEVICES



TELEDERMATOLOGICAL SCREENING SOLUTION VIA MOBILE DEVICES



AI IN CHEST IMAGING



AI IN ADAPTIVE RADIOTHERAPY



AI IN MAMMOGRAPHIC BREAST DENSITY



AI BASED RADIOTHERAPY TREATMENT PLANNING SOLUTION

**More COCIR
AI Use Cases
to follow**



Thank You!

Спасибо!

