Maastricht Conference on "20 years EU health actions", 22 May 2013

The role of agencies as a driver for EU policies

Fernand Sauer,
Honorary Director General, European Commission

BUILDING –UP PUBLIC HEALTH CAPACITIES AT EU & MS' LEVEL

20 years ago, Public Health used to be a highly specialised field, restricted to health ministries with limited capacities , managed by «health corporations », with very limited input from patients

Since then, building joint health capacities and running them smoothly, has become a major challenge for the Commission and the EU Member States

Over the last 20 years, several agencies have been created to support EU policies, in particular on health issues

Two case studies, pre- and post-DG SANCO's creation:

*- **EU Medicines Agency** since 1995, now related to SANCO*

*- **EU Centre for Disease Control**, since 2005*

DIFFICULT START FOR HEALTH IN DG SANCO, BACK IN 2000

1992-1999: health activities were conducted within DG Social Affairs,

Informal Health Council, High Level Committee on Public Health

1999 Health/Luxemburg is absorbed by the new DG SANCO, without health and safety at work . **SANCO focuses on food safety**

Deep crisis of small precursor health programs (collapse of external support)

2000: EU Health Strategy, but no internal resources for 1rst Health Program

Parliament insists on **strong structural arrangements** during negotiations of public health program (to start in 2003). This provides an opportunity to:

- mobilize civil society (EU Health Forum, European patient Forum)
- request more resources for health in SANCO
- move health policy activities from Luxemburg to Brussels,
- reinforce program management in Luxembourg (new Executive Agency)
- propose the creation of ECDC, after consultation of national institutes

PATIENTS' INVOLVEMENT

Early involvement of various patient groups in EMA and SANCO activities (EURORDIS)

50 Civil society NGOs: EU Health Forum, since 2001

Emergence of the European patient's Platform /2003

Representation of patients with Health Ministers in EU Groups (Pharma Forum, Patient Mobility)

Representation within EMA and ECDC Boards and in EMA scientific activities (COMP, PRAC, SAG)

EU support to patient groups

http://www.eu-patient.eu/

REINFORCING SANCO/HEALTH

Sanco Luxembourg (2000):

- Health Information
- Health Threats
- H. Determinants
- + Progr. Management (2002)

- **+ Executive Agency for Health Programme (2006)**

Sanco Brussels (2003):

- Health Strategy
- Health Measures
- Risk Assessment
- +Pharmaceuticals (2010)
- +Health services (2010)

Health in all policies:
Commission Interservice Committee on Health

INCREASING EU HEALTH CAPACITIES

"Health is wealth", "Enabling god health for all"

Health gap in accession countries!

Health crisis in southern Europe!

Sanco/ "health staff":

2000: 66 2005: 135 (PH program: 60 mio €/year)

2013: around 200 (including Progr. Executive Agency)

EU health research: amost 1 billion €/year

EMA + EFSA + ECDC, together:

staff: 1400, budget 370 mio €/year

BUILDING –UP PUBLIC HEALTH CAPACITIES AT EU LEVEL

1. EU agencies: pros and cons

2. What has EMA delivered?

3. What has ECDC delivered?

4. International and future perpectives

Overview of Health Agencies

1. Increasing health capacities:

pros & cons of EU agencies

WHY EU HEALTH AGENCIES?

- *No polical interference on scientific issues*
- *MS would not delegate to Commission alone*
- *Commission cannot cope with such technicalities*
- *Manage interfaces between national agencies*
- *Create and develop wide expert networks*
- *Pool best expertise available throughout EU*
- *Reduce/contain overall expertise costs*
- *Establish joint ownership national + EU*
- *Direct cooperation with Norway & Iceland*

DIFFICULTIES FOR EU AGENCIES

- *No easy creation (crisis driven)*
- *Re-nationalizing Community competences?*
- *Infringing on national prerogatives?*
- *Limiting growth of national resources?*
- *Increasing competition with national agencies*
- *Lack of visibility except for scandals/errors*
- *Lack of legitimacy in the eye of the public*
- *Inter-institutional frame to be clarified*
- *Budget austerity for expanding tasks*

AGENCY NETWORKS

- *Partnership with national/international players*
- *Not a 30th agency but a EU hub for agencies*
- *Provide a real and recognisable service*
- *Power of information versus over-regulation*
- *Exellence rather than blame culture*
- *Handling conflicts of interest*
- *Develop internal audits and anticipate controls*
- *Autonomy of staff to liaise with network experts*
- *International recognition of individual experts*
- *Provide expertise for EU international activities*

EU « Health Agencies »

1990: European Environment Agency (EEA), Copenhagen

1993: European Monitoring Centre for Drugs and Drug Addiction, Lisbon

1994: European Agency for Safety and Health at Work (EU-OSHA), Bilbao

1995: European Medicines Agency (EMA), London

2002: European Food Safety Authority (EFSA), Parma

2005: European Centre for Disease Prevention and Control (ECDC), Stockholm

2006: Executive Agency for Health & Consumer Programmes, Luxemburg

2007: European Chemicals Agency (ECHA), Helsinki

EU Health Research Agencies?

