

Rol van het RIZIV in de terugbetaling van
innovatieve geneesmiddelen en therapieën:
leidraad voor de patiënt

Francis Arickx

National Institute for Health and Disability Insurance

Social Security

Manages Compulsory Health Insurance

Stakeholders and Management

Problem setting

New generation pharmaceutical specialties (orphan drugs, biotechnological or personalized based medicines, ..) that often meet Unmet Medical Need but associated with fast increasing price tags while having a significant degree of clinical uncertainty

Growing need for alternative (financing) systems that can limit their budgetary impact while ensuring early access for patients



The Apothecary

*Insights into health
care and
entitlement reform.*

Opinions expressed by Forbes
Contributors are their own.

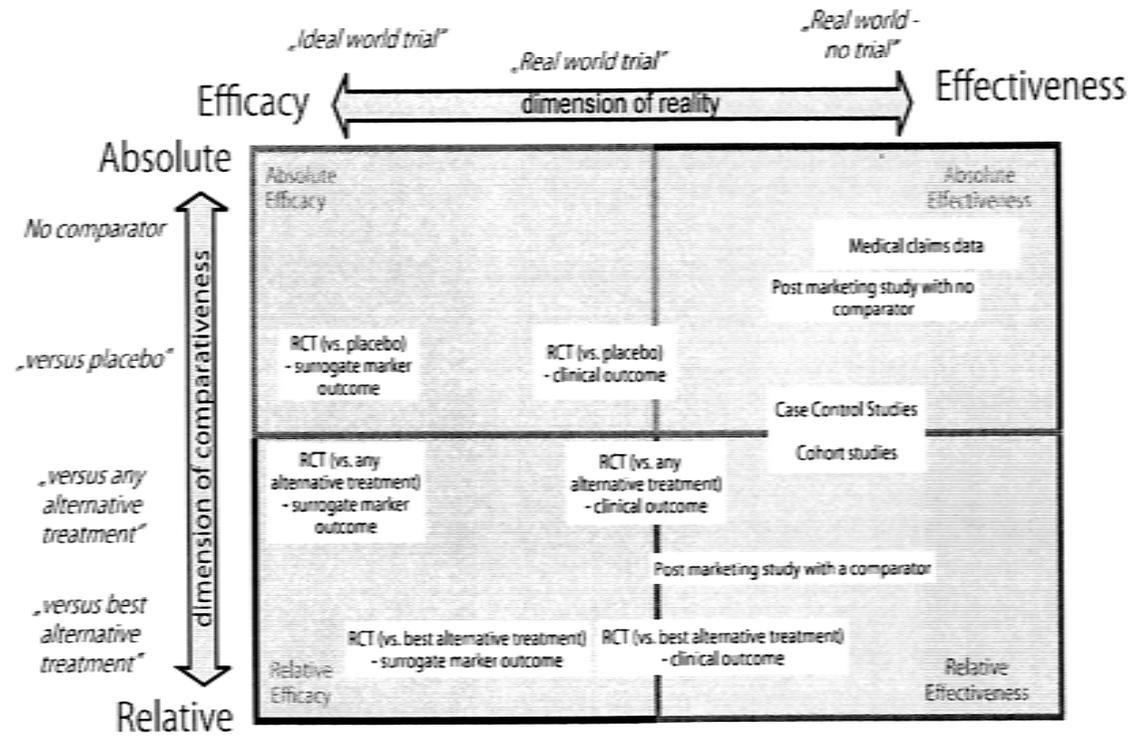
OPINION 5/16/2014 @ 10:01PM | 10.439 views

Sure, We'll (Eventually) Beat Cancer. But Can We Afford To?

 Paul Howard, Contributor

Matt Herper's [tour de force](#) article in the latest *Forbes* magazine suggests that companies and researchers are – perhaps – [turning the tables](#) on cancer using novel immunotherapies that are producing nearly unheard of outcomes even in late stage disease. The trillion dollar question: Can we afford to win the war on cancer, given current trends in drug development and pricing? [🐦](#)

Figuur 1: Absolute en relatieve werkzaamheid en doeltreffendheid (Pharmaceutical Forum)



Belgian EU presidency 2010 – Ministerial conference on pharmaceutical innovation
 Sept 23, 2010

