EDQM & European Pharmacopoeia: State-of-the-art Science for Tomorrow's Medicines

International Conference organised by the European Directorate for the Quality of Medicines & HealthCare (EDQM),

Council of Europe

19-20 June 2019, Strasbourg, France

EDQM & European Pharmacopoeia: State-of-the-art Science for Tomorrow's Medicines

Opening Plenary Session

Building Synergies to strengthen and support healthcare in Europe

International Conference EDQM and Ph. Eur. : State-of-the-art Science For Tomorrow's Medicines

Strasbourg, 19-20 June 2019

Health systems, medical products and innovation

Health

Cooperation between EC and EDQM

Legal and financial cooperation to implement the **pharmaceutical** and **SoHO** legislation.

- The European Pharmacopoeia, a legally binding instrument referred to in the EU legislation
- More than 35 ad-hoc technical cooperation projects
- Mutual representation to align the regulatory work
- Expertise to several EMA committees and working parties

Health

25th anniversary of the establishment of the European Network of Official Medicines Control Laboratories (OMCLs)

Centers of excellence for a more efficient protection of Public Heath

- Sampling & testing programme for medicines authorised for the EU

- Official Control Authority Batch Release (OCABR)

Health

Cooperation with EDQM

Major points of collaboration

- Procedure for ‘Certification of Suitability'
- Standard Terms database
- Guidance and standards for blood transfusion and for tissue/cell transplantation

More synergies are possible

- Falsified medicines
- Digital Health in pharmaceutical care

Health

Cooperation with EDQM

SoHO : new and Extended Grant Agreement with EDQM 2019 – 2021

- SARE analysis and SARE training
- B-QM (Blood Quality Management)
- B-PTS (Blood Proficiency Testing Scheme)
- Plasma Supply
- Contingency planning
- Harmonising Tissue and Cell activity data
- Neighbouring country assessments

HEALTH IN EU

SOCIO-ECONOMIC POLICIES COORDINATION

EU agenda for effective, accessible and resilient health systems

Strengthening effectiveness	Increasing accessibility	Improving resilience
Health systems performance assessment Patient safety and quality of care Integration of care	A fit-for-purpose health workforce Access to innovative medicines Optimal implementation of 2011 Directive on cross-border healthcare	Health technology assessment (HTA) Information for better governance eHealth, mHealth

Knowledge brokering - State of Health in the EU

HEALTH AT A GLANCE: EUROPE 1

November 2018

COUNTRY HEALTH PROFILES 2

November 2019

COMPANION REPORT 3

November 2019

VOLUNTARY EXCHANGES 4

First half of 2020

Coordination of economic policy
The European Semester

- Public expenditure on health account to about 8% of GDP and 15% of all public expenditure
- Health insurance and healthcare support social safety nets and active inclusion strategies
- Health of the population is a productive factor
- Health is an economic sector providing growth and jobs

Digital transformation of health

Hopes

- More **targeted** and personalised treatment
- Improved **diagnosis**
- Better **prevention**
- Greater **access** and less **inequalities**
- More **efficient** use of scarce resources…

Insel, T. R. (2019). Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again. *Nature*, *567*(7747), 171-173.

Health

Healthcare professionals : key links in the digital healthcare chain

Health

Communication (2018)233

Digital Health and Care

TRANSFORMATION OF HEALTH AND CARE IN THE DIGITAL SINGLE MARKET - Harnessing the potential of data to empower citizens and build a healthier society

European health challenges

- Ageing population and chronic diseases putting pressure on health budgets
- Unequal quality and access to healthcare services
- Shortage of health professionals

Potential of digital applications and data to improve health

- Efficient and integrated healthcare systems
- Personalised health research, diagnosis and treatment
- Prevention and citizen-centred health services

What EU citizens expect...

90% agree — To access their own health data (requiring interoperable and quality health data)

80% agree — To share their health data (if privacy and security are ensured)

80% agree — To provide feedback on quality of treatments

Support European Commission:

1 Secure access and exchange of health data

Ambition: Citizens can securely access and share (eg. with doctors or pharmacies) their health data anywhere in the EU.

Actions:
- eHealth Digital Service Infrastructure will deliver initial cross-border services (patient summaries and ePrescriptions) and cooperation between participating countries will be strengthened.
- Proposals to extend scope of eHealth cross-border services to additional cases, e.g. full electronic health records.
- Recommended exchange format for interoperability of existing electronic health records in Europe.

2 Health data pooled for research and personalised medicine

Ambition: Shared health resources (data, infrastructure, expertise...) allowing targeted and faster research, diagnosis and treatment.

Actions:
- Voluntary collaboration mechanisms for health research and clinical practice (starting with "one million genomes by 2022" target).
- Specifications for secure access and exchange of health data.
- Pilot actions on rare diseases, infectious diseases and impact data.

3 Digital tools and data for citizen empowerment and person-centred healthcare

Ambition: Citizens can monitor their health, adapt their lifestyle and interact with their doctors and carers (receiving and providing feedback).

Actions:
- Facilitate supply of innovative digital-based solutions for health, also by SMEs, with common principles and certification.
- Support demand uptake of innovative digital-based solutions for health, notably by healthcare authorities and providers, with exchange of practices and technical assistance.
- Mobilise more efficiently public funding for innovative digital-based solutions for health, including EU funding.