1. IMI (2008/2013) Innovative Medicines Initiative, based in Brussels,

Research done by academia, clinics, industry, SMEs, patient organizations, following open calls and peer evaluation.

for better prediction of safety and efficacy (toxicology, biomarkers, clinical) for drug developers to reduce the risk of failure during clinical trials

Run by Commission/EFPIA joint body, with 1 billion from EU (for academia and SMEs) and 1 billion from Industry

2. EDCTP (2003/2015) EU/Africa Partnership for clinical trials on AIDS, TB and Malaria, based in The Hague and Cape Town, with 200 millions € from EU, 200 millions from 16 MS.

50 clinical trials to adapt treatments to local conditions and build research, ethical and regulatory capacities and networks North/South & South/South

3. Experts' recommendation for a European Board for Public Health Research to coordinate research networks under HP2020.

Pharmaceuticals

What has the EMA* delivered so far?

** Named EMEA until 2010*

EU & INTERNATIONAL HARMONISATION

- 1965-1994: harmonisation of EU pharma legislation
- International Conference on Harmonisation (ICH) initiated by Commission in 1990 (www.ICH.org)
- Regulators and R&D experts from EU - Japan - USA
- Observers include WHO, Canada and CH
- ICH partners represent 90 % of world R&D
- Common Format and dissemination since 2000
- *VICH initiative in veterinary sector*

EU medicines' authorisations

Since 1995 - EU-wide authorisations through EMA

- 2000 - Orphan drug policy
- 2001- Codification of EU pharmaceutical legislation
- 2004 - Reform of the European authorisation system: extension of central and creation of decentralized system
- 2006- Incentives for SMEs and Paediatric Medicines
- 2007- Advanced Therapies
- 2010- Reinforced pharmacovigilance system
- 2011- Reinforced controls on active substances and falsifications

EU MEDICINES AGENCY (EMA)

- Evaluation of novel human and veterinary medicines
- Hub for 42 national agencies & 4.500 experts
- Staff: 700
- Budget: 230 Mio € (75% from fees)
- Management Board: all MS+
- 7 Scientific Committees + numerous working parties
- New Director: Guido Rasi

http://www.ema.europa.eu

EMA in the EU system

Protection and promotion of public and animal health

Rapid and EU-wide authorisation for innovative medicines

EMA is designed to coordinate and pool the existing scientific resources of Member States

EMA interfaces with all partners, through strong ICT networks

Links to other EU agencies:

Alicante/Stockholm/Lisbon/Copenhagen

No mandate for pharmaco-economics

SPECIFICITY OF EMA

- No financial support from host country
- Outside EURO zone: currency fluctuations
- Plethoric management boards (all MS ++)
- Highly media sensitive (Viagra, Vioxx)
- Strong stakeholders involvement (patients)
- Important fee revenue for EMA (75%)
- Risk assessment and most of risk management

EMA POSITIVE TRENDS

- EMA + Heads of Agencies Cooperation for a sound EU regulatory environment
- Reliable regulators (EMA & national)
- Early dialogue on R&D
- Science based evaluation process
- Quick and auditable decision making
- Increasing public confidence
- International benchmarking: ICH, FDA

EMA MAIN ACHIEVEMENTS

Central approval of **Medicines for human use** (since 1995):

- Around 800 EU marketing authorizations granted
- More than 3000 EMA scientific advices (2/3 clinical)

Orphan medicines (since April 2000):

- Around 1100 orphan designations and 80 marketing authorizations

Central approval of **Veterinary Medicines** (since 1995):

- EU marketing authorizations granted: 150
- Maximum residues limits for ‘new’ substances : 170
- EMA Scientific advice: 100

EMA MAIN CHALLENGES

- Maintain high quality and performances
- Continue to improve transparency and independence
- Continue to improve access to EMA safety & clinical data
- Effective pharmacovigilance*
- Track defective or falsified products and active ingredients
- Prevent shortages of medicines
- Better information to health professionals
- Improved patient information
- Prepare for personalized medicines

* *Benfluorex:Mediator crisis in France*

Communicable Diseases

What has the ECDC delivered so far?

DG SANCO's STEERING ROLE

1999 : EU Communicable Disease Network

Dedicated Surveillance Networks and EWRS: Early Warning and Response System, EPIET & EUROSURVEILLANCE

Subsequent decisions on disease coverage and case definitions and coordination work on:

- preparedness and response plans by the EU countries, early notification of cases, outbreak assistance and coordination of responses, surveillance and networking,
- reference laboratories to identify the strain quickly
- availability of vaccines and anti-viral drugs

Revised International Health Regulations (WHO, 2005)

Health Security risk management stays at SANCO

PRELIMINARY STEPS 2000-2001

Start of Dedicated Surveillance Networks
Pilot early warning system EWRS

European Council (Gothenburg, June 2001)
Health Council on Bioterrorism
Health Security Committee
EP request for « strong structural arrangements »

