Some EU initiatives relevant to the medtech sector

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European Commission
• State of Health in the EU
• Health Systems Performance Assessment
• EU cooperation on HTA beyond 2020
• Health and Care in the Digital Single Market
State of health in the EU

HEALTH AT A GLANCE: EUROPE 1
November 2016

COUNTRY HEALTH PROFILES 2
November 2017

COMPANION REPORT 3
November 2017

VOLUNTARY EXCHANGES 4
First half of 2018
COUNTRY PROFILES

The profiles form the backbone of the State of Health in the EU cycle.

https://ec.europa.eu/health/state/country_profiles_en
COMPANION REPORT

- **Cross-cutting** conclusions by the Commission, from the twenty-eight Country Health Profiles
- Linked to **shared policy objectives** across the EU countries, revealing potential for EU added value
- Follow the Commission Communication on effective, accessible and resilient health systems
Five key conclusions

#1

Health promotion and disease prevention pave the way for a more effective and efficient health system

#2

A strong primary care guides patients through the health system and helps avoid wasteful spending
Mandatory primary care referrals indicate strong gatekeeper systems in half of the Member States.
Integrated care tackles a labyrinth of scattered health services to the benefit of the patient.
Proactive health workforce planning and forecasting make health systems resilient to future shocks.
State of health in the EU
The patient is at the centre of the next generation of better health data for policy and practice.

Better health data contributes to patient outcomes whilst reducing wasteful spending in health care.
Commission Communication on Effective, Accessible and Resilient Health Systems

EU agenda for effective, accessible and resilient health systems

- Strengthening effectiveness
  - Health systems performance assessment
  - Patient safety and quality of care
  - Integration of care

- Increasing accessibility
  - A fit-for-purpose health workforce
  - Access to innovative medicines
  - Optimal implementation of 2011 Directive on cross-border healthcare

- Improving resilience
  - Health technology assessment (HTA)
  - Information for better governance
  - eHealth, mHealth
The Expert Group on Health Systems Performance Assessment

OECD

WHO

European Observatory

SRSS is involved and ready to provide follow-up technical assistance.
Expert group on HSPA
Strands of activity

- Annual work on priority areas
- Sharing of national experiences
- Tailored country-specific activities
- HSPA advocacy

2015: Quality of care
2016: Integrated care
2017: Primary care
2018: Efficiency
2019: Resilience
Integrated care is not a goal in itself; it is rather a precious tool when it addresses complex care needs.

Measuring integration is different from measuring the performance of integrated care.

Design principles, building blocks and system levers should be included as part of the framework for assessment of integrated care.

Integrated care models can be introduced with different goals in mind.

There is no single ‘right’ approach that would be applicable and valid for every system.
Expert Panel on Investing in Health

- Provides independent non-binding advice on effective ways of investing in health
- Established by Commission Decision 2012/C 198/06 following the Council conclusions of June 2011 'Towards modern, responsive and sustainable health systems'; renewed in 2017
- Currently working on benchmarking access to healthcare, performance assessment of primary care, and innovative payment models for high-cost innovative medicines.
EU cooperation on HTA

SUSTAINABLE EU COOPERATION ON HTA

2016

2020

Joint production

Quality Management

Early dialogues & Real world data generation

National implementation and impact

Strategy for EU Cooperation on HTA

Reflection Paper on synergies between regulatory and HTA issues

Inception Impact Assessment

Public consultation

Impact assessment

Commission proposal
EU cooperation on HTA
EU funded projects

EUnetHTA JAs (2010-2020)

- Trust between HTA bodies and capacity building
- Development of joint tools (e.g. EUnetHTA Core Model, POP EVIDENT databases)
- Piloting joint work (e.g. early dialogues, joint assessments)
- JA3 – upscaling of joint work

+ Low uptake of joint work ⇒ duplication of work
- Differences in the procedural framework and administrative capacities of Member States
- Differences in national methodologies
- No sustainability of current cooperation model
EUnetHTA Jas (2010-2020)

- **Joint work on medtech:**
  - Methodologies, guidelines
    - E.g. "Therapeutic medical devices" guideline (2015)
  - **Joint early dialogues:** 3 – SEED/EunetHTA 2 (total 11)
  - 1 planned EUnetHTA 3 (total)
  - **Joint assessments:** 3 – EunetHTA 2 (total 15)
  - **Collaborative assessments:** 7
    (carried out by a group of interested MS):
    [http://www.eunethta.eu/joint-assessments](http://www.eunethta.eu/joint-assessments)
Most of the Member States indicated that HTA procedures are in place at national level to inform pricing and reimbursement decisions about pharmaceuticals and medical devices.
EU initiative for strengthening EU cooperation on HTA

• **Addresses the shortcomings of the current cooperation model**

• **Objectives:**
  - Promote convergence in HTA tools, procedures and methodologies
  - Reduce duplication of efforts for HTA bodies and industry
  - Ensure the uptake of joint outputs in Member States
  - Ensure the long-term sustainability of EU HTA cooperation

**Adoption January 2018**
Key elements (1)

• Member State driven
  o MS → scientific work and decisions
  o EU → support function

• Focus on clinical assessment
  o no common appraisal
  o no common economic assessment

• High quality and timely output
  o Joint REA: at the time of MA (Pharma)/ later (Medtech)

• Mandatory uptake → no duplication at national level
• Transparency → stakeholders' involvement
• Fit for purpose → pharma vs medtech
Key elements (2)

• Possible areas of joint work
  • **Common tools and methodologies**
  • **Horizon scanning/topic selection**
  • **Joint early dialogues**
    - Multi-HTA
      - Parallel with regulators (e.g. parallel consultation with EMA)
  • **Joint REA** → **limited scope**
    - medical devices → relevant to MS, EU-added value
• **Pragmatic approach** → **phase-in approach**
Digital Single Market (DSM) Strategy (May 2015)

- The European Commission has placed digital at the core of its strategy, by setting the Digital Single Market as one of its 10 priorities.
- The aim is to open up digital opportunities for people and business and to make the EU's single market fit for the digital age.
3 Priority areas on Health and Care in the DSM

- Give citizens better access to their health data, everywhere in the EU
- Use digital services for citizen empowerment and person-centred care
- Connect and share health data for research, faster diagnosis and better health outcomes
Pillar I: Give citizens better access to their health data

The eHealth Digital Service Infrastructure (eHDSI)

1. Enabling the exchange of patient data across borders
   - **Patient Summary**: provides access to health professionals to verified key health data of a patient during an unplanned care encounter while abroad
   - **ePrescription**: enables patients to receive equivalent medication while abroad to what they would receive in their home country

2. To be expanded to full Electronic Health Records
Pillar II: Connect and share health data for research, faster diagnosis and better health outcome

- **Connect** different health data sets, scientific expertise and computing capacity federated across borders – **through a decentralised European digital health infrastructure**

- Advancement of **high-performance computing, big data analytics and cloud computing** for health research and personalized medicine

- **Use cases** (e.g. for **rare diseases** (European Reference Networks); for anticipating epidemics and accelerating EU-wide identification of infectious threats)
Pillar III: Use of digital services for citizen empowerment and patient-centred care

• Working with Member States and regions to deploy solutions:
  • that support user feedback and interaction between patients and healthcare providers,
  • that engage citizens in the prevention and management of chronic diseases

• Mobilize relevant EU funding (from EFSI, ESIF, Health Programme and H2020) and implement patient-centred integrated care
Thank you!

http://ec.europa.eu/health/