#DigitalSingleMarket #DigitalHealth #eHealth EU #EU_Health

Dots to be joined..

cross-border exchange of patient data in the EU

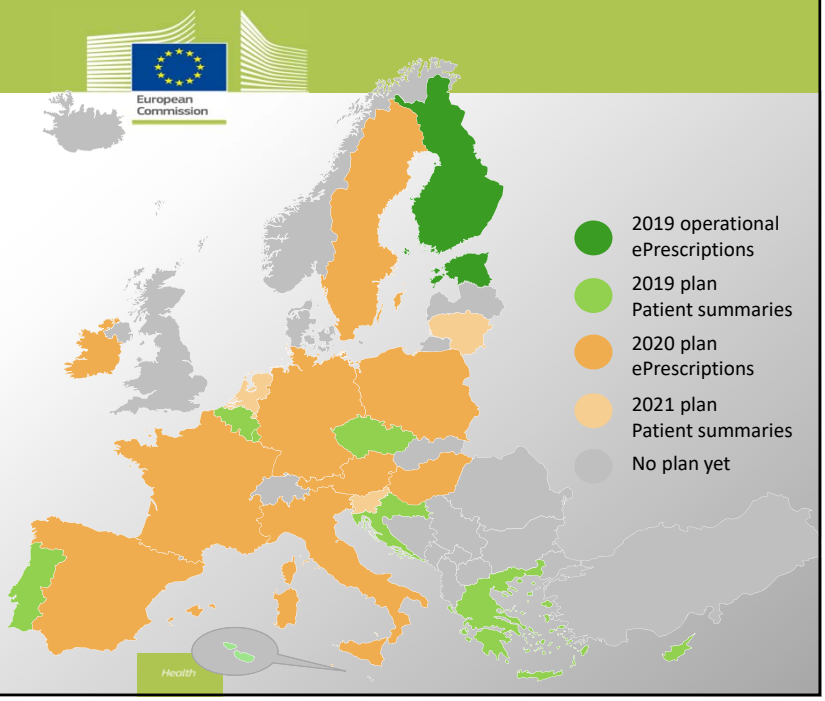
For example:

>1750 ePrescriptions

Patient summaries

And in the future...

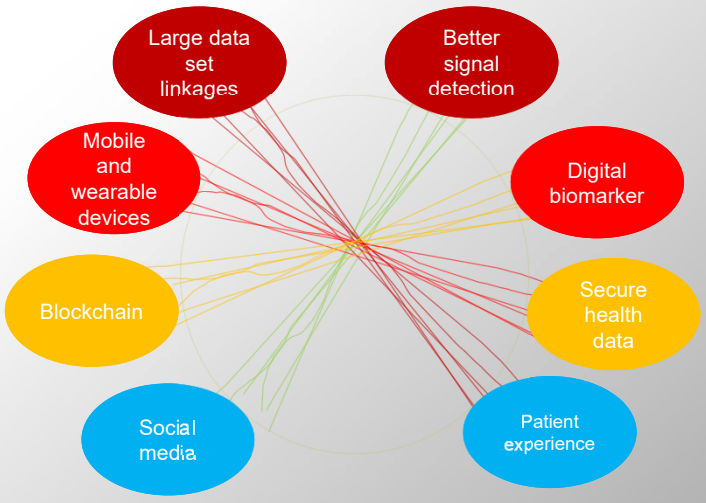
Electronic health records (EHR)



Dots to be joined…

Other examples:

Real World Data in Pharmacovigilance



European Reference Networks

Digital consultation

Share.
Cure.
Care.

