



European
Commission

2014-2020

EU HEALTH PROGRAMME CONFERENCE

BRUSSELS
30 SEPTEMBER 2019



Consumers, Health,
Agriculture and Food
Executive Agency



Objective 4

'Facilitate access to better and safer healthcare for Union citizens'

Parallel Session II



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Parallel Session II



Chair: **Anna-Eva Ampelas**, DG SANTE, European Commission

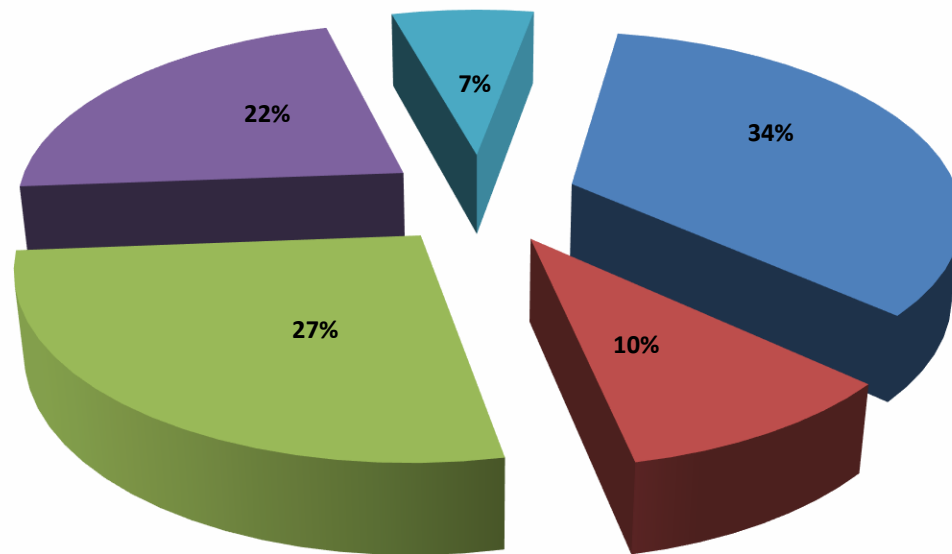
Co-chair: **Georgios Margetidis**, Chafea

- European Reference Networks for Rare Diseases: **Irene Mathijssen**, Erasmus University Medical Center, the Netherlands
- Rare diseases: **Yann Le Cam**, European Organisation for Rare Diseases (EURORDIS)
- Substances of Human Origin: **Paola Di Ciaccio**, National Institute of Health, Italy
- Antimicrobial resistance: **Marie-Cécile Ploy**, INSERM, France
- European Pharmacopeia: **Michael Wierer**, EDQM, Council of Europe



Objective 4: Facilitating access to better and safer healthcare for Union citizens

Budget allocation by objective 2014 - 2018



- 1. Promoting health and preventing diseases and foster supportive environments for healthy lifestyle
- 2. Protecting Union citizens from cross-border health threats
- 3. Contributing to innovative, efficient and sustainable health systems
- 4. Facilitating access to better and safer healthcare for Union citizens
- Horizontal actions



Main activities per thematic priorities

**EU Funding:
€ 62 m**

EURORDIS – European Organisation for Rare Diseases Association € 5 m

ERN- European Reference Networks (ERNs) Coordination of ERNs € 26 m
Other activities € 3 m

Cooperation program with CoE/EDQM on specific matters related the improvement of safety and quality of blood components and tissues and cells for human application and dissemination of best practices € 0.5 m

VISTART – Joint Action on vigilance and inspection for safety of transfusion assisted reproduction and transplantation € 2.3 m

GAPP – Joint Action on facilitatinG the Autorisation of Preparation Process for blood and tissues and cells € 1.2 m

JAMRAI – Joint Action on antimicrobial resistance and health care associated infections € 4 m

Data 2014 - 2018



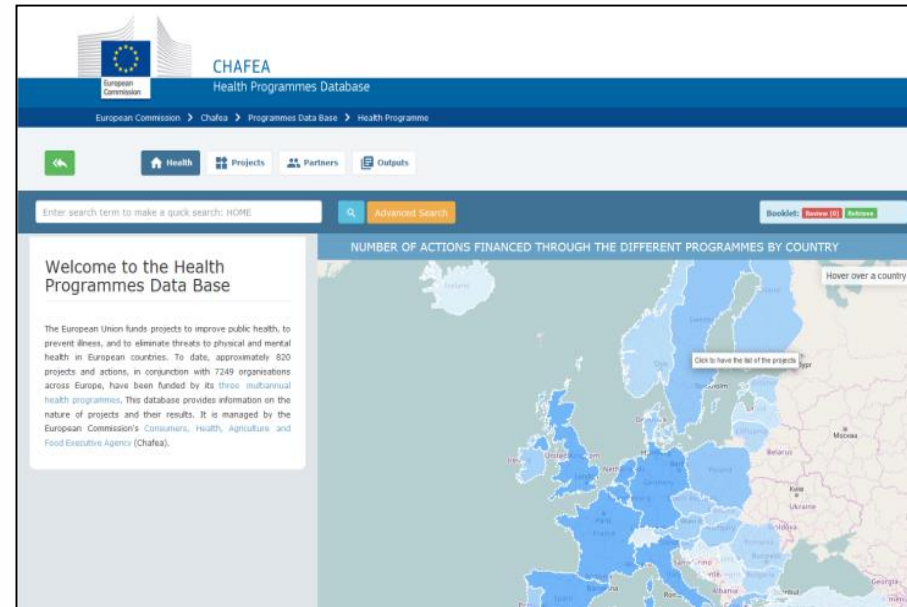
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Useful links