ECDC DESIGN: 2002

- State Epidemiologists Report
- Network Committee conclusions
- Internal drafts (R. Haigh, M. Kokki)
- Adoption 1rst EU Health Program
- Visit D. Byrne to US CDC in Atlanta
- G8 Health Security & WHO
- Crucial EP workshop (Trakatellis)
- « Bourlingster » staff seminars

SETTING-UP THE ECDC 2003-2005

- May & June 2003: « SARS » Councils
- July 2003: Commission proposal for ECDC
- December 2003, EU Council : Sweden to host ECDC
- European Parliament and Council agree with Commission in **one single reading**
- April 2004: ECDC Regulation (EC) 851/2004
- September 2004: 1rst Management Board meeting
- December 2004: designation of Director (Z. Jakab)
- May 2005: ECDC operational in Stockholm
- July 2005: handover of Commission financial files
- September 2005: handover of Commission scientific files

ECDC: European Centre for disease prevention and control

- Identify, assess and communicate with Member States and the Public

- on existing or emerging threats related to communicable diseases

- through pooling and coordination of national expertise and institutes

•http://www.ecdc.europa.eu

Director: Marc Sprenger

•Management Board (MS ++)

•Advisory Forum

•Expert panels

Links to WHO, US CDC

Staff: 300

Budget: 60 mio €

In Stockholm since 2005

ECDC DISEASES PROJECTS

- Seasonal influenza, pandemic influenza
- Tuberculosis, especially highly resistant strains
- Food and water-borne: botulism, brucellosis,TSEs..
- Diseases of environmental and zo-onotic origin
- Vaccine preventable diseases
- HIV, STI and blood-borne viruses
- Antimicrobial resistance* and healthcare-associated infections

* *In cooperation with EMA & EFSA*

ECDC scientific support

ECDC output is highly valued by national authorities:

- Bringing together people and knowledge, peer review
- Networking and coordination across Europe
- Encourage countries to develop own systems
- Risk assessments, scientific advice
- For countries with few resources, advice more authoritative
- ECDC can draw from wide sources and interpret for EU
- Support in crises
- Fast response to outbreaks
- Preparation for pandemic

ECDC INTERFACE WITH NATIONAL HEALTH INSTITUTES

- Much good will, many bright people
- Day to day contacts with ECDC staff are often positive
- Complexities of “multi-cultural” communication
- Advantage of ECDC outweighs concern
- Goodwill to try and solve problems together

Main issues:

- What are the Public Health problems with EU added value?
- Language – linguistic interface
- Reducing complexity/improving coordination

ECDC DEVELOPMENTS

Consolidate achievements:

- Surveillance (Tessy) and Epid. Intell. tools
- Emergency Operations Centre
- IHR Assistance for MS & Commission
- Lessons learned from pandemics
- High priority for disease specific work
- Cooperation with EMA and EFSA

Challenges ahead:

Future EU financial perspectives> 2013

Extending the scope of ECDC mission ?

EU health agencies

4. International and future perspectives

ECDC SUPPORT FOR INTERNATIONAL HEALTH

- EFTA and accession countries
- Bilaterals: USA-CDC, Canada, etc…
- the South-Eastern Europe Health Network
- the Euro-Mediterranean Partnership
- the Northern Dimension Health and Social Partnership
- International Organizations (WHO, OECD)

Commission in the lead for Global Health Security (+US, Canada, Japan, Mexico)

EMA & INTERNATIONAL PHARMA

ICH & VICH (harmonisation EU/Japan/US)

EEA: Norway+Iceland; cooperation with Switzerland

European Pharmacopoeia (36 countries+observers)

Past and future enlargements

Bilaterals with Russia, China, etc...

Mutual recognition agreements:

(US, Canada, Japan, Austral./N-Zealand)

WHO Certification Scheme, Counterfeiting

EU versus US AGENCIES

- **US FOOD AND DRUG AGENCY (FDA)**

  Rockville (Maryland) 1906

- **CENTER FOR DISEASE CONTROL (CDC)**

  Atlanta (Georgia) 1946

NIH National Institute for Health

- **EMEA: EUROPEAN MEDICINES AGENCY**

  London 1995

- **EFSA: EUROPEAN FOOD SAFETY AUTHORITY**

  Parma 2002

- **ECDC: EUROPEAN CENTRE FOR PREVENTION AND CONTROL OF DISEASES**

  Stockholm 2005

[Innovative Medicines Initiative and EDCTP]

MORE EU HEALTH AGENCIES OR ADDITIONAL TASKS?

Possible new tasks for EMA:

1. Take over formal authorisations (safe exceptional circumstances)
2. Adjust to personalised medicines
3. Authorise and monitor multi-national clinical trials
4. Create strong links to national health technology assessments
5. Supervise medical devices

Possible new tasks for ECDC:

Beyond communicable diseases: --

1. Major health threats (obesity)
2. General health monitoring,
3. Become gradually a « general health agency »
4. A hub for research networks?

Challenge for all health agencies:

Maintain good cooperation with SANCO & RESEARCH, MS,WHO

Survive drastic budget cuts