e-learning & e-training

Research

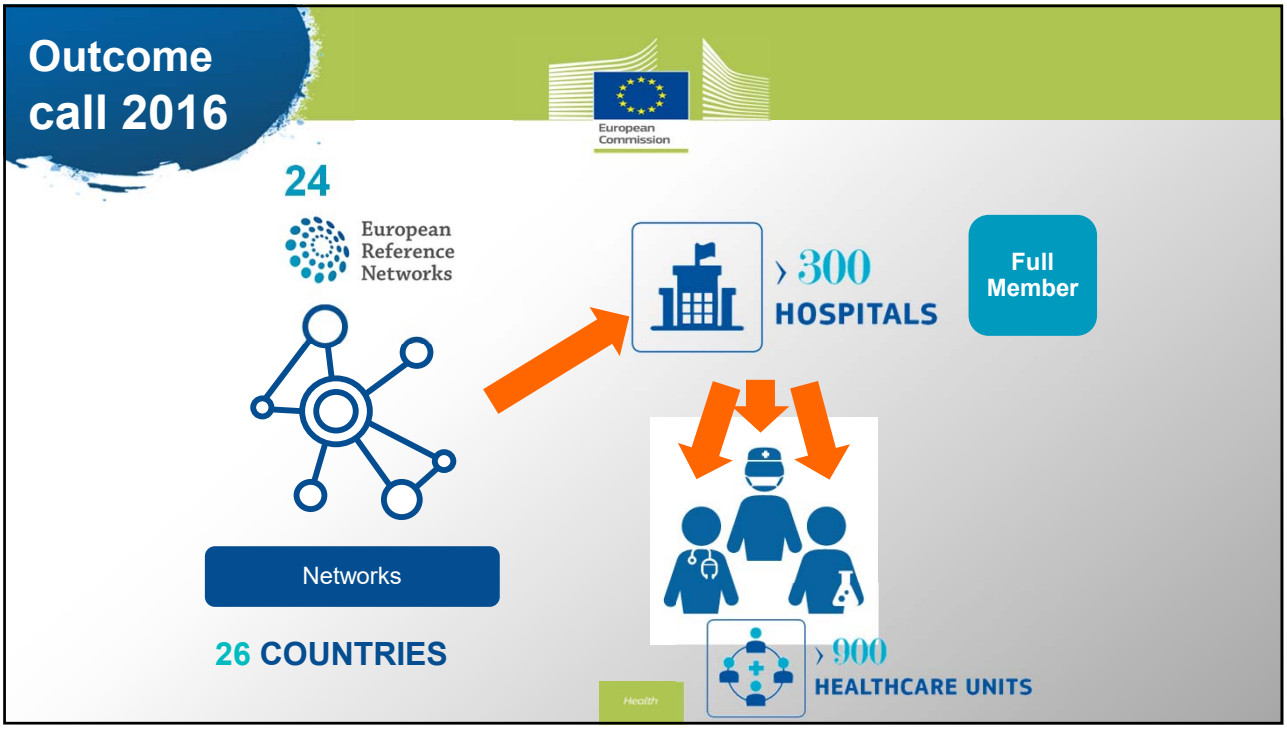
Knowledge generation

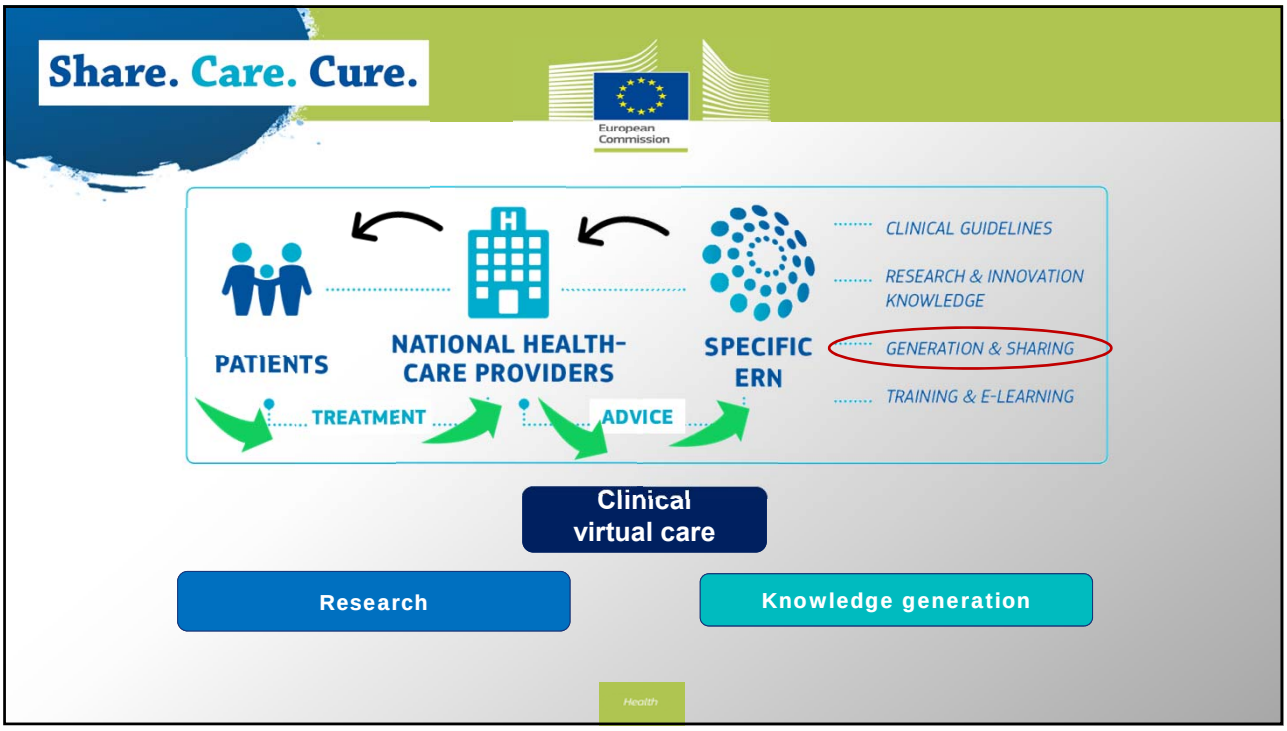
26 COUNTRIES

24 NETWORKS

>300 HOSPITALS

>900 HEALTHCARE UNITS


Outcome call 2016
European Commission
24
European Reference Networks
› 300
HOSPITALS
Full Member
Networks
26 COUNTRIES
› 900
HEALTHCARE UNITS
Health


Share. Care. Cure.
European Commission
PATIENTS
NATIONAL HEALTH-CARE PROVIDERS
SPECIFIC ERN
CLINICAL GUIDELINES
RESEARCH & INNOVATION KNOWLEDGE
GENERATION & SHARING
TRAINING & E-LEARNING
TREATMENT
ADVICE
Clinical virtual care
Research
Knowledge generation
Health

1 Mio Genomes

20 Signatures

1 Mio **genomes accessable** by 2022

Linking access to existing and future genomic database across the EU

Providing a sufficient scale for **new clinically impactful** associations in research

EU countries agreed to cooperate in linking genomic data across borders

THEY DID IT!
& more will too

Austria
Bulgaria
Croatia
Cyprus
Czech Republic
Estonia
Finland
Greece
Italy
Lithuania
Luxembourg
Malta
Portugal
Slovenia
Spain
Sweden
Netherlands
UK
Latvia

Health

EMA & HMA & BIG DATA

European Commission

HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Big Data taskforce

"Promote use of global, harmonised and comprehensive standards to facilitate interoperability of data"(p. 11)

Health

Examples of EU funding for digital in the budgetary period (2021-27)

European Commission

ESF+

ERASMUS

HORIZON EUROPE

Digital Europe

Health

ansm
Agence nationale de sécurité du médicament et des produits de santé

Globalisation and cross-border cooperation in Europe: the perspective of a national competent authority

Dominique MARTIN
Head of French National Agency for Medicines and Health Products Safety

International Conference organized by the EDQM on the occasion of the publication of the 10th Edition of the Ph. Eur. and the 25th Anniversary of the European OMCL Network and the Certification Procedure.

19-20 June 2019, Strasbourg, France

French National Agency for Medicines and Health Products Safety

- **Placed under the supervision of the Ministry of Health**
- **Part of the HMA**
- **Large area of expertise**
  - **Medicines**
  - **Biological products**
  - **Medical devices**
  - **(Cosmetics and tattoos)**

Our working experience

SURVEILLANCE
of benefit / risk ratio products in “real life”

EVALUATION
of medicines and health products

PHARMACOPOEIA
Strong involvement in all the activities

INSPECTION
of manufacturing, importation and distribution activities

LABORATORY
quality control

LEGAL AND REGULATORY
expertise for quality and coherent decisions

INFORMATION
& communication

SUPPORT DIVISIONS
HR, administration and finances, IS, flow management

Our strategy

- Enhancement of an policy of openness and information sharing.
- Making risk management the policy principle behind all our decisions.
- Strengthening the European involvement of ANSM.
- Combining performance and quality of life at work.

Impact and interest of integrated laboratories in the ANSM organisation

❖ **Fruitful integration in the matrix**

Regular requests by the others divisions

Control division considered as a real partner, appreciated added value of the control's results in the final decisions

❖ **Frequent wide solicitations and urgent situations:**

- Quality default of medicines and raw materials (e.g. sartans)
- Falsified, illegal or substandard medicines from illegal market in collaboration with customs, justice or police services
- Shortage of vaccines associated with GMP deviations or stability matters
- Microbiological contamination of medical devices (infusion tubing), …

Impact and interest of integrated laboratories in the ANSM organisation

❖ **Strong input in the assessment of generic products**

- Expertise in the field of pharmaceutical quality,
- Bioequivalence studies (biowaivers by dissolution)

❖ **Annual control program matches the needs of the product divisions and inspection campaigns**

Priorities well defined and the same for all divisions, by a risk based approach.

