MULTI-SECTOR WORKSHOP ON INNOVATIVE REGULATION

Challenges and benefits of harmonising the licensing process for emerging technologies

14-18 December 2020
MULTI-SECTOR WORKSHOP ON INNOVATIVE REGULATION

Challenges and benefits of harmonising the licensing process for emerging technologies

Welcome

Day 4 – Thursday 17 December
Session 5

Innovation without borders: challenges and successes of international co-operation on emergent medical technologies
Ms. Adriana VELAZQUEZ BERUMEN
MSc., Biomedical Clinical Engineer, Team Lead Medical Devices and In Vitro Diagnostics, MDD, Health Product Policy and Standards Department, HPS, Access to Medicines and Health Products Division, MHP, World Health Organization
WHO Regulatory updates and challenges

Convergancy and harmonization initiatives

Medical devices during the response to COVID-19,

Adriana Velazquez, Medical devices and in vitro diagnostics, December 2020
Medical Devices

- Medical Equipment
- IVDs
- Implantable Medical Devices
- Single Use, protective equipment
- Medical Software
- Surgical Instruments

Categories:
- Self-used
- Doctor/Nurse/Technician

Patients
To ensure improved access of safe, quality medical devices for COVID

- **R&D**
  - Industry and Academics: Research and development
  - Health Technology Assessment
    - Lists of Priority medical devices for COVID for procurement

- **Assessment**
  - Regulation process of medical devices
    - Lists of approved devices for marketing in country

- **Regulations**
  - Needs Assessment
  - Selection
  - Incorporation: (procurement, donations, loan...)
  - Safe use, training
  - Post market surveillance and adverse event report
  - Decommissioning,

To ensure improved access of safe, quality medical devices for COVID.
Sequence of process to ensure access to appropriate and safe health technologies
## Ensure medical devices improve patient safety

<table>
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<tr>
<th>Magnitude</th>
<th>Incidence</th>
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<tr>
<td><strong>4 out of 10</strong></td>
<td><strong>134 million</strong></td>
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<tr>
<td>Up to 4 out of 10 patients are harmed in primary and ambulatory care settings.</td>
<td>1.34 million adverse events occur each year in hospitals in LMICs, contributing to 2.6 million deaths annually due to unsafe care.</td>
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**Speak up for patient safety!**

No one should be harmed in health care.

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Ensuring safe care is a major challenge in all countries, rich and poor.
Support access to safe and affordable surgery for 5 BILLION PEOPLE that lack access

Lancet commission on Global Surgery
9 out of 10 cannot access basic surgical services!

Figure 1. Proportion of the population without access to safe, affordable surgery and anaesthesia by region

Ensuring safety of medical devices is a priority, so harmonization, convergence is indispensable
Safety and standards for all markets of medical devices is a priority

- Know regulations and standards
- **Ensure rapid registration through harmonization, convergence or reliance**
- Ensure Post-Market Surveillance & Feedback
- Work synergistically to help make healthcare and medical devices safer globally
Regulation is also needed in digital health and medical devices.

- Wearables
- Systems under digital health
- Clinical decision support systems
- Software as medical device
- Personalized medicine
- CADx
- AI

Digital Medical devices in hospitals and patients

Analog or mechanic medical devices

- Surgical instruments
- Most single use devices
- Implantable prosthesis

Digital health systems with no clinical or patient interface

- Surveillance
- Education
- Public health
2015 WHO survey on national authorities on HTA indicated mostly clinical effectiveness and safety of product are assessed in the case of medical devices. (WHA60.23)
WHO Model Regulatory framework for medical devices and other publications
Essential principles for safety and performance
Global Atlas of medical devices

The Global Atlas is being updated December 2020!
https://www.who.int/medical_devices/countries/regulations/en/
Global context: different assessment tools collecting information from Regulatory Authorities and affiliated institutions.
Development of the WHO Global Benchmarking Tool (GBT)
Integration of medical devices into WHO GBT