**European Commission Directorate-
General for Health and Food Safety
(SANTE) website**
https://ec.europa.eu/health/home_en

Chafea Website
https://ec.europa.eu/chafea/health/index_en.htm

Chafea Project Database (2003-2019):
https://webgate.ec.europa.eu/chafea_pdb/health/





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European Reference Networks for Rare Diseases



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Irene Mathijssen

Erasmus University Medical Center, the Netherlands



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Irene MATHIJSEN

Coordinator ERN CRANIO, ERN Coordinators Chair
Erasmus MC Rotterdam, the Netherlands

The European Reference Networks on Rare Diseases



ERN: content and objective

- Access for all European patients to expert centers
- Knowledge travels, not the patient
- Sharing knowledge between experts and patients



ERN: results

- Electronic platform for consultations with the experts
- European guidelines, developed with patients
- Sharing knowledge e.g. via webinars



ERN: uptake and follow-up

- At start, Western Europe and now inclusion of other MS
- In coming years, complete coverage of MS
- Upgrade of affiliated centers to full members



ERN: benefits for EU citizens

- EU citizen with rare disease can trace the expert centers and obtain information on diagnosis and treatment
- EU citizen can get a digital consultation via a local health care provider
- EU citizen can participate in ERN activities, including dissemination



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Rare diseases



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Yann Le Cam

European Organisation for Rare Diseases (EURORDIS)



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Session II_Objective 4: Facilitate access to better and safer healthcare for Union citizens

Yann LE CAM
Chief Executive Officer
EURORDIS – Rare Diseases Europe

Rare Diseases: Operating Grant, Joint Actions, ERNs



Rare Diseases Community Actions: content and objective

Operating Grant:

- Consolidating the RD patient community
- Build capacity and empowering patient community
- Engaging patient community into implementation and monitoring of legislation and strategies

Joint Action: priority health issues, deserving to be tackled at the EU level

- Improving health outcomes of people with rare diseases and rare cancers
- Enabling the implementation of recommendations of Expert Groups, harnessing the rare disease community

European Reference Networks (ERNs):

- Contributing to build a EU wide infrastructure pooling knowledge and resources across Europe for highly specialised care
- Leading and supporting patient resources within and for ERNs





Rare Diseases Community Actions: results

Operating Grant:

- Strong and growing membership, outreach, dissemination in 7 languages
- Training activities consolidated in EURORDIS Open Academy
- Rare Disease Day, awareness raising campaigns
- Strong patient involvement in EMA activities & committees; ERNs and HTA activities

Joint Actions:

- Orphanet and OrphaCodes: standard common language and tools for health & research; go-to database
- Support to the establishment & development of ERNs (policy workshops, matchmaking tool)
- 15 EUROPLAN National Conferences & State of the Art
- Concrete recommendations prepared with and adopted by MSs for national uptake

European Reference Networks:

- EU flagship initiative with networks in 24 clinical areas
- Networks ERN Assessment Manual & Toolbox – EURORDIS led consortium
- Over 300 patients involved working together in 24 European Advocacy Patient Groups (ePAGs)



Rare Diseases Community Actions : uptake and follow-up

Operating Grant:

- Membership reached 869 organisation, the community is increasingly complex, 40 national alliances, 68 federations
- Outreach and information dissemination targeted to membership sub-groups
- Scaling-up training for more patients and the depth of actions requires different areas and different levels of trainings

Joint Actions:

- 25 National Plans/Strategies for RDs are structured around same priorities in MSs, but require much more follow up & support
- Guidelines and technical recommendations, but still to be implemented in national policies based on best practices + new policy areas to be tackled
- OrphaCodes uptake has increased (over 11 MS), their value recognised – yet MS uptake has to increase, toolkits and guidelines are available

European Reference Networks:

- With 900 HCP Members in 300 hospitals, 26 EU MS, there is potential for uptake by more EU countries, full and affiliated members, sub-clinical groups so to increase disease and geographical coverage
- Scope for more extended patient involvement, with better anchorage in each ERNs and governing bodies (Boards, Steering Committees and TFs)



Rare Diseases Community Actions: benefits for EU citizens

Operating Grant:

- Structured, robust RD movement, with fair and objective representation of 25 million people in EU, and one of most vulnerable group in society
- Greater public awareness of RD and main promoter of RD policy
- Patient-centred RD policy and decision making in ERNs, HTA and EMA activities
- Competent, autonomous patient reps, for meaningful engagement in activities of common interest

Joint Actions:

- Reliable database, a common language for RDs for health information systems, with improved visibility of RDs
- Meaningful and effective policy making in the RD field, co-created by all stakeholders in the community
- Strong integration between EU policy and national policy, with EU cooperation fostering better national uptake and structural changes in national systems

European Reference Networks:

- Paradigm shift in healthcare delivery, planting the seeds of a EU-wide healthcare system in an area with high EU added value
- Cross-country sharing of knowledge and resources with (potential) improved diagnosis and care RD patients
- Better patient involvement, overall ERN data strategy, integration in national HC systems



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Substances of Human Origin



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Paola Di Ciaccio

National Institute of Health, Italy



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Paola DI CIACCIO

Head of Foreign Affairs Division,

Italian National Transplant Centre, Italian National Institute of Health, Rome, Italy

VISTART and GAPP JAs: how the program has contributed to improve quality and safety of Substances of Human Origin



GAPP





VISTART and GAPP: content and objective

- ***Inspecting:*** a common framework for harmonized targeted verifications of quality standards in Tissue Establishments for **blood, tissues and cells**
- ***Vigilating:*** a shared approach to the notifying, assessing and investigating **serious adverse events and reactions**, disseminating the culture of safety and scanning horizon for new emerging risks
- ***Authorizing:*** how to assess and authorize preparation processing in blood and tissue establishments, in order to ensure effectiveness and safety



VISTART and GAPP: results

- Inspection **guidelines** for EU Competent Authorities, common **training programme** for Inspectors, **joint inspection programme**
- Guidelines for **reporting SARE and identifying new risks** related to donation of SOHOs
- Approval of SOHO product processing:

Seven regulatory principles



Action: uptake and follow-up

- Ongoing discussions on a **common training program** for inspectors, as a tool of standardization of inspection methods. A proposal for common requirements **EU register** of international BTC inspectors has also been put forward: *under discussion in the Inspection Expert Subgroup chaired by EU Commission. All Member States.*
- VISTART supplied the basis for revision of official EU templates for **reporting of serious adverse events and reactions**, under Directive 2004/23/EU, as well as rapid alerts platforms for blood, tissues and cells: *under discussion in the Vigilance Expert Subgroup chaired by EU Commission. All Member States.*
- **Principles** for authorizing preparation processes: the basis for a devoted Joint Action (GAPP, 24 partners from 17 Member States) started in May 2018:
 - Good practice guidelines (plus 3 technical annexes) and platform for knowledge sharing



Action: benefits for EU citizens

- Inspections: Harmonization quality, training scheme, inter-MS scheme, support smaller countries
- Vigilance: A watchful awareness of what went wrong supplies precious information to avoid subsequent adverse events
- Authorization: proper pathway to tackle new products, gathering evidence at EU level, exchange of expertise, getting ready for the future



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Antimicrobial resistance



Marie-Cécile Ploy

INSERM, France



EU-JAMRAI

Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections

Marie-Cécile PLOY

EU-JAMRAI Coordinator - INSERM

TOPIC: Antimicrobial resistance

ACTION: Europe fostering synergies to keep antibiotics working



Action: content and objective

- **Tackling AMR:** 44 European partners and more than 40 international stakeholders working together to make EU a #BestPracticeRegion identifying and implementing evidence based measures to fight against AMR and HCAI.
- **Bridging the gap between declarations and actions:** We foster synergies to #KeepAntibioticsWorking producing concrete recommendations and promoting awareness and commitment by governments and stakeholders.
- **One health approach:** We work to ensure that all MS have a #OneHealth AMR strategy recognizing that human health, animal health and environment are interconnected.