FOCUS Drugs and raw material

FOCUS Vaccines and biological products

FOCUS Blood derivatives medicines

Medical devices…

Relationship with EDQM

In the frame of the conference, point of view of a HMA focused on:

- **Pharmacopoeia**
- **Certification**
- **OMCLs network**

Involvement in Ph. Eur.

HISTORY

1964 Signature of the Convention on the Elaboration of an European Pharmacopoeia in Strasbourg

8 countries (including France), today 38 members states and 30 observers over the world. French/English official languages.

1975 Directive 75/318/CEE

1981 Directive 81/852/CEE

Mandatory character of European Pharmacopoeia monographs when requesting marketing authorisation for human and veterinary use.

Involvement in Ph. Eur.

- **Strong involvement since the beginning, in different groups**
  - A French participation in 50/63 Groups
  - 19/63 represented by ANSM
- **Benefits**
  - Promotes public health
  - Provides a legal and scientific basis for the quality control of medicines
  - Allows to have official and harmonised standards
  - Facilitates the free movement of medicinal products in Europe
  - High reactivity in urgent situation (e.g. sartans monographs and dedicated WG)

Involvement in Ph. Eur.

- **Focus on new finished products monographs**

2011 The Presidium decided to prepare a reflection paper, presented in 2012.

2012 A pilot phase was launched with a dedicated Working Party.

2014 First monograph was published and came into force on April 2016 (Pharmeuropa 26.3).

→ **Provide support for the market surveillance (OMCLs), guidance to the industry (especially for generics)...**

Involvement in Ph. Eur.

- **Focus on biological products monographs**

  Initiate new monographs & manage the follow-up as project leader for blood products, vaccine and biotechnology derived products

  Strongly involved in the revision of the biological monographs regarding the state of the art

- **General texts**

  Gene transfer medicinal product, cell substrate…

- **Biological Focus on the establishment of Biological Reference Preparations (BRPs)**

  Project leader / scientific advisor or participation under the egidium of EDQM for many BSP to the request of DBO (blood products, vaccine and other biologicals products).

Certification of Suitability

Procedure established in 1994.

Check the suitability to control chemical and microbiological purity (and TSE risk), and the compliance of the sites to GMP

- **Participates to ensure the quality of substances and their compliance to European requirements.**
- **Facilitates the assessment of MA applications.**
- **Inspectors are appointed by competent authorities or EDQM inspectors.**
- **ANSM strongly involved.**

Certification of Suitability

Sartan crisis showed the importance of CEP:

immediate actions were taken and concerned CEPs were reviewed.

Possibility to suspend or withdraw CEPs.

Noticeable reactivity and coordination by EDQM, and fruitful collaboration within the network.

Involvement in OMCLs network

HISTORY

- Network created in 1994.
- Based on the collaboration with the aim to save money (avoiding duplication of work) and to facilitate access to state-of-the-art technologies and methods.
- Now almost 60 full members (3 in France, including ANSM for human medicines), 12 associated members.

Involvement in OMCLs network

Advantages / benefits

- Strong and efficient collaboration, high level of competences.
- Same QMS (ISO17025).
- Mutual recognition of results by HMA.
- OCABR Batch release procedure for Vaccine and Blood: securing market for highly sensitive products.
- Analytical force/capacity with high reactivity (see example).
- Implementation of risk based approach for the market surveillance, shared within the network via the dedicated database.
- Saves money and resources.
- Samples exchange.

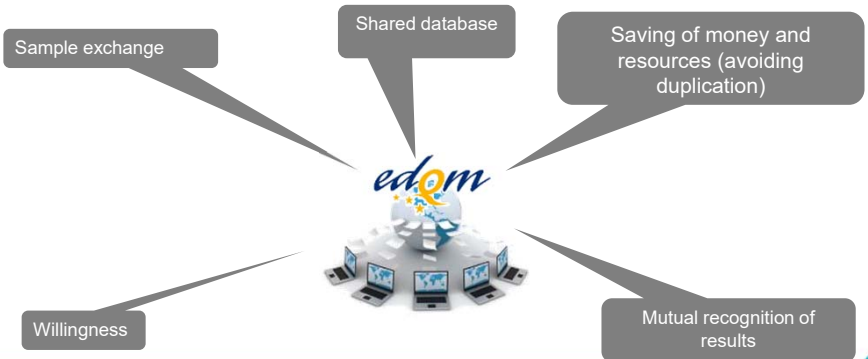
ANSM tested about 900 samples in 10 years, and benefits by about 2 800 results concerning products authorised in France.

ansm

Market surveillance

Shared programme

European Marketing Authorisation
= same file, same composition, specifications, methods...



Involvement in OMCLs network

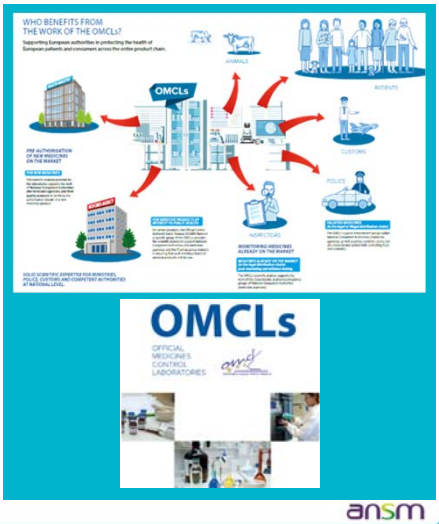
Recent example

- Sartans crisis (some sources contaminated by nitrosamines) showed the high level of collaboration.
- Data and result were immediately shared, via dedicated group steered by EDQM.
- Allowed to develop and provide to network and manufacturers analytical methods, to control many samples in short time, to confirm OOS results and manufacturer's results…
- Several thousands of samples were controlled and results shared: independent and rapid results important to take and justify decisions.

