MEP's Interest Group

ri de ridder   28/06/2017

a payer's toolbox

- horizon scanning
- priority setting
- early dialogue
- early access schemes
- managed entry agreements with evidence gathering
- real life data
- patient related outcome measurement
- clinical guidance and good clinical practice
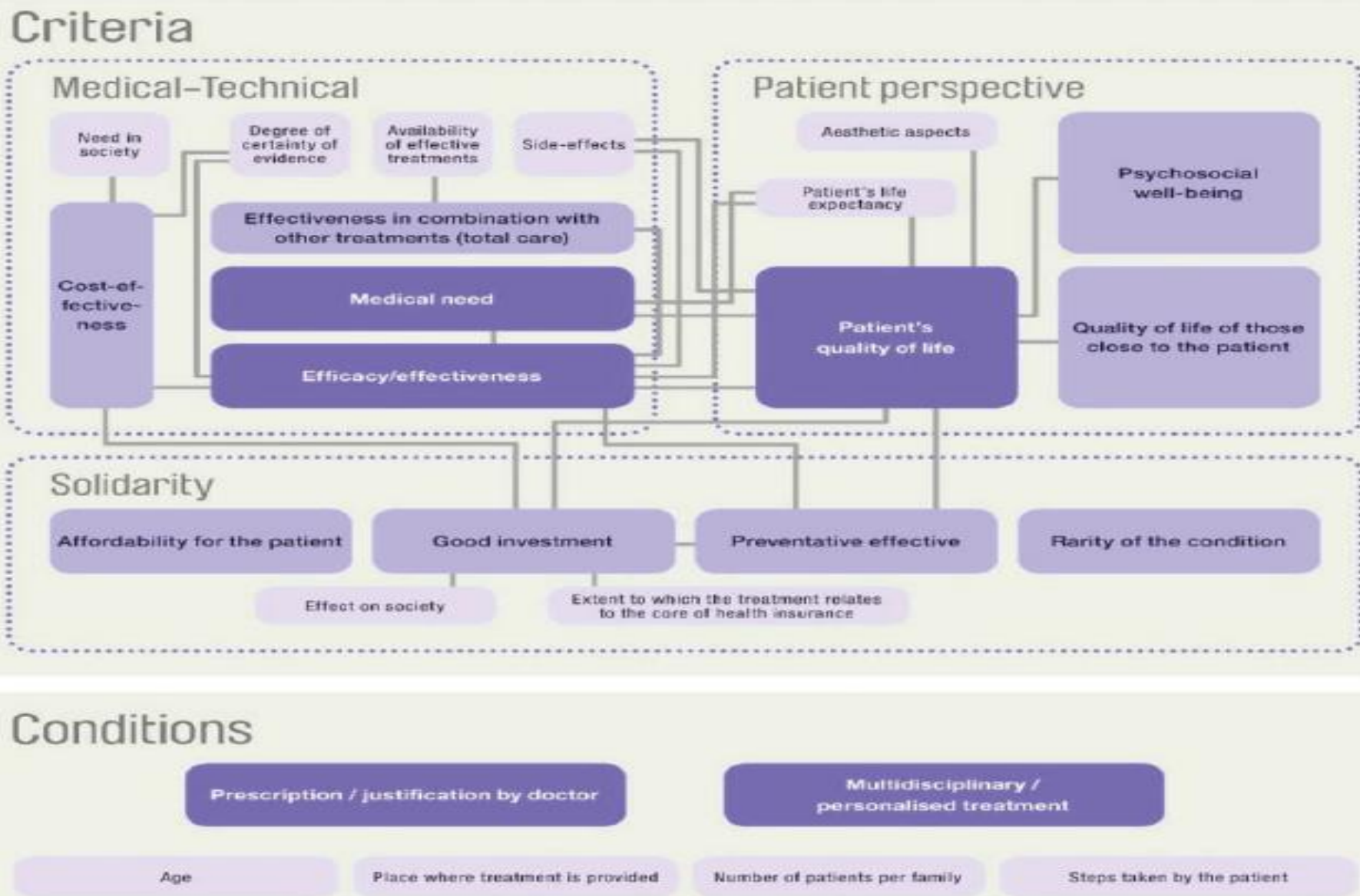
prioritization at Belgian payer level

- prioritization « Unmet medical need »:
- prioritization of unmet needs in year Y-1 for the applications which could be introduced in year Y by applicants.