Action: results

- Strengthening national and EU response against AMR
 - Mapping and assessing National Action Plans
 - Transforming EU through peer reviews: 9 country-to-country visits
 - Setting up a network of supervisory bodies
- Improving infection prevention and control
 - IDENTIFYING THE GAPS on implementation, research and communication
 - FILLING THE GAPS implementing pilot models (universal infection control framework) and ranking research gaps in infection control and prevention, in collaboration with the JPIAMR



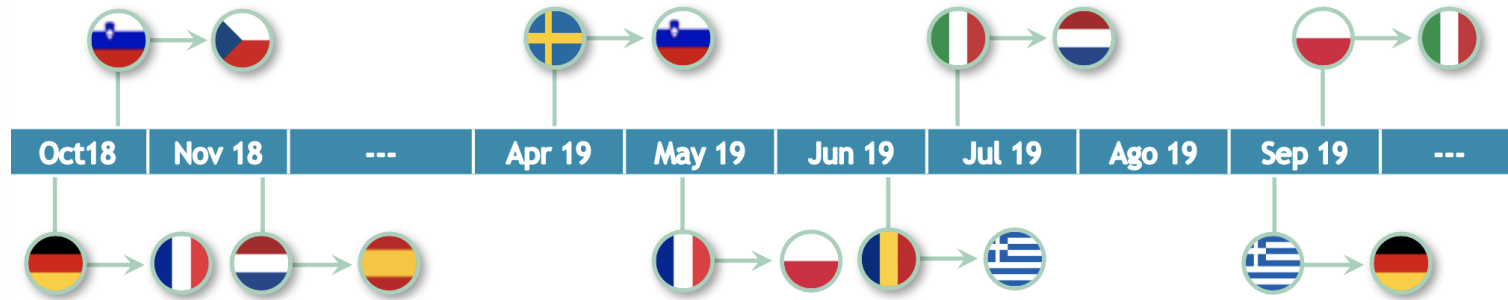
Action: results

- Reducing antibiotic use: stewardship and surveillance
 - In human health (core components) and real-time surveillance system of antibiotic use and resistance
 - In animal health: European AMR surveillance network in veterinary medicine
- Raising awareness
 - #OneHealth butterfly effect: small changes can have large effects
 - Contest for an antibiotic resistance symbol

Action: uptake and follow-up

- Uptake:

9 country-to-country visits to date...



- Follow-up:

- **Integration:** adoption of the JA outputs at member states level (national, local, regional) into, for example, national policies (NAP), national actions or programs, etc.
- **Sustainability:** strategy defining which elements/deliverables/results will be further developed, consolidated or run and by which entity/organisation this will/should be done
- Involving Member States and Stakeholders



Action: benefit for EU citizens

- Increasing awareness on AMR
- Behavioural change
- Better implementation of infection control and prevention
- Sharing experience between all sectors (human-animal-environment)
- Providing evidence-based recommendations to policy makers and keeping AMR high on the political agenda for a better patient safety
- Reducing antibiotic use and antibiotic resistance burden



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European Pharmacopeia



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Michael Wierer

EDQM, Council of Europe



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Dr Michael WIERER

(Head of Medicines Division, DBO, EDQM/Council of Europe)

EDQM Grant:

OMCL Network and Biological Standardisation Programme



EDQM grant: content and objective

- **Quality of Medicines**

Monitoring to ensure that EU citizens have access to medicines of appropriate quality

- **Manufacturer-independent Market Surveillance by testing**

Establishing and maintaining a network of Official Medicines Control Laboratories (OMCLs) that aims at work-sharing and optimised use of knowledge and resources

- **Standardisation of Biologicals**

Providing reliable tools for the testing of complex products



EDQM grant: results

Pillar 1: The **OMCL Network** provides

- efficient output during concerted routine surveillance test programmes
- ability to react rapidly and effectively in crisis situations (such as the Sartan case)
- mutual recognition of test results in Member States

Pillar 2: The **Biological Standardisation Programme** establishes

- methods and standards, embracing, where appropriate, the principles of Directive 2010/63/EU (Replace, Reduce, Refine the use of animals)
 - ✓ e.g. Acellular Pertussis vaccines safety test method:
a variable animal test replaced by a more precise *in vitro* method



EDQM grant: uptake and follow-up

Pillar 1: OMCL Network

- Every year, about 30 OMCLs from EU/EEA MS participate in market surveillance testing activities and share about 1000 test reports for generic medicines
- Sartan case: Provision of scientific input, methods and analytical results for about 3800 samples
- Increasing recognition of the value of the Network among stakeholders

Pillar 2: Biological Standardisation Programme

- The new method for the Pertussis Vaccines included in the European Pharmacopoeia
- Legally binding as of 1/1/2020 in 38 Council of Europe member states
- To be applied by all manufacturers and OMCLs



EDQM grant: benefits for EU citizens

Pillar 1: OMCL Network

- The OMCL surveillance programme for generics is a reassurance for patients that generic medicines are of appropriate quality
- Sartan case: withdrawal of contaminated batches and support of the development of safe quality requirements

Pillar 2: Biological Standardisation Programme

- Common standards for quality control testing
- Biological medicines e.g. human plasma and vaccines can be independently controlled; appropriate quality is confirmed before they reach the patient



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