Involvement in OMCLs network

Network is also a way of communication to promote our work

- Communication to professional, stakeholders, ministry, patients… is promoted within the network as well as at a national level
- Benefits (public health and costs) of preventive work and not only in case of crisis could be more explained and emphasized
- New types of medicines (MAb, GT…) are coming in force. The network provide an additional guarantee for patients to access innovative, safe and effective biotech medicines.



Discover how OMCL contribute to protect your health in Europe and beyond:

https://www.edqm.eu/en/discover-how-official-medicines-control-laboratories-contribute-protect-your-health-europe-and-0

ansm
Agence nationale de sécurité du médicament et des produits de santé

Avertissement

- Lien d'interêt : personnel salarié de l'ANSM (opérateur de l'État).
- La présente intervention s'inscrit dans un strict respect d'indépendance et d'impartialité de l'ANSM vis à vis des autres intervenants.
- Toute utilisation du matériel présenté, doit être soumise à l'approbation préalable de l'ANSM.

Warning

- Link of interest: employee of ANSM (State operator).
- This speech is made under strict compliance with the independence and impartiality of ANSM as regards other speakers.
- Any further use of this material must be submitted to ANSM prior approval.

Contributions of the General European OMCL Network (GEON) to the protection of Public Health

Patricia Courselle, Strasbourg 19 June 2019

What is an OMCL?

- Definition
- Objectives & Missions
- Scope of analysed products
- Roles of OMCLs in Europe
- OMCLs' stakeholder environment

Definition

Official **M**edicines **C**ontrol **L**aboratories are:

- Independent public laboratories
- Established and nominated by National Authorities
- Analysing medicinal products, already or to be marketed, for human and veterinary use

Mission and Objectives

OMCL Mission:

- Support national regulatory authorities in quality control of medicines for human and veterinary use
- Ensure quality, safety and efficacy of medicines to enhance patient and animal welfare

OMCL Objectives:

- Test medicines independently from manufacturers
- React quickly in times of crisis to perform tests and investigate issues

Products

Analysed medicines for human and veterinary use

Chemical products

Immunological products
Vaccines

Blood
Plasma derivatives

Biological products

Herbal medicines

Homeopathic medicines

Stockpiled medicines

What is an OMCL?

Products

Analysed ingredients, preparations…

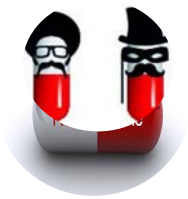
Medicines

Active Pharmaceutical Ingredients and excipients

Gene therapy products

Allergen products (for diagnosis and treatment)

Radiopharmaceutical products



Falsified medicines and medicines in disguise

Products

List of **Non-medicinal** products analysed by OMCLs

- Primary packaging materials
- Medical devices
- Diagnostic products
- Food supplements
- Premixes for medicated feeding stuffs for veterinary use
- Cosmetics
- Tattoo ink







Roles of OMCLs in Europe

Pre- and Post-marketing test programmes of medicines & active ingredients:

- Innovator medicines
- Generic medicines and biosimilars
- Unlicensed/unauthorised products
- Suspected falsified/illegal medicines

Emergency testing e.g. in case of adverse reactions of medicines

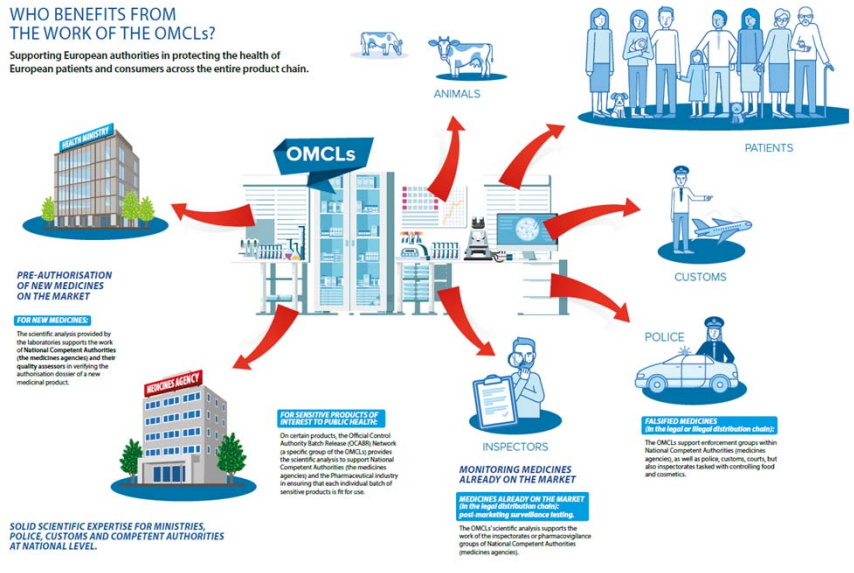
Packaging and labelling controls

Roles of OMCLs in Europe

OMCLs' activities lend support to:

- **M**arketing **A**uthorisation Dossiers (in evaluating the quality part)
- Test methods to be included in the European Pharmacopoeia
- **G**ood **M**anufacturing **P**ractice inspections (as laboratory experts)
- Quality defect report evaluation
- Pharmacovigilance investigations

Benefits of OMCL Testing



OMCLs' stakeholders

Government-type Stakeholders (e.g. Regulators and Other Groups)

- *The Heads of Medicines Agencies (HMA) Group / EMA*
- Agency Inspectorates, Assessors and Pharmacovigilance Groups
- Police/Customs Groups & Forensic Laboratories/Customs Labs
- Food Inspectorates & Food Testing Laboratories
- Cosmetics Inspectorates and related Testing Laboratories

External Stakeholders

- The General Public
- Healthcare Professionals
- The Pharmaceutical Industry

What is the GEON?