  → introduction of propositions from companies before the 15th of May (Y-1)

- every year, the General Council of NIHDI establishes a list of unmet needs before the 31th of October. Applications will only be possible for medicines meeting these unmets needs.

KCE

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

MULTI-CRITERIA DECISION ANALYSIS FOR THE APPRAISAL OF MEDICAL NEEDS: A PILOT STUDY

Figure 3 – Criteria and conditions for reimbursement identified by the citizen panel

Figure 7. Nineteen criteria and six conditions for reimbursement of interventions in health care
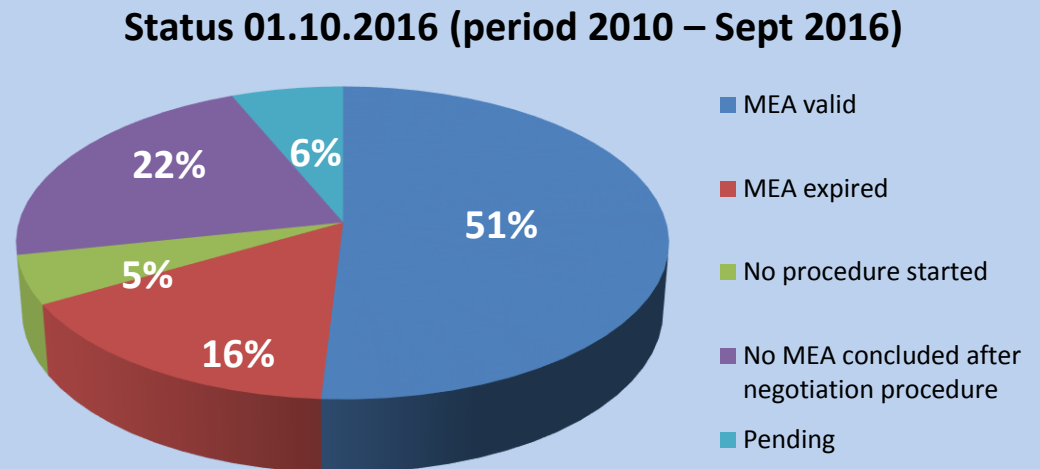
Criteria

Medical–Technical

- Need in society
- Degree of certainty of evidence
- Availability of effective treatments
- Side-effects
- Cost-effectiveness
- Effectiveness in combination with other treatments (total care)
- Medical need
- Efficacy/effectiveness

Patient perspective

- Aesthetic aspects
- Patient's life expectancy
- Psychosocial well-being
- Patient's quality of life
- Quality of life of those close to the patient

Solidarity

- Affordability for the patient
- Good investment
- Preventative effective
- Rarity of the condition
- Effect on society
- Extent to which the treatment relates to the core of health insurance

Conditions

- Prescription / justification by doctor
- Multidisciplinary / personalised treatment
- Age
- Place where treatment is provided
- Number of patients per family
- Steps taken by the patient

Source: Raeymaekers, 2015 [5]

Horizontale gestapelde staafgrafiek met de volgende aandoeningen (van boven naar beneden):

- Amyotrofe Lateraal Sclerose (ALS)
- Pancreaskanker BRCA+
- Duchenne spierdystrofie
- Acute lymfoblastische leukemie (ALL)
- Acute myeloïde leukemiee (AML) FLT3 positieve
- Recidiverend en/of gemetastaseerd plaveiselcelkankers van het hoofd-halsgebied (SCCHN)
- Ernstige bloedingen en coagulopathie met fibrinogeendeficiëntie
- Osteogenesis imperfecta
- Gemetastaseerd borstkanker ER+/HER2-
- Gemetastaseerd borstkanker BRCA+
- Recidiverende of refractaire Chronische Lymfatische Leukemie met 17p deletiemutatie   (17p del R/R...
- Niet kleincellig longkanker (L2)
- Lysosomale zure lipase deficiëntie
- Sporadic inclusion-body myositis (sIBM)
- Alzheimer
- Chronische hepatitis C bij patiënten met chronische nierziekte stadium 4/5
- Alpha-1 antitrypsine deficiëntie (AATD)
- Clostridium difficile infecties (preventie van de recidieven)
- Hidradenitis Suppurativa
- Hypoparathyroidie

Legenda:
- life threatening result
- QOL result
- rarity result
- social vulnerability result
- societal impact result

X-as: 0, 2, 4, 6, 8, 10, 12

Total number of MEA procedures

April 2010 – September 2016

159 demands for MEA procedure

- 8 not approved by minister: no MEA procedure started after demand company

- 106 MEAs concluded (81 valid, 25 expired)

