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The Common European Transparent Value Framework for Coordinated Access to OMP:

New European Collaborations, Challenges & Solutions

The MoCA Project

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Starting Point of the reflection process (1)

- **Global Financial Crisis: Health system shock → cuts on public spending in Health**
- **Response: MS applied a variety of diverging policies: maintain, decrease or increase levels of public expenditures on health or reallocate funds within the health system, to maximise efficiency**
- **Policy-makers need to consider the impact of the reforms (to secure financial stability) on the fundamental goals of PH systems**
- **Policy tools likely to promote PH goals: Strategic purchasing, where contracts are combined with quality indicators (incl. patient reported outcomes & feedback); HTA combined with transparency measures; price reduction for pharmaceuticals combined with cost-effectiveness evidence; protect access to healthcare services, especially for regular users of healthcare**
- **Policy tools likely to undermine PH goals: Reducing scope of health services coverage; reduce population coverage; increase delays for accessing services**

(1) WHO Report on "Health policy responses to the financial crisis in Europe", 2012

Starting Point leading to the MoCA

- **MS face important challenges to provide affordable & sustainable access to medicines to address unmet medical needs of citizens**

- **Some MS limit access to OMPs due to high costs impacting too much on the PH budget. This is not the way to go: "Policy makers should be guided by a focus on enhancing VALUE in the health system rather than deciding cuts"**

- **Overall Philosophy: There must be a change in the *Business Model* because the weight of the OMPs within the health budget is being considered as "un-sustainable". *BM: how a company makes money and sustains its profit over time – basically "how a company does business"***

- **The EC and some Member States have decided to get together and see how to address this issue which includes a regulatory aspect, an HTA aspect and a pricing aspect**

- **The pricing aspect of OMPs it the one mainly addressed within the MoCA**

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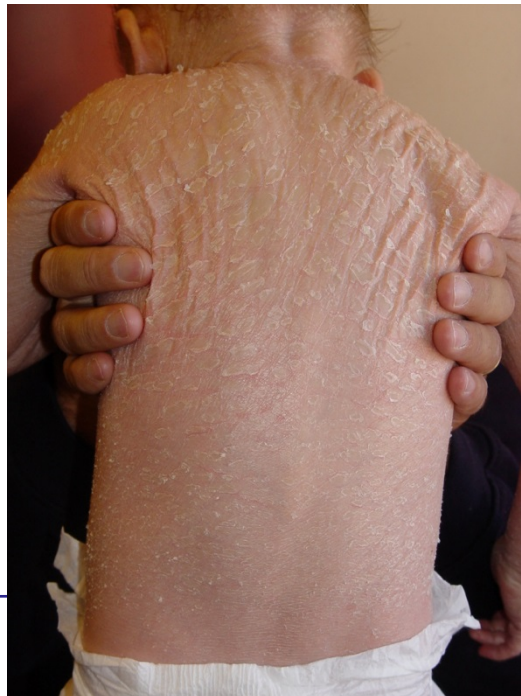
Process on Corporate Responsibility

- **Recognition that the European pharmaceutical sector faces major challenges**
- **Process on Corporate Responsibility in the field of Pharmaceuticals, set up in September 2010 – by Commissioner for Industry Antonio Tajani, within DG ENTR**
- **Objective: Initiate a reflection process amongst MS, industry and other involved parties on how to address societal and industrial challenges**

→ **How reconcile commercial imperatives with the needs of society?**



Process on Corporate Responsibility

The process is comprised of three independent platforms and work areas:

- **Transparency and ethics in the pharma sector**
- **Access to medicines in Europe, in the context of P&R**
- **Access to medicines in developing countries - with a focus on Africa**

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Platform on Access to Medicines in Europe

- The Platform is dedicated to improving collaboration amongst MS & stakeholders in order to find
- common non-regulatory approaches
- Within the existing legal framework
- to facilitate P&R decisions for authorised medicines
- thereby improving access for patients

- Within this Platform, several working groups allowed for stakeholders to test ideas and develop new concepts. One of these WG is the one on a Mechanism of Coordinated Access to OMPs (MoCA)

- To conclude the project, a final report & recommendations from the MoCA WG were formally endorsed by the Steering Group in April 2013, in Dublin

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Unmet Medical Needs & Solidarity in Europe

The WG on a Mechanism for Coordinated Access to OMPs (MoCA):

Objective: to reflect on creative ways of collaborating to provide real access to OMPs for patients with UMN, in a sustainable & affordable way.