The General European OMCLs Network

- GEON set-up & history
- Composition/Member ship
- Objectives and benefits of the GEON
- Quality Management Activities and risk-based approach
- The GEON Surveillance programmes and other testing activities

History

The GEON creation & set up:

- Devised in 1994 by the EU Commission & Council of Europe
- To promote the collaboration of OMCLs across Europe (and beyond)
- Set up in 1995 by the European Directorate for the Quality of Medicines & HealthCare (EDQM)
- With financial support from the EU

The GEON organisation:

- Annual work programmes decided with National Authorities and the European Medicines Agency (EMA)
- EDQM: Secretariat and co-ordination of the Network activities and joint programmes

1st meeting in Strasbourg 1994

21 countries

AT – BE – BG – CH – DE – DK – EL – ES – FI – FR – HU – IE – IT – LU – NL – NO – PL – PT – SE – SI – UK

1st GEON Annual Meeting 1997, Bled

Composition

Currently **71 OMCLs** from **43 countries**

Members and Observers of the European Pharmacopoeia Convention

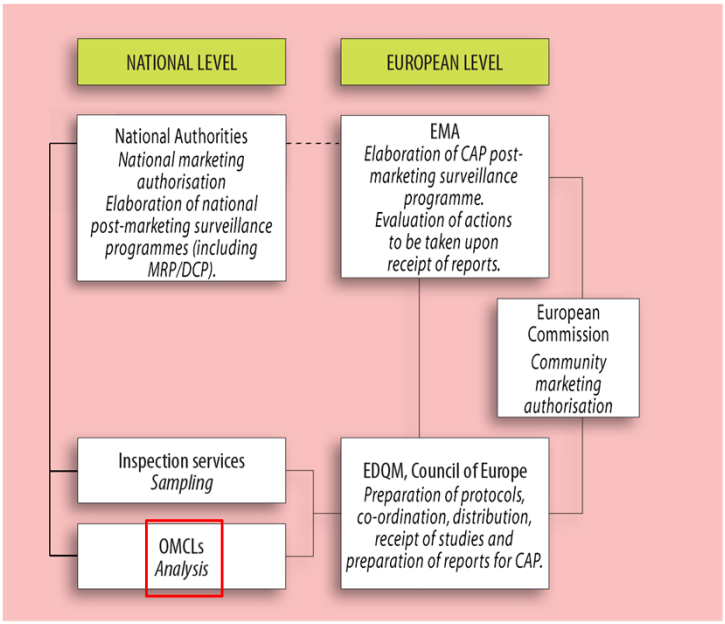
- **Full, associate or limited membership**

- 27 out of the 28 EU countries (except Malta)
- 7 European non-EU countries: Belarus, Bosnia & Herzegovina, Republic of Moldova, Russian Federation, Serbia, Republic of North Macedonia, Ukraine
- Norway (EEA) & Switzerland (MRA)
- 7 non-European partners (Australia, Canada, Israel, Kazakhstan, Morocco, Singapore and Taiwan FDA): associate members as observers to Ph. Eur. Convention

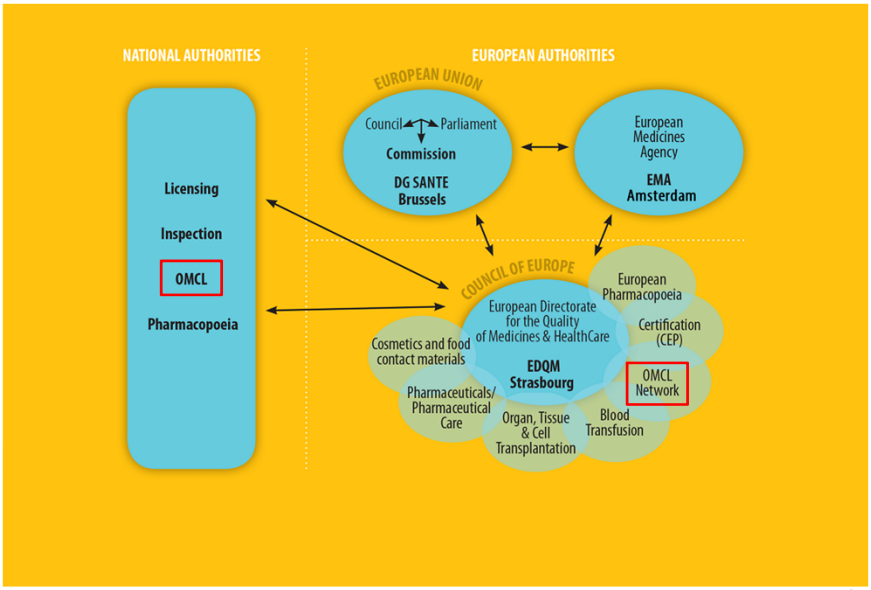
Status: March 2019

23rd GEON Annual Meeting 2018, Sarajevo

OMCLs within regulatory environment



OMCLs within regulatory environment



Objectives

Protecting public and animal health through independent surveillance testing of medicines (and selected products)

Benefits

Mutual Recognition

Independent

Common Quality standard

Sharing workload/
Reduce duplication

Sharing information

Crisis Management

Collaboration/networking

Expertise/novel
scientific methods

Quality Management Activities

Coordination by EDQM

- Publishing OMCL Network Guidelines, Procedures, etc.
- The MJV/MJA programme
- The Proficiency Testing Scheme (PTS)
- Risk Based Approach Sampling
- Training & Educational Activities
- The SUP (Suspicious Unknown Products) Programme

Zoom in on GEON's Surveillance programme & other Testing activities

- Surveillance programmes
- Other Testing activities

The CAP Programme

For innovative biological/biotech products as well as IVMPs (Immunological Veterinary Medicinal Products) and for products including new active substances authorised via the Centralised procedure.