- 35 no MEA

- 10 procedures pending

Status 01.10.2016 (period 2010 – Sept 2016)

Pie chart legend:
- MEA valid — 51%
- MEA expired — 16%
- No procedure started — 5%
- No MEA concluded after negotiation procedure — 22%
- Pending — 6%

HEALTHDATA AT a glance

MISSION

Facilitate the exchange of data for scientific & policy supporting purposes between healthcare professionals and researchers in order to **reduce the administrative burden.**

ACHIEVEMENTS 2016

- Development and roll-out of open-source **data collection software in all Belgian hospitals** (roll-out in labs ongoing)
- **8 registries live** with data collection via healthdata (HD4DP)
- Technology-independent information architecture: **clinical building blocks**

TARGETS FOR 2017

- Development & roll-out of data collection software for primary **care actors (GPs etc) & patients (PROMS) & all Belgian labs**
- Development & roll-out **system-to-system interface to re-use data from EPD**
- **20+ registries** using healthdata for data collection
- Go-live of reporting platform healthstat.be
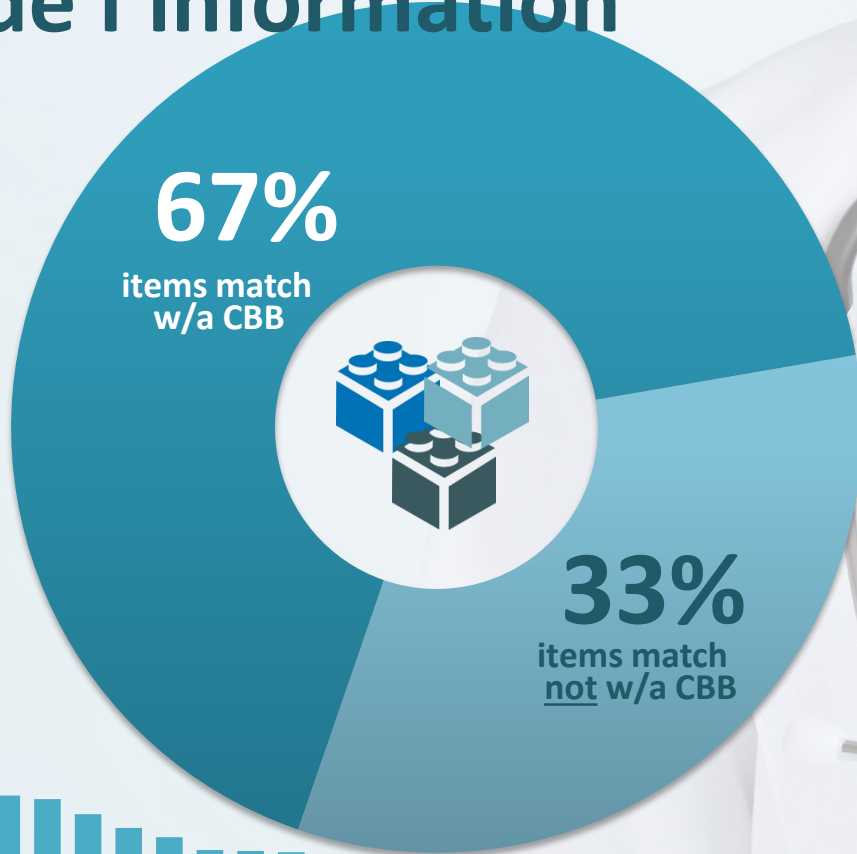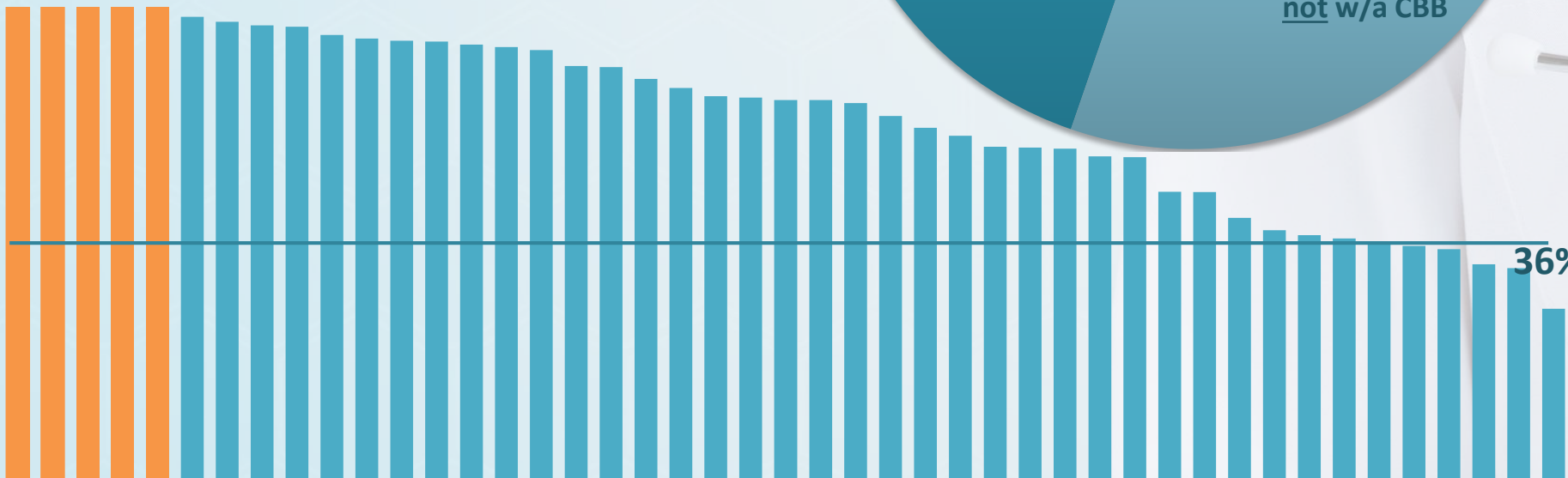
Standardisation de l'information