price.. *what is on the price tag..*

value.. *what's it worth..*

cost.. *of goods..*



Goals

Access to promising therapies for patients

Access to the 'market' for pharmaceutical companies

Manage uncertainties

Solution

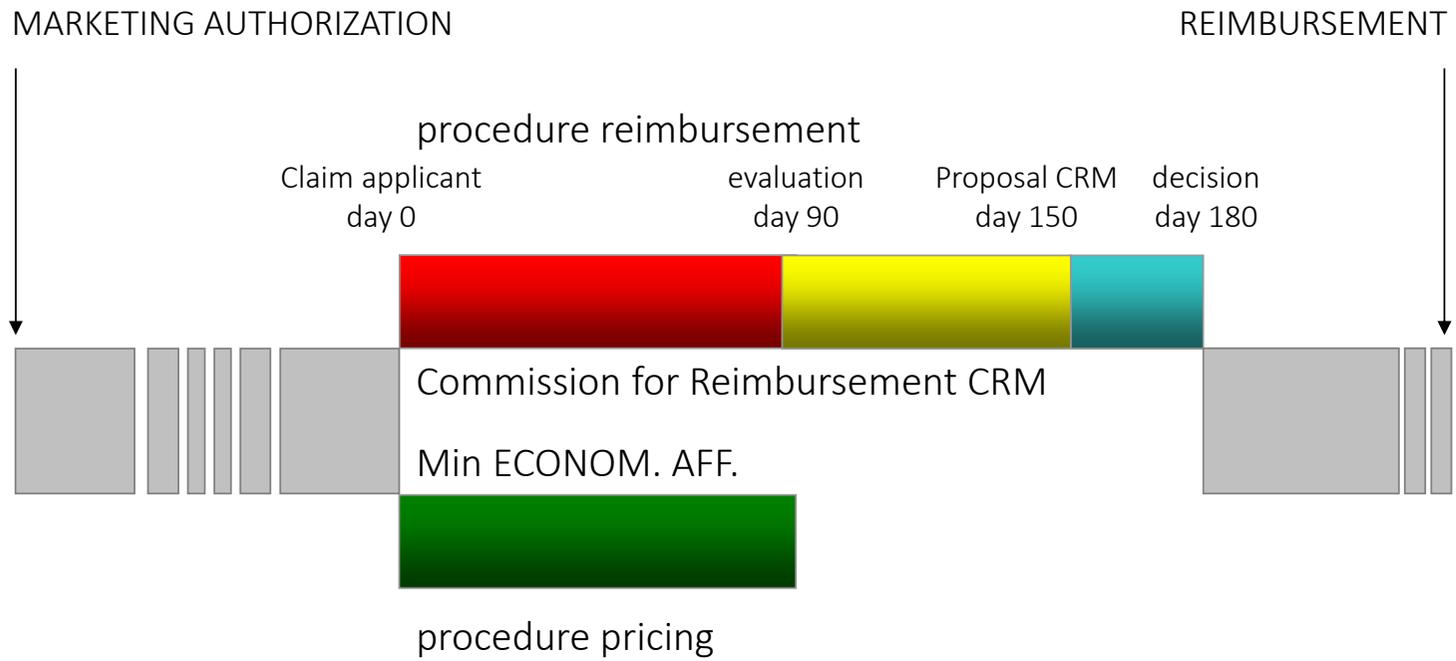
CLASSIC REIMBURSEMENT

UNMET MEDICAL NEED – CATT CAIT

Financial intervention for promising therapies for severe/fatal diseases with no reimbursed alternative treatment

MANAGED ENTRY AGREEMENTS

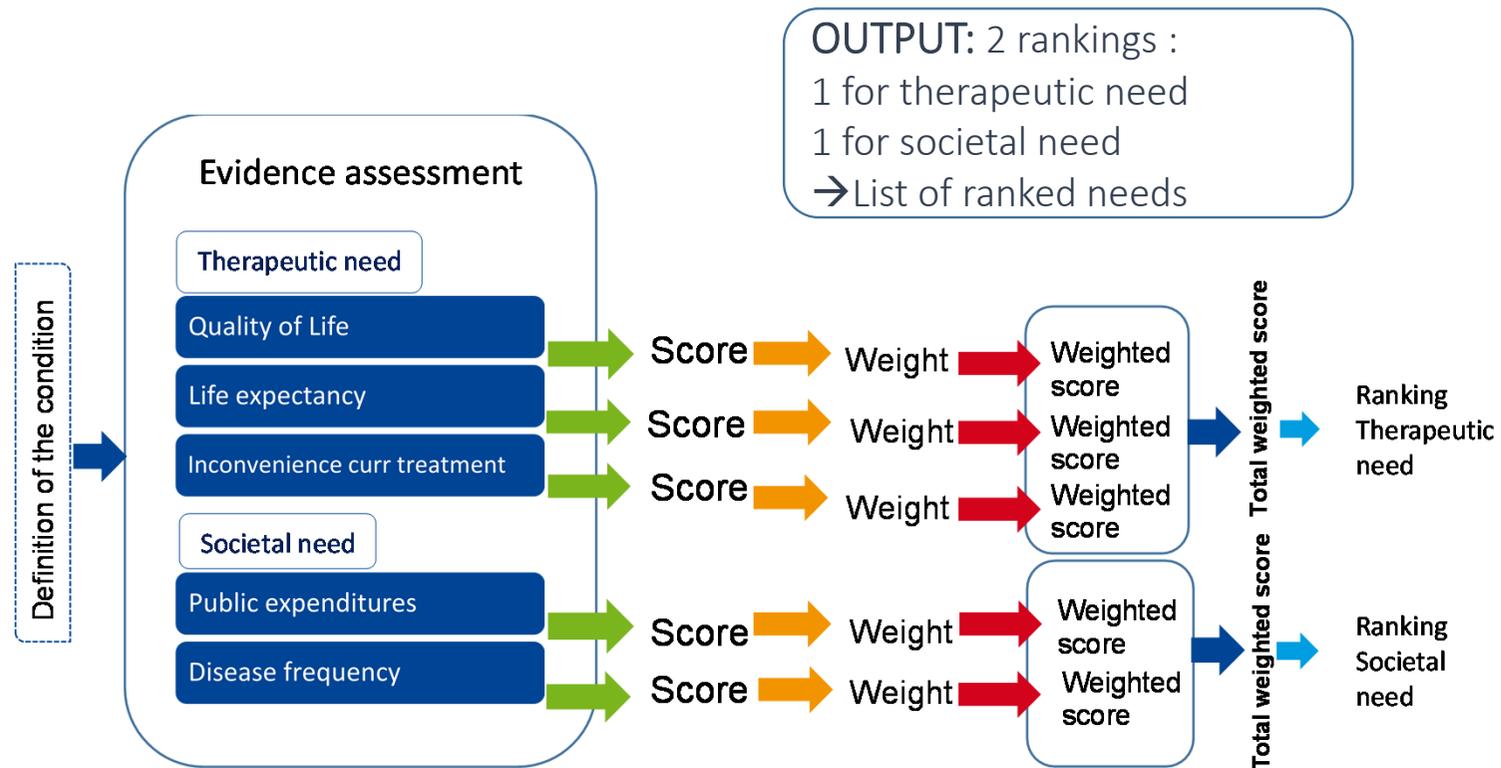
Temporary agreements to set a justifiable cost relating to the expected added value and risk linked to uncertainty