- WHO PQT/Diagnostics assessment tool
- PAHO medical devices assessment tool
- WHO medical devices assessment tool
- First Medical Devices Expert Group Meeting
- Meeting with PAHO expert* to unify WHO and PAHO tools
- Second Medical Devices Expert Group Meeting
- Presentation of WHO GBT during PAHO Regional WG meeting of MD Regulation
- Publication of Global Model Regulatory Framework for MD
- Mapping of GBT vs. PAHO medical devices tool
- Testing the GBT for MD assessment in Iran
- WHO (EMP) internal coordination meeting
- Recruiting a Consultant** to work on integration of MD into GBT

* Dulce Maria, CECMED, Cuba
** Keith Smith, TGA, Australia
Harmonization initiatives for standards, compliance, approvals

IMDRF

Post market surveillance,

Standards ISO 14971,....
Regional harmonization initiatives

AMDF

AHWP  GHWP

IMDRF

EUROPEAN, LATIN AMERICAN INITIATIVES
Medical devices are indispensable to test, treat patients and protect health care workers

Personal protective equipment, in vitro diagnostics and medical equipment
Priority medical devices list for the COVID-19 response and associated technical specifications

Priority list of PPE and technical specifications including QA and standards recognition


WHO Priority medical devices for COVID-19:

- Surgical Masks
- Non Surgical Masks
- N95 masks
- Googles
- Faceshields
- Gloves
- Gowns

…
Catalogue COVID products, include PPE, medical equipment and IVDs assessed by WHO (for 120 LMI countries)

Challenges the QA process and review standards compliance

On line supply portal to the catalogue

Personal protective equipment types

https://www.who.int/publications/i/item/emergency-global-supply-chain-system-(covid-19)-catalogue
Innovative technologies for COVID-19 response.
Challenge: to assess innovations

Innovator submits prototype or available product to international innovators call

Funding agency selected product or independent innovators submit for WHO assessment

WHO review dossier. Expert panel and external review from LMIC

Pitch presentation to expert panel. Feedback to developer. Voting for approval

If approved: published in WHO compendium, clearinghouse

Even procurement by WHO or other partners
R & D and Technology Access Pool.
Regulatory challenges for local production

Regulatory updates (including medical devices)
Conclusion

• Medical devices and IVDs are indispensable for COVID, other outbreaks and universal health coverage.

• WHO is working on tools to advance the regulation of medical devices in the regions and globally

• Many challenges are posed by the need to have medical devices but limited regulatory oversight specially for innovative technologies and in LMIC

• Rapid advancement of regulatory process is needed, to support access to COVID19 products
Ms. Francesca COLOMBO

Head of the Health Division, Organisation for Economic Co-operation and Development (OECD)
Innovation Without Borders: Challenges and Successes of International Co-operation in Emergent Medical Technologies

Francesca Colombo
Head of the Health Division
OECD Directorate for Employment, Labour and Social Affairs

17 December 2020
My talk today

• Regulatory approval of new medical technologies

• Harmonisation and collaboration in regulatory requirements for medical technologies across countries

• Learning from the COVID-19 pandemic
REGULATORY APPROVAL OF MEDICAL TECHNOLOGIES
Regulation of medicines is more stringent and more harmonised than for medical devices

Medicines
• Approval of new medicines is based on demonstration of quality, safety and efficacy and positive \textit{benefit-risk balance}
• Clinical evidence is always required
• Already a high degree of harmonisation of methods, approaches, quality standards

Medical Devices
• Highly heterogeneous array of products
• Shorter life cycles, less clinical data
• Evidence requirements vary
  o Linked to level of risk to patients
  o Clinical evidence not always required
  o Compliance with essential principles of safety and performance
• Less harmonisation of regulatory methods and approaches
Several international and regional regulatory harmonisation initiatives exist for medicines

- Harmonisation of medicines regulation is well developed
  - ICH develops methods and standards for evaluation of medicines
  - PIC/S develops and maintains harmonised standards for manufacturing inspection
  - other fora promote cooperation and engagement (eg. ICMRA)
- While regulatory approval is generally a national decision
  - EMA manages approval of medicines for EU countries
  - Other regional initiatives are also emerging (eg AMRH, GCC)

International Council for Harmonisation (ICH)
International Coalition of Medicines Regulatory Authorities (ICMRA)
Pharmaceutical Inspection Co-operation Scheme (PIC/S)
Regional initiatives: e.g. European Union, African Medicines Regional Harmonization (AMRH), Gulf Co-operation Council (GCC)
HARMONISATION & COLLABORATION ACROSS COUNTRIES
Regulatory co-operation, collaboration and convergence are challenging - but worthwhile