- **Decisions on P&R of pharmaceuticals are exclusive competence of the MS - Art.168(7) of the Treaty : each Government is responsible for the organisation of its healthcare system and for taking measures to ensure its financial stability. The principle of subsidiarity fully apply**

→ Participation to this project is based on voluntary basis & does not commit participants to any future actions outside of the project

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MoCA Membership

Based on a Voluntary participation

- **The platform is chaired by the EC: DG ENTR**
- **13 Member States nominated representatives from their relevant competent authorities in charge of P&R of pharmaceuticals: Austria, Belgium, Estonia, Finland, France, Hungary, Italy, Lithuania, Malta, Netherlands, Portugal, Spain & Sweden**
- **Stakeholders representatives also participated: patients EPF/EURORDIS, industry EFPIA, EuropaBio, GIRP(1) & EUCOPE (2), Doctors CPME(3) and payers AIM(4) and ESIP(5)**

(1) European organisation of pharmaceutical full-line wholesalers
(2) European Confederation of Pharmaceutical Entrepreneurs
(3) Standing Committee of European Doctors
(4) Association Internationale de la Mutualité
(5) European Social Insurance Platform

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MoCA: guiding principles

- **Identify the value of a new OMP**
- **Build trust when exchanging information aimed at supporting national decisions on P&R**
- **Build upon existing initiatives and structures in other fora**
- **Proceed in a step-wise approach**

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MoCA: the process

Three Work Packages:

- **WP1: Identifying the UMN & assessing the OMP (Italy & EFPIA)**
- **WP2: Organising a structural access (Spain & ESIP)**
- **WP3: Organising the individual access (Belgium & EURORDIS)**

Most useful outcome is the EU TVF which gives an indicative set of criteria to reach a consistent assessment of the value of a new OMP throughout participating countries.

This tool therefore facilitates value-based pricing discussions.

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MoCA: WP1

WP1 - Identification of the disease (UMN) & assessment of the OMP

This WP takes on board the main elements of the CAVOMP (early dialogue, compilation of scientific reports, etc.)

→ It helps to evaluate the UMN through some coordinated preparatory steps such as RD classification, horizon scanning, early involvement in clinical development plans & patient registries…

It also includes the definition of the prevalence of the therapeutic indication (this is also called for in the EUCERD Recommendation on CAVOMP) = identifying the number of patients who will be treated, as close as possible to reality, to allow for accurate budgeting forecast

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MoCA: WP3

WP3 – Treatment / Individual access

- **To facilitate individual access, MoCA should complement implementation of national plans, establishment of patient DB & registries, elaboration of standard of diagnosis and care. Important that MS and stakeholders do implement what they have already committed to.**

Stressed that the funding for OMPs has to be secured by national budgets rather than by hospital budgets.

There must be a national coordination of OMP budget with a national representative to engage into discussions amongst MSs on the MoCA.

→ This element, strongly defended by EURORDIS, have been kept within WP2, which has a more financial focus.

The importance of the role to be played by ERN was also underlined in the context of the Individual access discussions.

MoCA: WP2 – Structural access EU Transparent Value Framework

In WP2 is the mechanism of coordinated access!

The EU TVF provides a framework to volunteering MSs discussing together to assess the value of OMPs in a transparent and consistent way

This tool provides criteria (which may evolve over time) to assess the value of a new OMP and is to be used in the context of a transparent value-based pricing discussion, involving payers and companies.

→Value determination is a dynamic process

→Maybe one day also non-OMP…

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EU Transparent Value Framework

The EU TVF would help assessing new OMPs according to how much (the degree) they fulfil the following criteria, at a given point in time, compared to other therapeutic alternatives. This would help start priced-value negotiations from an agreed base.

And should lead to more predictable market conditions

And ultimately more equitable access for patients

Criterion	Low	Medium	High
Available alternatives / UMN, incl. non pharma options	No UMN	Alternatives exist but still UMN	No alternative: major UMN
Effectiveness relative to alternatives, incl. no treatment	Some improvement	Major improvement	Curative
Response rate	< 30%	30 to 60 %	> 60%
Degree of certainty	promising	plausible	unequivocal

The EU TVF

The EU TVF is not a calculator it is a « framework of discussion » on the basis of 4 main criteria and 2 complementary ones (rarity and severity of the condition):

1. **UMN: OMP is approved IF it adds value over existing therapies (significant benefit) BUT the degree of addressing UMN may differ help the P&R authorities**

2. **(Relative) effectiveness relative to alternatives: it supports more accurate evaluation (the input mainly from HTA authorities)**

3. **Response rate: response rate to the same medicine will vary according to ● which marker is used and ● what time frame is considered. The RR is an important determinant of the value**

4. **Degree of certainty: "Benefits outweigh risks based - on available evidence". The certainty of this claim may vary. OMPs with conditional approval have low levels of evidence at time of MA but evidence will be generated through post-MA studies and coverage will be confirmed (or not…). Coordinated approach will provide a larger patient base for post-MA studies**

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The EU TVF: next steps

The MoCA will now be tested through concrete pilots, applying the EUTVF and may one day apply to non-orphans…

14 June: meeting of payers led by Belgium to evaluate how to start the process.

The results of all the working groups of the Platform on Access to Medicines in Europe will be used as "food for thought" for developing activities in the context of the new industrial policy in pharmaceuticals.

This new policy: we hope it will maximise the performance of the Health systems rather than focus on identifying areas in which cuts might most easily be made

This new policy is expected for 2014.

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THANK YOU

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