ETA ETR – prioritizing Unmet Medical Needs

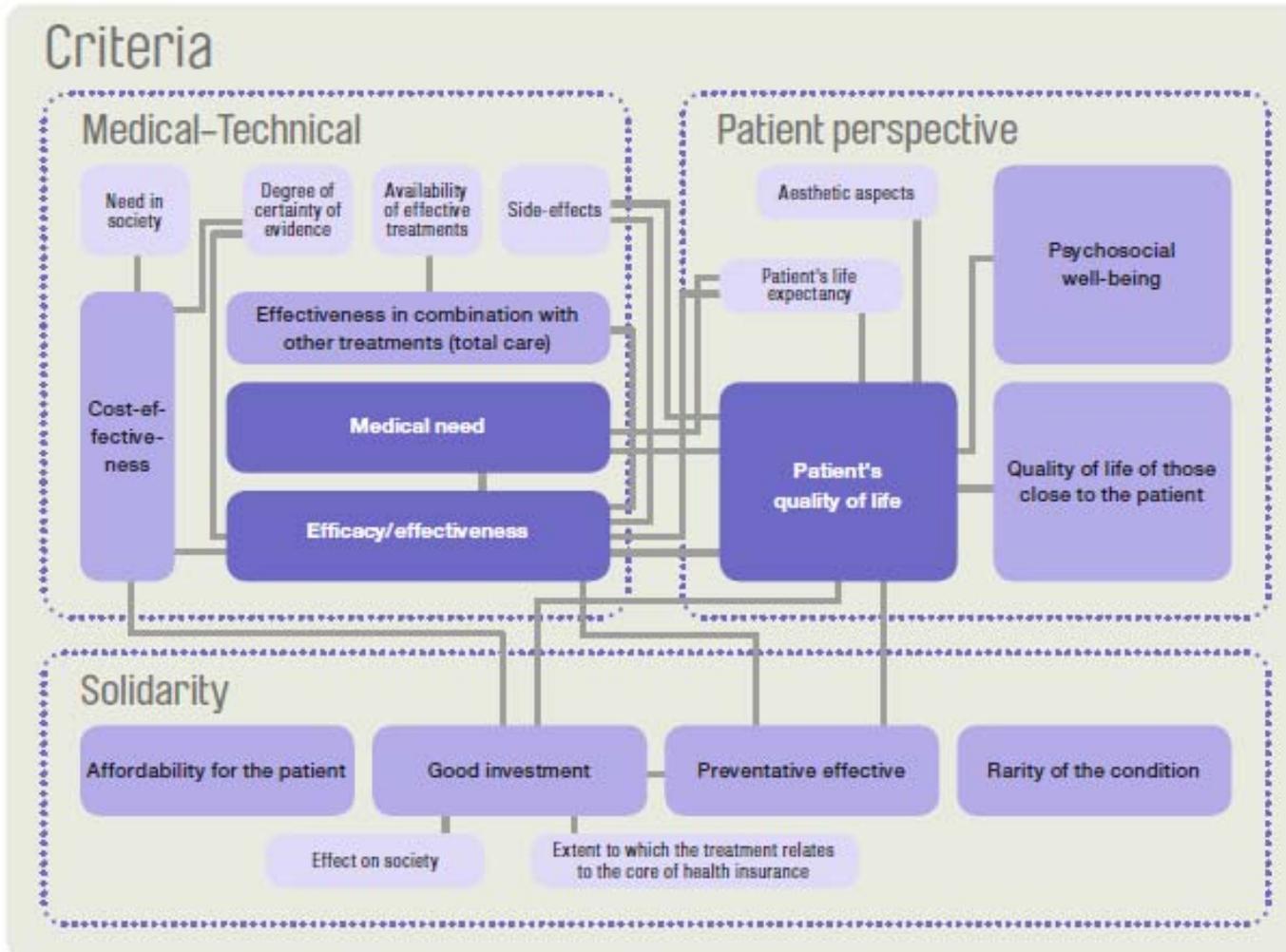
KCE (Belgian health care knowledge centre)