Advantages

• Leveraging resources of multiple regulators reduces duplication, and can increase efficiency, quality of evaluation
• Creates efficiencies for manufacturers through alignment of standards, processes, and documentation
• Increases ability to compare products and therefore creates potential for increased competition

Challenges

• Desire to retain national decision-making
• Significant investment required to establish cooperation, build confidence, set shared standards
• Requires a degree of ‘like-mindedness’
Different types of harmonisation are possible

**Aligning standards**

Setting *standards for evaluation* that are similar or identical to the standards applied other regulators, while maintaining independent review processes and decision-making (e.g. adopting ICH Guidelines).

**Work sharing**

Regulators in two or more jurisdictions *share activities* to accomplish a regulatory task to achieve efficiencies, while maintaining independent decision-making (e.g. ACSS initiative).

**Reliance**

Taking into account decision *criteria or assessments by another regulator in decisions*, while remaining independent decision-making.

**Recognition of decisions**

Relying on or recognising the decision of another regulator to make a national decision.

Reliance and recognition can be:

- unilateral
- bilateral (mutual)
- multilateral (e.g. EU)
<table>
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<tr>
<th>Topic</th>
<th>Description</th>
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<tbody>
<tr>
<td>Aligning standards</td>
<td>High level of multilateral alignment of methods of evaluation, through ICH Guidelines</td>
</tr>
<tr>
<td>Work sharing</td>
<td>Still evolving, but promising examples of work-sharing among major regulators, with some regional examples.</td>
</tr>
<tr>
<td>Reliance</td>
<td>Generally only by regulators with limited skills/resources, but can be an extension of work-sharing</td>
</tr>
<tr>
<td>Recognition of decisions</td>
<td>Mostly unilateral, except under regional agreements (eg EU, GCC)</td>
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</table>
Improving regulatory “reliance” can help improve efficiencies, but requires trust.

LEARNING FROM THE COVID-19 PANDEMIC
COVID-19: emergency approval of vaccines, flexibility in approach by regulators

- Urgent need for new products in a pandemic
- Requires rapid approvals and active post-marketing surveillance

**Pre-market**
- Fast-tracking applications
- Acceptance of more preliminary evidence => rolling reviews
- Exemptions

**Examples**
- US FDA: Emergency Use Authorisation
- European Medicines Agency: Conditional Marketing Authorisation, rolling review
- TGA: rolling review, exemptions for certain MDs, mock-up vaccine (pandemic influenza)
- Health Canada: temporary regulatory pathway

**Post-market**
- Pharmacovigilance - active and passive surveillance
  - Separate processes between countries, but building on harmonisation of adverse event classification and nomenclature, communication between regulators, data aggregation by WHO
- Long term follow-up of clinical trial data and collection of RWE to confirm effectiveness
- Progression from emergency authorisation to full marketing authorisation
A major challenge will be securing public trust

WHICH BEST DESCRIBES WHY YOU WOULD NOT TAKE A VACCINE FOR COVID-19?

More broadly, challenges remain for quick approval of innovative products to address unmet needs

- Key challenges in ensuring
  - That the regulatory framework and skilled resources keep pace with technological advances and increasing product complexity
  - Timely and efficient approval while still ensuring safety and maintaining public trust

- Still unclear if and how new models and tools (e.g., AI, machine learning, regulatory sandboxes) can be safely applied to medicines regulation
  - Area for potential collaboration among regulators
  - Limited exploration to date – being trialled in mHealth, FDA using pilot sandbox approach to certain medical devices
In conclusion

• Broad recognition of **advantages in increasing collaboration & harmonisation**
  – well advanced in aligning standards and methods, less advanced in work-sharing, reliance, recognition – but continuing

• Further **regulatory harmonisation offers benefits** for regulators, payers, industry, patients
  – rapid scientific advances => need to **assess more complex, technically challenging products**
  – support regulators to **use limited resources efficiently**
  – **reduce regulatory burden** on industry, without compromising rigour
  – **promote more rapid patient access** to innovative products