WORK IN PROGRESS

42 CBB's

46 Projects mapped

3142 items

67% items match w/a CBB

33% items match <u>not</u> w/a CBB
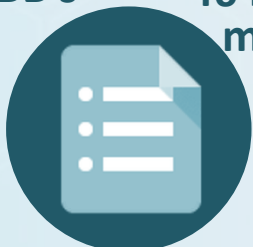
100%

36%

Mechanism of Coordinated Access to Orphan Medicinal Products (MoCA)

MoCA – addressing the last cornerstone: The Payers

MoCA is a

- **voluntary**

- **non-legislative**,

- **non-regulatory** and

- **non-binding collaboration**

Among stakeholders* who are willing to work together to provide **real** access to a **real** solution for **real** patients with **real** unmet medical needs

* Patients: EURORDIS and individual patients or patients' organisations relevant to a specific Orphan Medicine on an ad-hoc basis

* Payers: 13 Volunteer National competent authorities for P&R, members of MEDEV (Medicines E

* Pharmaceutical Industry: candidate MAA / MAH (mostly SME's, including start-ups)

the transparent value framework

Criterion	Lower Degree	Medium Degree	High Degree
Available Alternatives/ Unmet Need, including non-pharmaceutical treatment options	yes, new medicine does not address unmet need	yes, but major unmet need still remains	no alternatives except best supportive care – new medicine address-es major unmet need
(Relative) Effectiveness, Degree of Net Benefit (Clinical Improvement, QoL, etc. vs. side effects) relative to alternatives, including no treatment, societal impact, etc.	incremental	major	curative
Response Rate (based on best available clinically relevant criteria)	<30%	30-60%	>60%
Degree of Certainty (Documentation)	promising but not well-documented	plausible	unequivocal

Experience to date

Overall:

No of Participating Companies	10
No of Products Discussed	13
Small Molecules	4
Biologicals	3
Advanced Therapies	4
Other	2

Product status @ 1ˢᵗ dialogue:

Authorised	2
MA submitted	2
Post phase 2/Phase 3	4
Phase 1/2	4
Pre-clinical	1

Collaboration Protocol on the Reimbursement of Medicines

April 2015:   NL + B
September 2015: + L
June 2016:   + A

draft organizational structure BeNeLuxA

Overall Coordination
- Political mandate
- Oversight of DTF's
- Communication
- Representative per country + DTF chairs

- Daily coordination by CoCo team
- Operational management of IT and Communication

Domain Task Forces
- Technical collaboration
- Work based on set Working Agreements and Workplans
- Nationally appointed experts

Thematic Working Parties
- Collaboration on specific topics, issues and pilot projects

Initiative Steering Committee

CoCo coordination team

Horizon Scanning

Health Technology Assessment

Information Sharing

Pricing and reimbursement, incl joined negotiations

Product specific coalitions/task forces

Product specific coalitions/task forces

Product specific coalitions/task forces

Strong correlation

Strategic Information Exchange