EPF AGM
Brussels, 13 April 2011

Policy Snapshot

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Cross-Border Healthcare

- EPF intensively involved in the legislative process through 2 readings – Directive is not 'perfect', but an important milestone:
  - Patients' right to seek healthcare in other MS and be reimbursed
  - Legal basis for MS cooperation in key areas:
  - *Quality and safety*; HTA; eHealth; rare diseases.
- MS can limit application of the rules under a restricted set of criteria (prior authorisation, exceptions to reimbursement) – MS must *inform EC* of any limitations.
- Prior authorisation for: overnight hospital care/specialised equipment/safety risk to patient or population

Cross-Border Healthcare (ii)

- Principle of *non-discrimination* in access to care and concerning prices set by healthcare providers
- Reimbursement = the same level as at home (options to reimburse full cost, extras
- Direct cross-border payments: optional provision
- National contact points for information – must consult PO

- Many provisions leave room for interpretation by MS – a lot depends on how they are implemented at national level
- Patients' involvement is key

Pharma Packace: Pharmacovigilance

- Aims to strengthen the EU pharmacovigilance system for detection, assessment and prevention of adverse effects
- MS must have in place systems with appropriate expertise –collect reports on all suspected adverse events (incl. overdoses, misuse, abuse and medication errors)
- Key points for patients include:
  - Eudravigilance will become single point of collection – content accessible to the public
  - Patients will be able to report directly to national authorities
  - Improvements to medicines packaging
  - MS to set up national medicines information portals

Pharma package: Falsified Medicines

- Draft Directive adopted by EP on 16 February 2011
- Key points for patients:
  - European-wide safety features for better traceability – only prescription medicines , with some exceptions
  - Stronger rules for inspection and enforcement, penalties set at national level
  - System of product recalls and rapid alerts
  - Provisions on illegal Internet sales – EU logo for legal online pharmacies, information portals & campaigns
- Somewhat short on patient involvement – put opportunities for proactive involvement – e.g. national information campaigns

Pharma Package: Information to Patients

- EP adopted first reading report on 24 November 2010
- EPF: broadly favourable, though some room for improvement
  - National information portals in EU countries
  - Industry must make available certain information – may also make available certain restricted information with pre-approval by MS
  - MS responsible for monitoring – flexibility concerning national systems
  - Quality criteria to be adopted
- Commission to publish amended proposal shortly – likely to take on board some of EP position but more narrow in scope
- Still necessary to push for wider EU strategy on ITP *and* Health Literacy – initial support from EP rapporteur & EC on this

Clinical Trials

- Review of Directive 2001/20/EC (in effect since May 2004); EC to put forward proposal in 2012
- EPF responded to the first public consultation in 2009-2010
- Key points:
  - Meaningful patients' involvement in clinical trials;
  - Patients' access to quality information regarding clinical trials;
  - Meaningful informed consent;
  - Transparency concerning results;
  - Access to treatments after the end of clinical trials.
- Second public consultation: EPF Member consultation ongoing – first input by 15 April – final comments by 11 May 2011.

Access to Medicines Platform

- Commission initiative on corporate responsibility in the field of Pharmaceuticals – started in late 2010
- Non-legislative: enhanced cooperation to tackle delays to market and barriers to access to medicines
- EPF represented in Steering Group
  - Five project groups: Orphan drugs – Small markets – Managed entry agreements – Non-prescription drugs – Biosimilars
  - Additional project: Identification of unmet medical needs, exploration on prioritisation / definition of innovation
- EPF will involve members and PAG to give input into this work during 2011-2012.

Patient Safety & Quality of Care

- Commission's PSQC Working Group:
  - EPF contributed to the Communication and Council Recommendation – explicit patient involvement aspect
  - EC report on its implementation by June 2012
  - EPF will survey members to get a patient perspective
- Joint Action on PS&Q
  - Follow-up to the success of the EUNETPAS project – EPF active input; Also builds on the work of the PSQC Working Group.
    I. *Implementing Council Recommendation*
    II. *Starting MS cooperation on quality*
    III. *Fostering patient involvement & empowerment*

Older Patients and Ageing

- Focal area for EPF in 2011–2012
- Priority of the Hungarian & Polish EU Presidencies
- European Year for Active Ageing – 2012
- New EU "Innovation Partnership" on Healthy & Active Ageing - "triple win" + overall goal of increasing healthy life years by 2 (2020)
  - EPF extensive response to public consultation in January 2011 – we are represented in Steering Group
  - EPF will seek input from members on specific work areas
  - EPF Polish Presidency conference policy link to the Partnership

Health Inequalities

- EPF has provided extensive input into EC Communication (10/2009) and EP report (02/2011) – focusing on importance of patient-centered care and above all health literacy as a key strategy
- EU initiatives to date somewhat disappointing – however:
- EPF will continue to integrate HI in other policy areas and activities, e.g.:
  - Structural Funds
  - Information to Patients / Health Literacy
  - Preparation of next EU programming period
  - Upcoming EC Communication on Chronic Diseases

Anti-discrimination

- EC proposal (July 2008) for prohibiting discrimination on grounds of religion, disability, age or sexual orientation – outside employment
- Preliminary background research done by EPF Secretariat; discussion in Policy Advisory Group (March 2011)
- Aim: to ensure that patients with chronic diseases are covered by the Directive (work on definition, provide concrete examples of discrimination)
- Council divided on this dossier – next progress report due in mid-2011

Other topics

- **European Medicines Agency** (EPF representation in PCWP and Management Board; working groups on 3rd country clinical trials and Eudravigilance)
- **Medical Devices** – exploratory process on the possible revision of the EU legislative framework
- **Professional Qualifications Directive** – upcoming Green Paper
- **Animal research** – input into new EU Directive
- **eHealth** – projects and political initiatives
- **HTA** – Joint Action and EPF's own research on patient involvement in HTA

EPF Policy Advisory Group

- Created by AGM in 2009 in response to growing demand on EPF – growing membership, increasing complexity of health policy at EU level
- Supports the policy work of EPF Secretariat and Board, complements the EPF member consultation process
- Meets ~ 2x a year in Brussels
- Currently 11 members nominated by EPF member organisations
- Open to all interested EPF member organisations

THANK YOU !

ANY QUESTIONS ?