• Some priorities/areas for further work
  – greater **harmonisation of outcome measures** in clinical trials, and of **trial requirements**
  – collaboration in **evidence generation** (eg following accelerated approval procedures)
  – building **public trust** in novel products (eg novel vaccines, new technologies)
  – pursuing **collaborative approaches** to evaluating novel technologies and to developing more adaptive regulatory frameworks
Staying in touch with the OECD

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Visit our website
www.oecd.org/health
www.oecd.org/health/pharmaceuticals.htm
Dr Harald ENZMANN
Chair of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), Head of Section "European and International Affairs" at the German Federal Institute for Drugs and Medical Devices
Multinational Regulatory Networks for Medicines

Harald Enzmann

Disclaimer

• The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to the BfArM or to the European Medicines Agency (EMA).

• I am employed by a regulatory agency, and have nothing to disclose.
Agenda

- Regulation of medicines - why?
- Harmonizing Regulatory Decisions - EMA
- Harmonizing Regulatory Requirements - ICH
Regulation of Medicines: Protecting Patients

USA 1937
Sulfanilamide, diethylene glycol

FDA didn’t regulate drug safety at the time, but was able to seize bottles of Elixir Sulfanilamide on a technicality—"elixir" was a designation reserved for drugs containing ethanol (FDA homepage).


Germany 1961
Thalidomide

1964: Registration based on pharmaceutical quality, safety and efficacy.

McBride, Australia (!) published this letter in Lancet.
General Principle of Regulation of Medicines

Marketing Authorization Decision

Benefit Risk Balance

Unfavourable Effects

Favourable Effects

Evaluation of benefits and risks based on the assessment of Efficacy, Safety and Pharmaceutical Quality

Decision

Benefit Risk Balance

Assessment

Efficacy

Safety

Pharmaceutical Quality

Without

Socio-economic considerations
Multinational Regulatory Networks for Medicines

Regulatory decisions for up to 27 countries

Regulators and Industry
17 Members

https://www.ich.org
Multinational Regulatory Networks for Medicines

Regulators from 27 European countries

Regulatory decisions for up to 27 countries

Regulators and Industry 17 Members

Regulatory requirements
https://www.ich.org
Authorization Decisions at EMA and in the European Network

National authorities in 27 Member States of EEA

24 official languages
Authorization Decisions at EMA and in the European Network

Innovative products*
Centralized procedure at CHMP

National authorities in 27 Member States of EEA
24 official languages

Generic products**
National authorizations
MRP, DCP at CMDh

CMDh: Coordination Group for Mutual Recognition and Decentralised Procedures; DCP: decentralised procedure; MRP: mutual recognition procedure; *Regulation (EC) No 726/2004; ** most generic procedures in DCP and MRP, few submitted to EMA
Authorization Decisions at EMA and in the European Network

National authorities in 27 Member States of EEA

24 official languages

Generic products**

National authorizations

MRP, DCP at CMDh

Persisting conflicts between national authorities:
Referral at CHMP

Innovative products*

Centralized procedure at CHMP

Referrals for MRP, DCP

CHMP: Committee for Medicinal Products for Human Use; CMDh: Coordination Group for Mutual Recognition and Decentralised Procedures; DCP: decentralised procedure; MRP: mutual recognition procedure;
*Regulation (EC) No 726/2004; ** most generic procedures in DCP and MRP, few subitted to EMA
Decisions Making at EMA’s CHMP

1 committee member per Member State (27)
1 committee member each from Norway and Iceland
5 co-opted Members

Regular meeting each month
Opinion by consensus or majority

CHMP: Committee for Medicinal Products for Human Use
EMA / CHMP Achievements
(January 2020 – October 2020)

European Marketing Authorization

- **Started**: 99 (incl. 11 generics)
- **Finalised**: 92 (incl. 11 generics)
  - Positive opinions: 76
  - Negative opinions or withdrawn applications: 16

Refferrals from CMDh
(unsolvable differences between Member States)

- **CHMP opinion**: 10
- under evaluation: 2

CHMP: Committee for Medicinal Products for Human Use;
CMDh: Coordination Group for Mutual Recognition and Decentralised Procedures
Multinational Regulatory Networks for Medicines

Regulatory decisions for up to 27 countries

ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

Regulators and Industry 17 Members
https://www.ich.org
International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