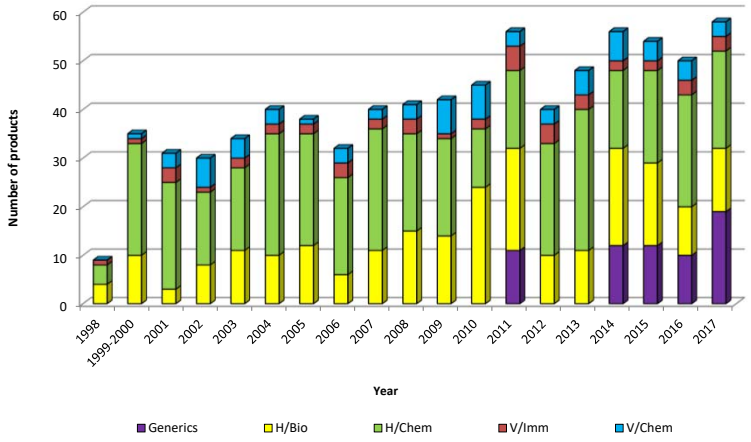
- Overall responsibility =>European Medicines Agency (EMA)
- Operational support => EU/EEA OMCL Network, National Inspectorates & the EDQM
- Each annual sampling and testing plan => EMA (input CAP Advisory Group) Risk-based criteria

2014: CAP generic products

2019-2023: Formal authenticity checks of Parallel Distributed CAPs, CAP Biosimilars testing, CAP API testing

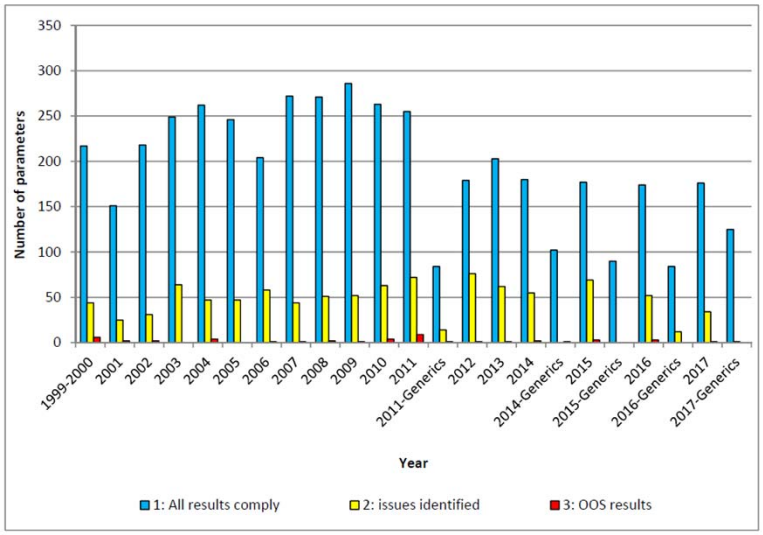
The CAP Programme

Number of products tested and distribution of categories



The CAP Programme

Testing outcomes



The MRP/DCP Programme

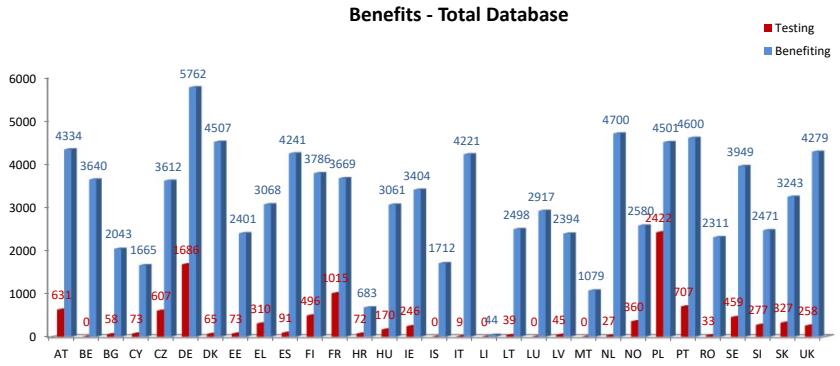
Medicines authorised via the European *Mutual Recognition Procedure* (MRP) and the *Decentralised Procedure* (DCP)

This surveillance programme is restricted to EU/EEA members

- Sampling and testing plans are established by the individual OMCLs
- Information about planned testing activities and test results via a secure IT platform (access restricted to OMCLs and MA)
- Whenever possible national programmes are adapted and samples are exchanged - applying the principle of work-sharing - to avoid overlap testing
- The majority of products are generics

The MRP/DCP Programme Statistics

In total: 10672 projects



Benefits Ratio: 1:9 (2002-April 2019) Status: April 2019

The MSS Programme

Wide range of products open to all OMCL's:

- *Testing product groups (a series generics, a series herbal drugs...)*
- *Specific pharmaceutical forms (modified-release tablets, inhalators)*
- *Performing specific tests (heavy metals, dissolution..)*
  - *Common protocol for testing (scientific advisor)*
  - *National level sampling*
  - *Common test report*

Overview **quality** of focused products on European market

Where appropriate **revision** relevant Ph. Eur. monograph and/or general chapters and test methods

Continual **improvement in testing** of those medicines.

The MSS Programme

- **Market Surveillance Studies: OMCL contribution to quality and safety of medicines on the market**

  Dr Lone Olsen, Danish Medicines Agency (DKMA), Denmark

OCABR/OBPR Programme

Independent testing and release of batches of human biological medicinal products (vaccines, blood and plasma derivatives) and immunological veterinary medicinal products (IVMPs) for marketing by CA or OMCL

WHY ?

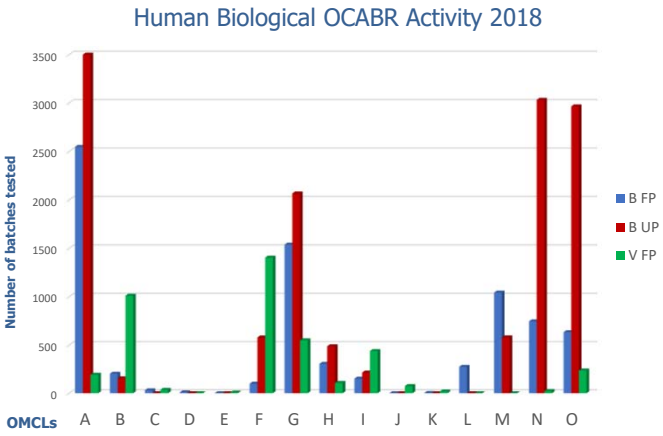
- recognised variability inherent in the products, in their production and test methods
- used - i.e. in prevention campaigns for healthy children and in helping compromised individuals e.g. blood clotting factors for haemophilia patients
  - Article 114 of EU Directive 2001/83/EC as amended (for human vaccines and medicinal products derived from human blood and plasma)
  - Articles 81 & 82 of EU Directive 2001/82/EC, as amended, for immunological veterinary medicinal products (IVMPs)

OCABR/OBPR cont'd

Mutual Recognition underpins this programme

- A batch is tested/examined in only 1 OMCL before placed onto the market
  - Independent check of quality
  - Compliance with spec of approved MA dossier
- Review of the manufacturers' batch production records and test results
- Compliant batches are issued an EU OCABR certificate
- Mutually recognised within the EU/EEA, Switzerland and Israel (human vaccines only), and is also recognised as a sign of quality in other parts of the world.