“A multi-criteria decision approach for the appraisal of unmet needs: A pilot study”



<https://kce.fgov.be/publication/report/multi-criteria-decision-analysis-for-the-appraisal-of-medical-needs-a-pilot-study>

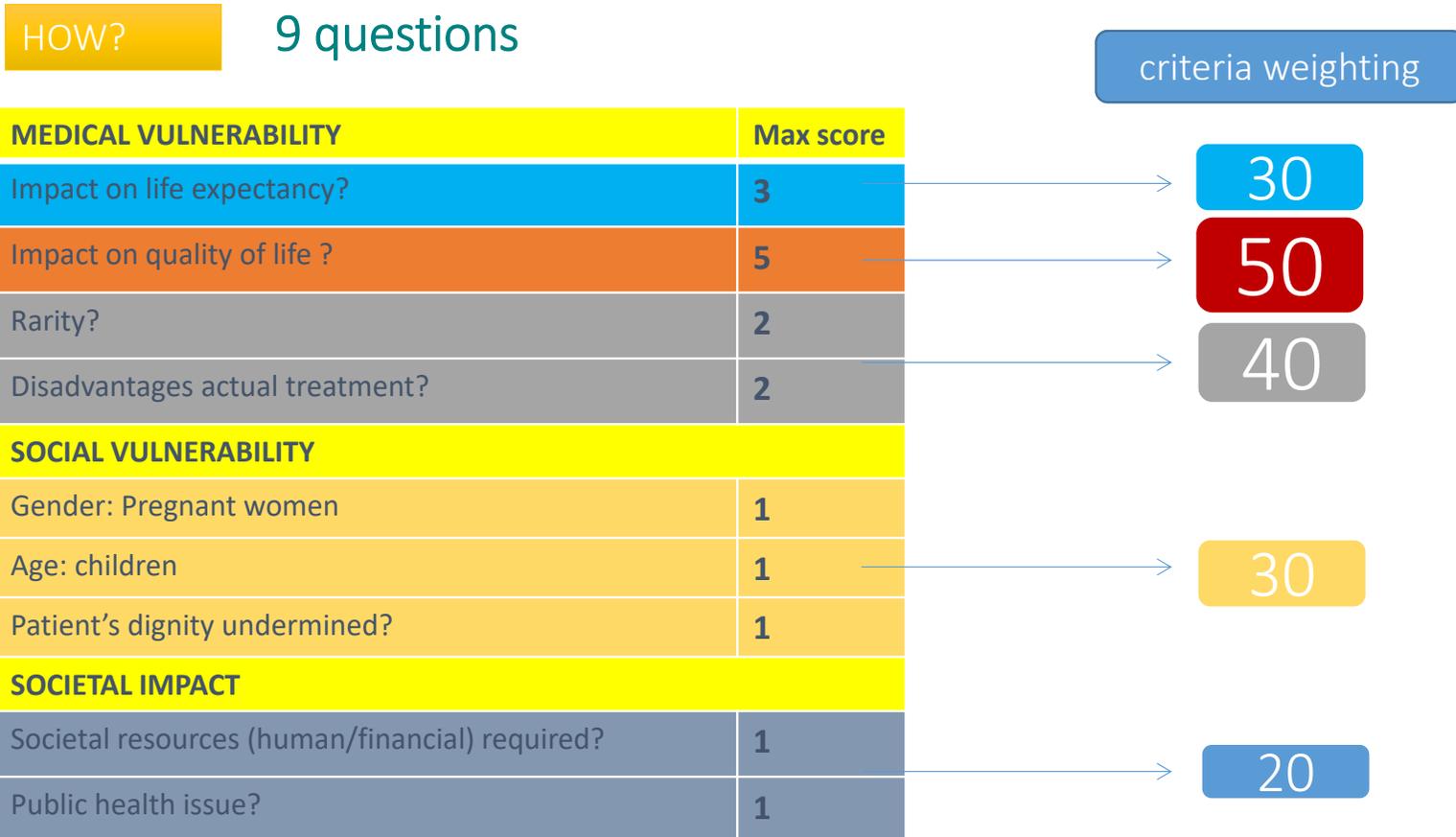
ETA ETR – prioritizing Unmet Medical Needs