Founding Members
Regulatory
• FDA, United States
• EC, Europe
• MHLW/PMDA, Japan

Industry
• EFPIA
• JPMA
• PhRMA

Regulatory Members
• Health Canada, Canada
• Swissmedic, Switzerland
• ANVISA, Brazil
• HSA, Singapore
• MFDS, Republic of Korea
• NMPA, China
• TITCK, Turkey
• TFDA, Chinese Taipei

Industry Members
• BIO
• Global Self-Care Federation
• IGBA
Consens Building at ICH

Achievements since 1990

Guidelines
- **Efficacy** (20)
- **Safety** (12)
- **Pharmaceutical Quality** (14)
- **Multidisciplinary Guidelines** (13)

Standards
- **CTD** The Common Technical Document
- **MedDRA** Medical Dictionary for Regulatory Activities
- **Electronic Standards for the Transfer of Regulatory Information - ESTRI**

ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
Comparison of International Regulatory Networks for Medicines

- Regulators only
- Binding majority decisions
- Based on specific legislation

- Regulators and Industry
- Consensus principle
- Voluntary membership
Thank you very much for your attention!

Contact

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Ph.D., M.S., Director, Office of Neurological and Physical Medicine Devices (OHT5), Office of Product Evaluation and Quality (OPEQ), Centre for Devices and Radiological Health, U.S. Food and Drug Administration
OECD Nuclear Energy Agency & Canadian Nuclear Safety Commission Workshop

A Few Best Practices Supporting the Development of Emerging Technologies

A FDA Staff Perspective
December 17, 2020

Carlos Peña, PhD, MS
Director
Office of Neurological and Physical Medicine Devices
Center for Devices and Radiological Health, FDA
Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.

The U.S. is the world’s leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety.

U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance.

Devices are legally marketed in the U.S. and remain safe, effective, and of high-quality.

Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.
What is a Medical Device?

• Definition of a medical device is specified in section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321) *

• Section 201(h) states in part:
  – The term “device”…means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is…”

  – “…intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man…” or

  – “…intended to affect the structure or any function of the body of man and which does not achieve any of its primary intended purposes through chemical action....”
A Risk Based Approach for Medical Devices since 1976

Increasing Risk
Classification determines extent of regulatory control (Risk Based)

Class I
low risk
- Generally exempt from premarket review
- In some cases require 510(k) / De Novo

Class II
Moderate/Controlled Risk
- Requires 510(k) to demonstrate substantial equivalence / De Novo if no classification exists

Class III
High Risk
- Requires PMA (Premarket approval)

General Controls [Electronic Establishment, Registration, Electronic Device Listing, Quality Systems, Labeling, Medical Device Reporting (MDR)]

Performance standards
Special Controls [Controls to address safety and effectiveness]

Clinical performance data (to support a reasonable assurance of safety and effectiveness)
Experience in Moving Neurological Medical Devices From Bench to Market

Clot Retriever for Ischemic Stroke
Epilepsy DBS
ADHD Neurodiagnostics
DEKA Prosthetic Arm
Cefaly Medical Device For Migraine
Microcatheters for the neurovasculature
Reducing FDA Review Timelines

Median Days to Full IDE Study Approval

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<th>FY11</th>
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A Few Medical Device Regulatory Concepts

- Device classification is based on risk
- Use valid scientific evidence
- Weigh benefit vs. risk to determine safety and effectiveness
- Provide “reasonable assurance” of safety and effectiveness
- Consider least burdensome means
- Assess based on the indication for use
Increasing **Regulatory Transparency**

**NEW Targeted Guidance for Sponsors (and Developers & Innovators)**

- Presubmission Guidance
- IDEs for Early Feasibility Clinical Studies Guidance Document
- Design Considerations for Pivotal Clinical Investigations
- Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions
- **Clinical Considerations for IDEs for Neurological Devices Targeting Disease Progression and Clinical Outcomes**
Benefit Risk Considerations

Several considerations when evaluating Benefits and Risks:

• What are the **probable benefits**? Type, magnitude, duration, etc.
• What are the **probable risks**? Type, severity, probability, duration, etc.
• **Additional Factors**, such as:
  – Uncertainty
  – Patient tolerance for risk and perspective on benefit
  – Alternative therapies and their risk profiles