The OCABR/OBPR Programme Statistics



15 OMCLs performed OCABR for the Network in 2018

OMCLs have different profiles and different capacities

Total vaccine = 4094 batches (296 monovalent bulks)

Total blood = 7852 batches

Total plasma pools = 13611

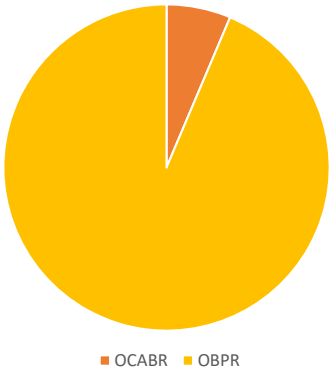
Work-sharing spreads the load and allows all member states access to independently controlled batches

B = blood, V = vaccine, FP = Final Product, B UP = upstream product i.e. plasma pool viral safety screen

The OCABR/OBPR Programme Statistics

Veterinary IVMP Batch Release Activity 2018

~8500 IVMP lots total
~540 tested for OCABR



7 OMCLs contributed to OCABR and 14 CA/OMCLs contributed to OBPR for the Network in 2018

OMCLs/CAs have different profiles and different capacities

Only a sub-set of IVMPs is eligible for OCABR according to a pre-determined list

All IVMPs are eligible for OBPR

Work-sharing spreads the load and allows all member states access to independently controlled batches

OCABR = Official Control Authority Batch Release (protocol review and testing)
OBPR = Official Batch Protocol Review (protocol review)

OCABR/OBPR cont'd

- **Official Control Authority Batch Release (OCABR): benefits, challenges and perspectives**

  Dr Volker Öppling, Paul-Ehrlich-Institut (PEI), Germany

API Surveillance

Working Group on API Testing was established in 2011

Fostering **collaboration** in quality control and "fingerprint analysis" of APIs on European market

Raising **awareness** of valuable OMCL contributions

- *Sharing information via a common API testing database*
- *Developing sampling strategies/RB selection of API samples*
- *MS programmes applying, amongst others, chemometric methods*
- *Organising training for Network members*
- *Drafting relevant OMCL Network documents*

API Surveillance

- **API Testing: how OMCLs can support the control of APIs**

  Dr Eric Deconinck, Sciensano, Belgium and Mr Yvan Grange, National Agency for Medicines and Health Products Safety (ANSM), France

Gene Therapy Products

Working Group created in 2008 to foster collaboration between OMCLs active in the field of GTP testing

Goals of the WG:

- Sharing of knowledge and latest technologies
- Establishment of methods and reference standards
- Centres of Excellence

Target vectors:

Adenovirus-associated vectors (AAV), Plasmids, Poxvirus vectors, Retro-/lentivirus vectors, Non-replicative adenovirus vectors (AV), HSV1-based vectors

Need for more manpower: more OMCLs and/or include external partners, i.e. academia/manufacturers, in collaborative studies

OMCL
Falsified Medicine Testing Activities

Some OMCL's collaborate routinely with **customs, police, law courts and health authorities** on the identification and quantification of falsified/illegal medicines.

Decision in 2004

- to better **co-ordinate** the work of individual OMCLs
- to **share information** between all GEON members
- to set up **common programmes** with help of EDQM

Benefits

"Anti-Falsified medicines" activities

- Facilitates the **sharing** of **technical know-how** and **expertise** on the detection of falsified/illegal medicines
- Facilitates the **sharing** of **intelligence** and **information** in this area between OMCLs and NCAs
- Helps OMCLs **develop competencies** in falsified medicines testing activities
- Offers a **forum** for OMCLs active in this area to **exchange information** with other **stakeholders**
- Speaks as **one voice** with stakeholders

OMCL

Falsified Medicine Testing Activities

- **Combatting falsified medicines - the EDQM's holistic approach in support of the MEDICRIME Convention**

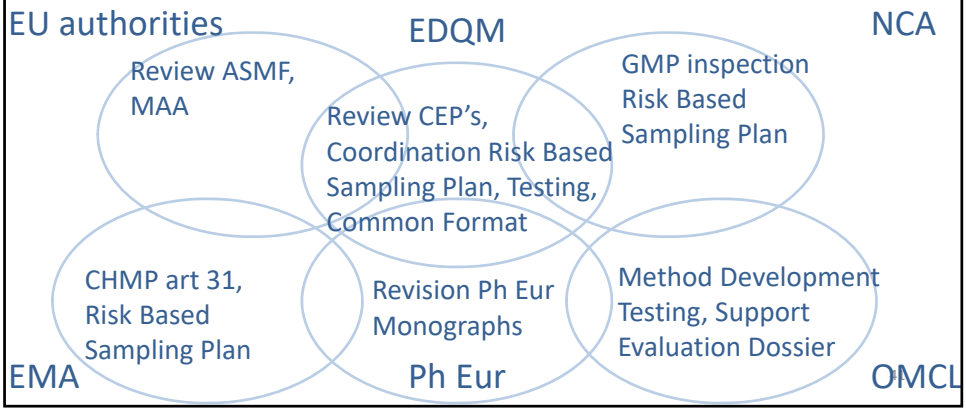
  Dr Karl-Heinz Buchheit, EDQM, Council of Europe

- **The contributions of OMCLs in the fight against Falsified and Illegal Medicines**

  Mr Stephen Young, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Example of crisis management

June 2018: Valsartan manufactured by Zhejiang Huahai Pharmaceutical contaminated with NDMA (nitrosodimethylamine)(possible carcinogenic)



crisismanagement

Example of crisis management

OMCL network contribution to regulatory action with respect to the "sartan crisis",

poster by M. Wierer, R. Wanko, M. Bertrand

General European OMCL Network

For more information on the activities of the **General European OMCL Network** please consult the section "OMCL Network" on www.edqm.eu

General European OMCL Network

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