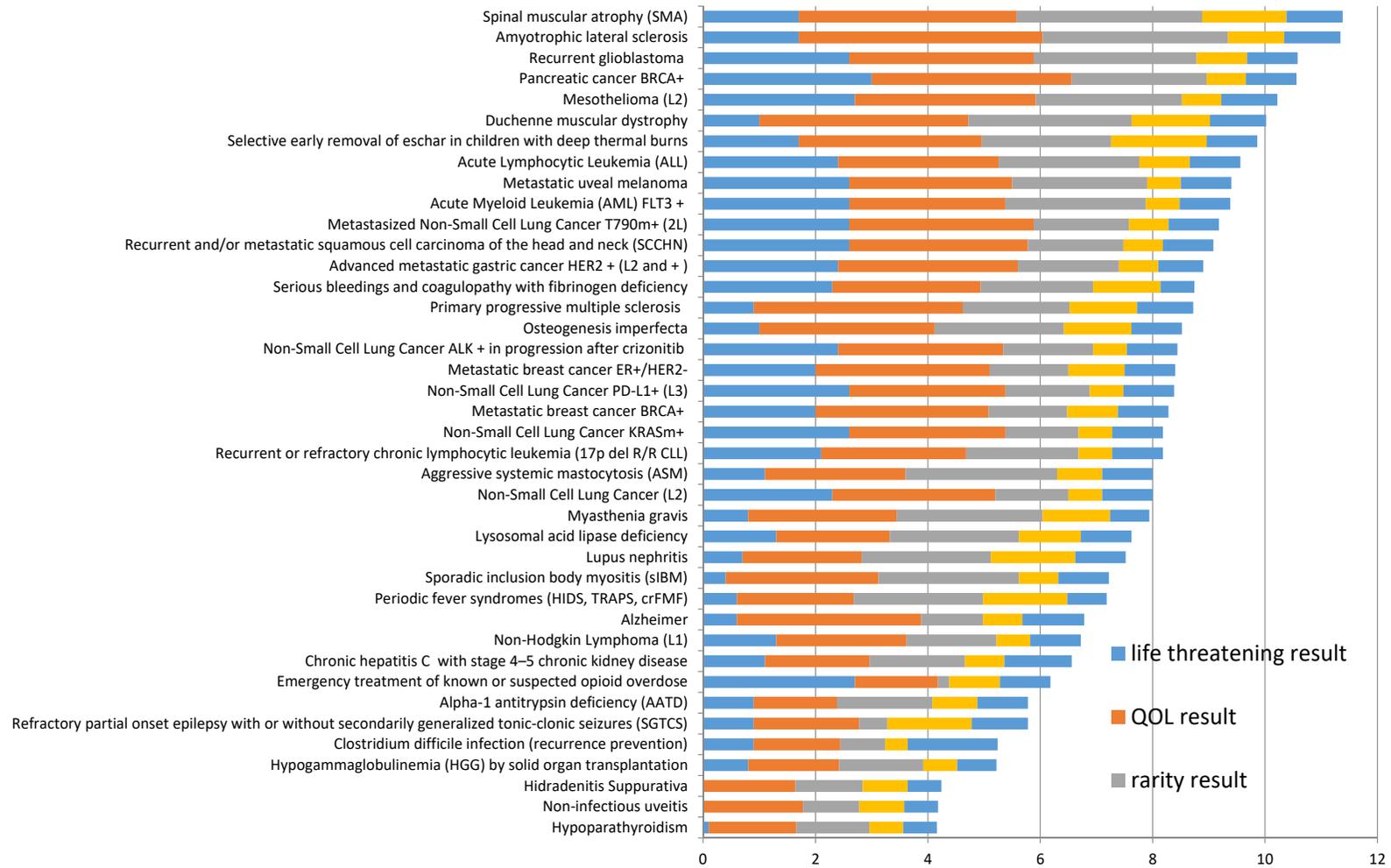
Nineteen criteria and six conditions for reimbursement of interventions in health care

Reimbursement in health care: an agenda for change (King Baudouin Foundation – final report 2012-2015)

ETA ETR – prioritizing Unmet Medical Needs



ETA ETR – prioritizing Unmet Medical Needs



A Managed Entry Agreement (MEA) is an arrangement between a manufacturer and payer/provider that **enables access** to (coverage/reimbursement of) a health technology subject to specified conditions.

These arrangements can use a variety of **mechanisms** to **address uncertainty** about the **performance** of technologies or to manage the adoption of technologies in order to **maximize effective their use**, or **limit their budget impact**.

Source: Int J Technol Assess Health Care. 2011 Jan;27(1):77-83.

Access to promising therapies for patients

→ Early access

Access to the 'market' for pharmaceutical company

→ Fair reward for value (= incentive for investment)

Manage clinical uncertainties

→ Additional studies in subgroups? Registries?

Manage budget

→ balance between payer's ability and company's revenue expectations

MANAGED ENTRY AGREEMENTS

Financial schemes

- Pre-specified budget caps, discounts or rebates

Performance based schemes

- Reimbursement rate is related to the actual future performance with a pre-specified definition of response



With regard to risk-sharing agreements (article 81), the government's policy will be to encourage **contracts that place health results for the patient at the centre ('Pay for Performance')**, rather than purely financial agreements. This approach is in line with the general policy approach taken by the Minister, which focuses on maximising the quality of patient care.

