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

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
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 Health

- Sampling & testing programme for medicines authorised for the EU
- Official Control Authority Batch Release (OCABR)

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
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 2018
  - 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
**Hopes**

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

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**Digital transformation of health**


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**Healthcare professionals**

Healthcare professionals: key links in the digital healthcare chain

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**Healthcare professionals**

**Patients**

**Data**

**Machines**
Digital Health and Care

European health challenges
- Aging 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 citizens’ health services

What EU citizens expect...
- 90% agree to access their own health data (important and quality health data)
- 80% agree to share their health data (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 easily access and share their data with doctors and health data anywhere in the EU
   - Actions:
     - Enable secure and cross-border access to health data
     - Implement new cross-border services (e.g., prescriptions and reimbursement)
     - Provide tools to securely exchange health data
     - Foster European standards for cross-border health data exchange

2. Health data pooled for research and personalised medicine
   - Ambition: Secure health research data.
   - Actions:
     - Strengthen European research initiatives in health and care
     - Facilitate cross-border exchange of patient data for research and innovation

3. Digital tools and data for citizen empowerment and person-centred healthcare
   - Ambition: Citizen can monitor their health, support new discoveries and interact with their doctors and care providers.
   - Actions:
     - Foster the supply of innovative digital health solutions
     - Support data sharing between healthcare providers
     - Support citizen empowerment in healthcare decisions

For example:
- Electronic health records (EHR)

And in the future...
- Cross-border exchange of patient data in the EU
- >1750 ePrescriptions
- Patient summaries

2019 operational ePrescriptions
2019 plan ePrescriptions
2020 plan patient summaries
2021 plan ePrescriptions
No plan yet
Dots to be joined…

Other examples:

Real World Data in Pharmacovigilance

Large data set linkages

Better signal detection

Mobile and wearable devices

Digital biomarker

Social media

Secure health data

Patient experience

Mobile and wearable devices

Blockchain

Social media

Better signal detection

Digital biomarker

Secure health data

Patient experience

European Reference Networks

Digital consultation

e-learning & e-training

Research

Knowledge generation

26 COUNTRIES

24 NETWORKS

>300 HOSPITALS

>900 HEALTHCARE UNITS

24 NETWORKS

>300 HOSPITALS

>900 HEALTHCARE UNITS
Outcome call 2016

24 European Reference Networks

26 COUNTRIES

› 300 HOSPITALS

› Full Member

› 900 HEALTHCARE UNITS

Share. Care. Cure.

PATIENTS

NATIONAL HEALTHCARE PROVIDERS

SPECIFIC ERN

CLINICAL GUIDELINES

RESEARCH & INNOVATION KNOWLEDGE

GENERATION & SHARING

TRAINING & E-LEARNING

Clinical virtual care

Research

Knowledge generation
1 Mio Genomes 20 Signatures

1 Mio genomes accessible 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

Link to existing and future genomic database across the EU

Providing a sufficient scale for new clinically impactful associations in research

EMA & HMA & BIG DATA

"Promote use of global, harmonised and comprehensive standards to facilitate interoperability of data" (p. 11)
Examples of EU funding for digital in the budgetary period (2021-27)

ESF+

ERASMUS

HORIZON EUROPE

Digital Europe
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), …

- **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
    - Vaccines and biological products
    - 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)

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**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

- 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.**

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**Market surveillance**

**Shared programme**

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

- Sample exchange
- Shared database
- Saving of money and resources (avoiding duplication)
- Willingness
- Mutual recognition of results
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.

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:
AVERTISSEMENT

- Personnels
- Personnels salariés de l’ANSM ou opérateurs de l’État
- La présente intervention s’inscrit dans un strict respect de l’autonomie
et indépendance des entités qui en font actes comme décisions.
- Toute utilisation de matériel personnel doit être soumise
à l’approbation préalable de l’ANSM.

Avertissement

- Les personnels, employés de l’ANSM (État opérateur),
- Cette action est réalisée dans le respect de l’autonomie
et indépendance de l’ANSM en termes d’actions.
- Tout usage de matériel personnel doit être soumis à l’approbation
préalable de l’ANSM.

Warning

- EU officials, employees of ANSM (State operator),
- This action is realized in accordance with the independence
and impartiality of ANSM with respect to actions.
- 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 Medicines Control Laboratories 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
- Analysed medicines
- Immunological products
- Vaccines
- Blood
- Plasma derivatives

Biological products
- Herbal medicines
- Homeopathic medicines
- Stockpiled medicines

Products
Analysed ingredients, preparations...

Medicines
- Allergen products (for diagnosis and treatment)
- Radiopharmaceutical products

Active Pharmaceutical Ingredients and excipients
- Gene therapy products

Falsified medicines and medicines in disguise
What is an OMCL?
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

What is an OMCL?

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:

- **Marketing Authorisation Dossiers** (in evaluating the quality part)
- Test methods to be included in the European Pharmacopoeia
- **Good Manufacturing Practice** inspections (as laboratory experts)
- Quality defect report evaluation
- Pharmacovigilance investigations

Benefits of OMCL Testing

**WHO BENEFITS FROM THE WORK OF THE OMCLs?**
Supporting European authorities in protecting the health of European patients and consumers across the entire product chain.
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/Membership
- 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

What is the GEON?

1st meeting in Strasbourg 1994

21 countries

AT – BE – BG – CH – DE
– HU – IE – IT – LU – NL
– UK

1st GEON Annual Meeting 1997, Bled
What is the GEON?

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

What is the GEON?

23rd GEON Annual Meeting 2018, Sarajevo

OMCL ANNUAL MEETING 2018 SARAJEVO
OMCLs within regulatory environment

What is the GEON?

NATIONAL LEVEL

National Authorities
National marketing authorisation
Elaboration of national post-marketing surveillance programmes (including MIV/DCP).

Inspection services
Sampling

OMCLs Analysis

EUROPEAN LEVEL

EMA
Elaboration of CAP post-marketing surveillance programme.
Evaluation of actions to be taken upon receipt of reports.

EDQM, Council of Europe
Preparation of protocols, co-ordination, distribution, receipt of studies and preparation of reports for CAP.

European Commission
Community marketing authorisation
Objectives

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

Benefits

- Expertise/novel scientific methods
- Crisis Management
- Collaboration/networking
- Common Quality standard
- Sharing information
- Independent
- Sharing workload/Reduce duplication
- Mutual Recognition
- 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

- Generics
- H/Bio
- H/Chem
- V/Imm
- V/Chem

Year

Number of products
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


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)
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

Human Biological OCABR Activity 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

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)

• 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)

OMCL network contribution to regulatory action with respect to the “sartan crisis”,
poster by M. Wierer, R. Wanko, M. Bertrand
For more information on the activities of the **General European OMCL Network** please consult the section “OMCL Network” on [www.edqm.eu](http://www.edqm.eu).

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