GUIDANCE: Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approvals and De Novo Classifications
http://www.fda.gov/RegulatoryInformation/Guidances/ucm267829.htm
Mobile Medical Applications Guidance (2015)

• Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff

• Purpose:
  – Provide clarity and predictability for manufacturers of mobile medical apps
  – Provide information on FDA’s current thinking

http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf

Questions? digitalhealth@fda.hhs.gov
Investing in Review - A New Office at FDA
Center for Devices and Radiological Health (CDRH) Organization
Pathway for Neurological and Physical Medicine Regulatory Submissions

CDRH

Strategic Partnerships & Innovation
Office of Center Director
Office of Communication & Education
Office of Science & Engineering
OPEQ Product Evaluation
Office of Mgmt
Office of Policy

Cardiovascular
Ortho
Surgery, Infection Control
Ophthalmic, Anesthesia
ENT
Gastrorenal
OB/GYN General Hosp.
Invitro Diagnostics, Rad Health

Office of Neurological and Physical Medicine Devices
Pre-Submissions

WHAT: an opportunity to obtain FDA feedback prior to IDE or marketing submission

Guidance Document

“Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff”

(Document issued on February 18, 2014)
It’s About the Patients

Thank You
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Workshop Moderator

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Executive Vice-President and Chief Regulatory Operations Officer Regulatory Operations Branch
Canadian Nuclear Safety Commission (CNSC)
Dr William HEETDERKS
PhD, MD, Consultant to the United States National Institutes of Health, Former Senior Regulatory Official at the United States Food and Drug Administration
How can necessity drive regulation?: A COVID diagnostics story

How can innovative products be approved quickly while still ensuring safety and maintaining public trust?

- Process change: from 510k to EUA and templates
- Communication change: from parallel tracks to weekly discussions
- Duration change: from ‘this point forward’ to ‘until further notice’
- Implementation change: from sequential to parallel and at risk
MULTI-SECTOR WORKSHOP ON INNOVATIVE REGULATION: Challenges and benefits of harmonizing the licensing process for emerging technologies

Session 5 - Innovation without borders: challenges and successes of international co-operation on emergent medical technologies

Dr Emmanuelle VOISIN
PhD, Founder & CEO, Voisin Consulting Life Science
Innovation Without Borders:

Challenges and successes of international co-operation on emergent medical technologies

Emmanuelle Voisin

CEO & Founder, Voisin Consulting Life Sciences
A need for a shift towards innovation-enabling regulations

• Foster innovation by supporting experimentation

• Develop a dialogue between regulators and innovators
  o Provide advice and guidance through agile regulatory framework/approach to follow the pace of innovation
  o Get educated on disrupted technologies to identify early new regulatory challenges

• Dedicate specific resources to streamline regulatory processes
  o Develop alternative “out of the box” routes
  o Make burden bearable by start-ups and innovators

• Collaborate cross-country and cross-expertise
  o Harmonize regulations
  o Learn from other domains on their responses to innovation
  o Share databases
Current disruptors and principles for rethinking regulation

Disruptors

Challenges
- Pace of scientific and technological change
- New business models
- Data privacy and security
- AI based challenges

Emerging technologies
- Tools powered by AI and machine learning
- Genome sequencing and gene editing
- Robotic Process Automation (RPA)
- Blockchain
- Internet of Medical Things

Future of Regulation

1. Adaptive regulation
   - Shift from "regulate and forget" to a responsive, iterative approach

2. Regulatory sandboxes
   - Prototype and test new approaches by creating sandboxes and accelerators

3. Outcome-based regulation
   - Focus on results and performance rather than form

4. Risk-weighted regulation
   - Shift from one-size-fits-all regulation to a data-driven, segmented approach

5. Collaborative regulation
   - Align regulation nationally and internationally by engaging a broader set of players across the ecosystem

Source: Deloitte Center of Government Insight analysis
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Dr Emmanuelle VOISIN
PhD, Founder & CEO, Voisin Consulting Life Science
QUESTIONS FROM PARTICIPANTS

• Question 1
• Question 2
• Question 3
MULTI-SECTOR WORKSHOP ON INNOVATIVE REGULATION

Challenges and benefits of harmonising the licensing process for emerging technologies

Thank you for your participation today and see you all tomorrow!