Source: Pact of the Future. 2015.

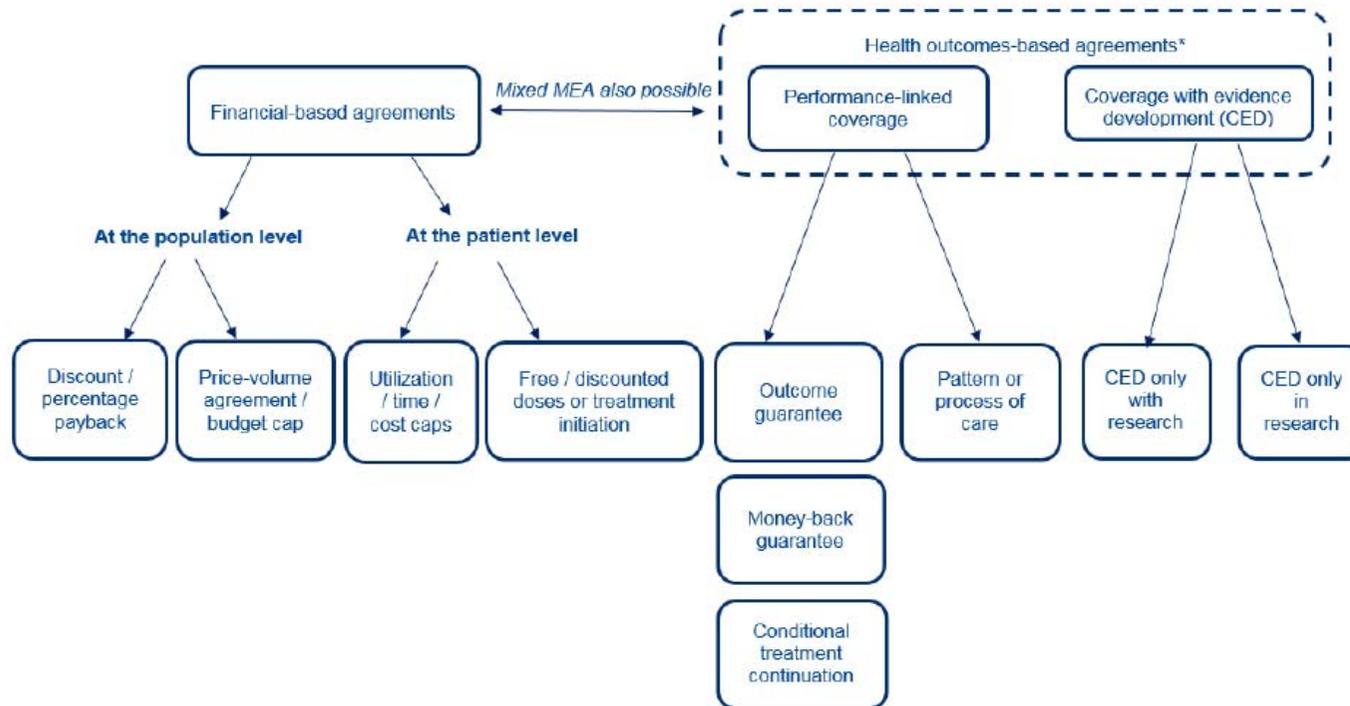
MANAGED ENTRY AGREEMENTS

“Despite their proliferation, MEAs should **not become a quick-fix solution** to addressing the risk and uncertainty arising from the introduction of new therapies; instead, they should be **integrated into a process of managed introduction of new therapies** starting with **horizon scanning** and forecasting activities, proceeds to **HTA assessment** and continues with **post-marketing studies and surveillance.**”

Source: Panos Kanavos and Alessandra Ferrario. Managing Risk and Uncertainty in Health Technology Introduction: The Role of Managed Entry Agreements. Global Policy Volume 8 . Supplement 2 . March 2017



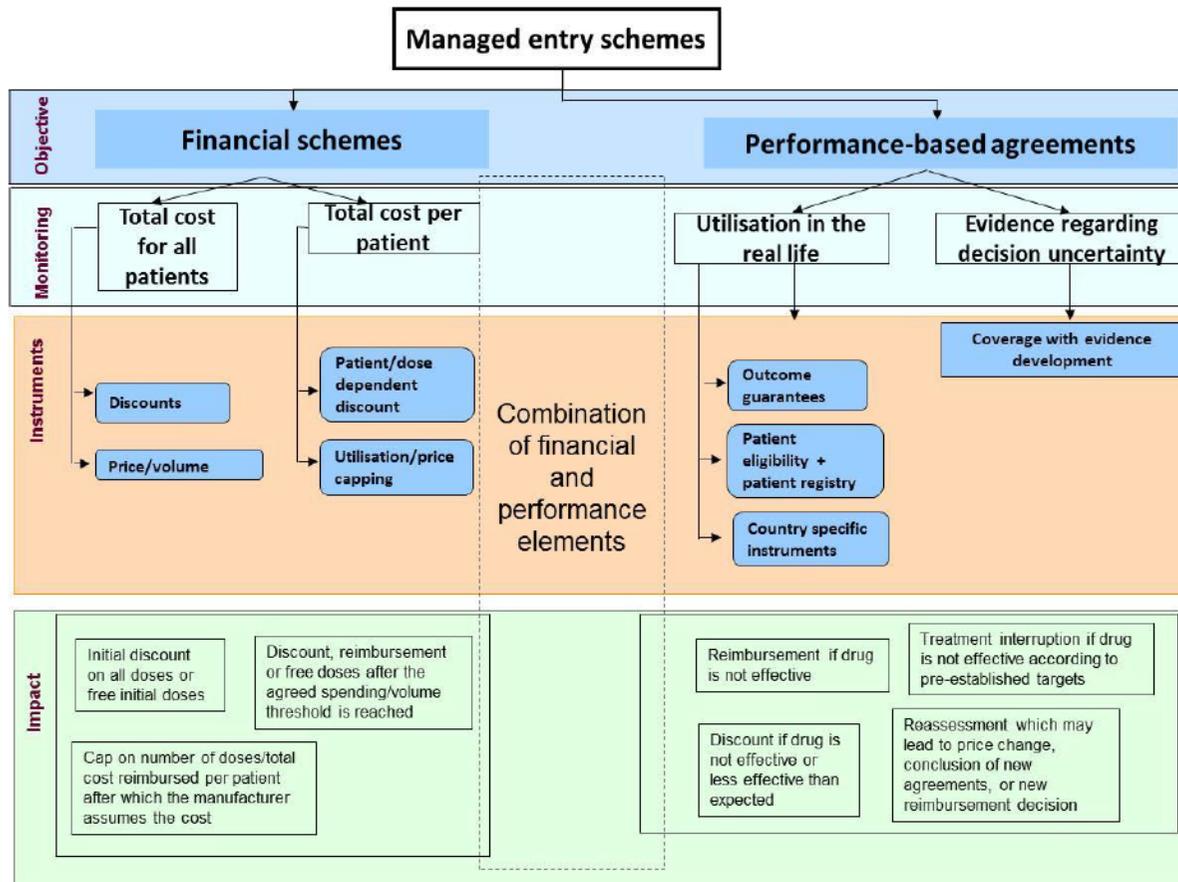
Figure 1 – MEA taxonomy used in this report



*Term used in the literature to encompass performance-linked coverage and CED. It should also be noted that some experts also use the term "performance-based agreements" at this level (e.g. OECD 2017 or EC 2011)^{2,3}. Source: adapted from the literature²⁻⁵

https://kce.fgov.be/sites/default/files/atoms/files/KCE_288_Improve_Belgian_process_managed_entry_agreements_Report.pdf

Figure 9.5: Proposed taxonomy for MEAs



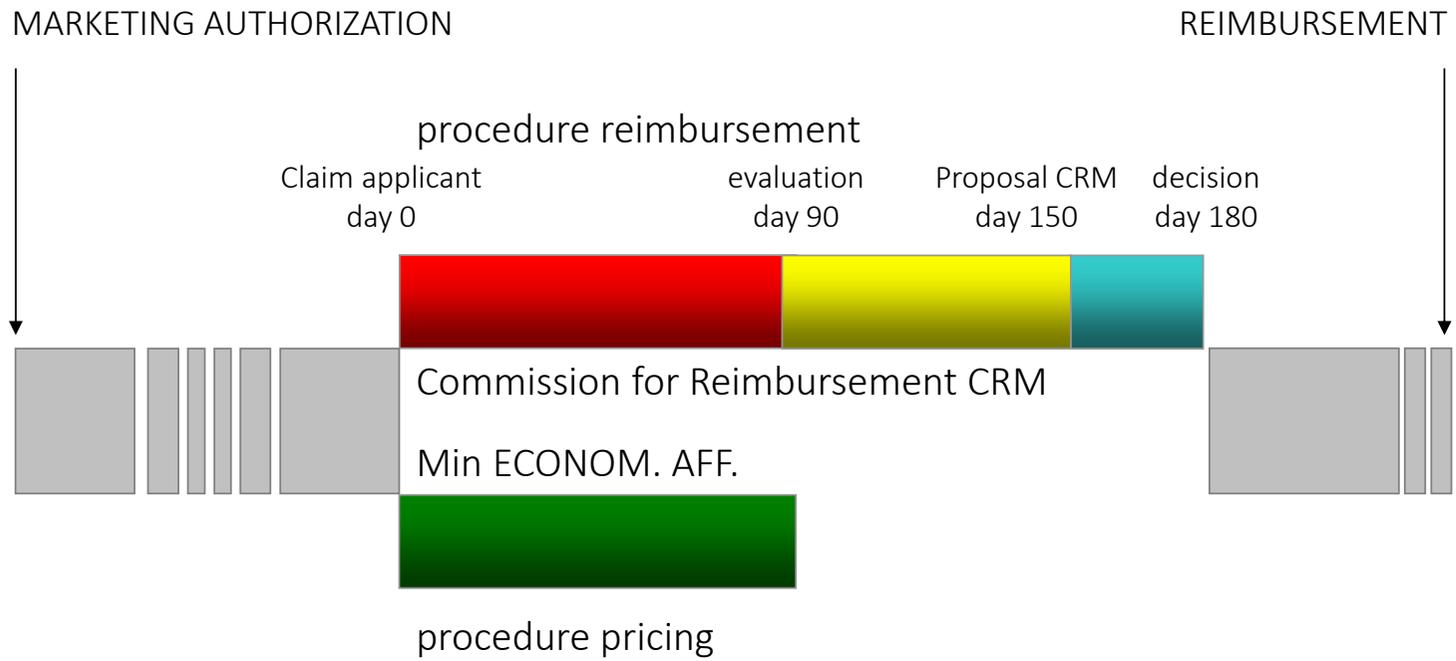
Ferrario, Alessandra and Kanavos, Panos (2013) Managed entry agreements for pharmaceuticals: the European experience. EMINet, Brussels, Belgium. London School of Economics

Sources of uncertainty

Matter of value and/or cost in relation to value

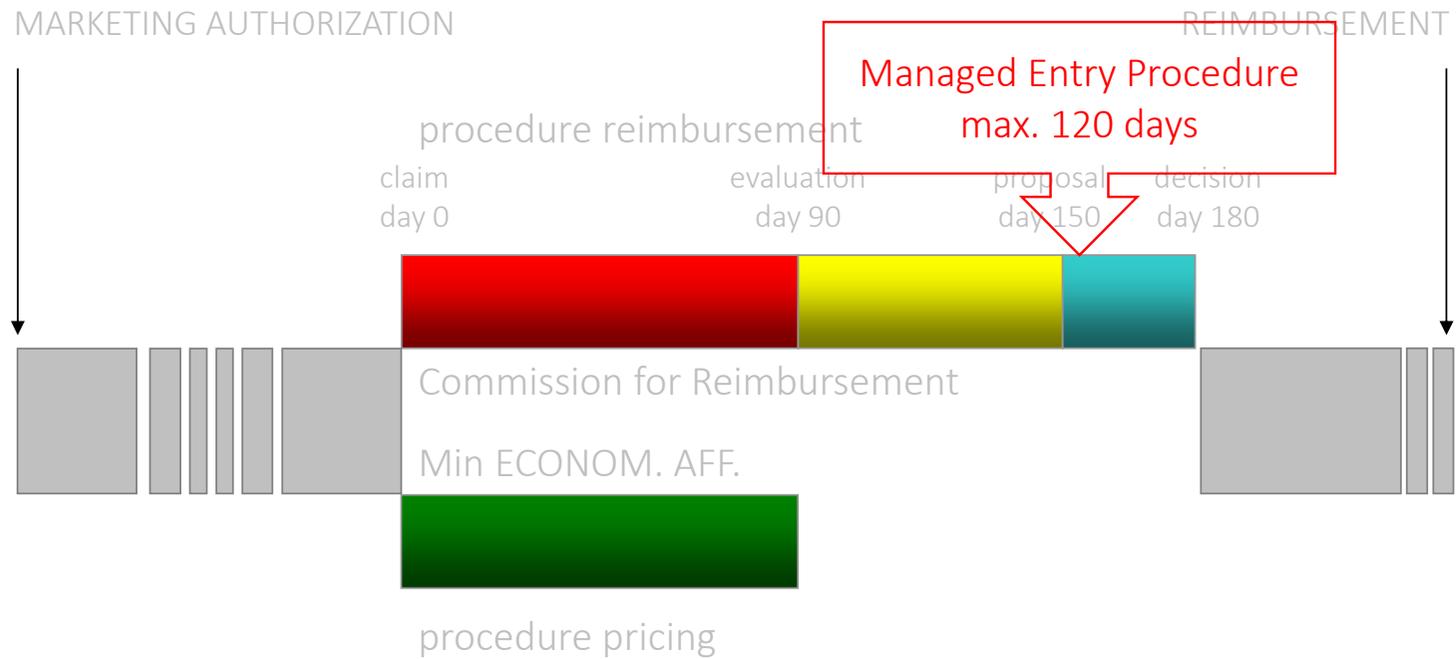
| | |
|--------------------|---|
| Clinical | Long-term and comparative effectiveness |
| | Place in therapy |
| | Long-term safety profile |
| Economic | Future costs |
| | Cost-effectiveness |
| | Measures of QoL |
| Utilisation | Number of eligible patients |
| | Market share |
| | Treatment duration |
| Financial | Overall impact on healthcare budget |

Sources: Chassang, Mantua, Snowberg, Xoxi e Pani, Sustainable reimbursements: towards a unified framework for pricing drugs with significant uncertainties. CESifo working papers January 2018

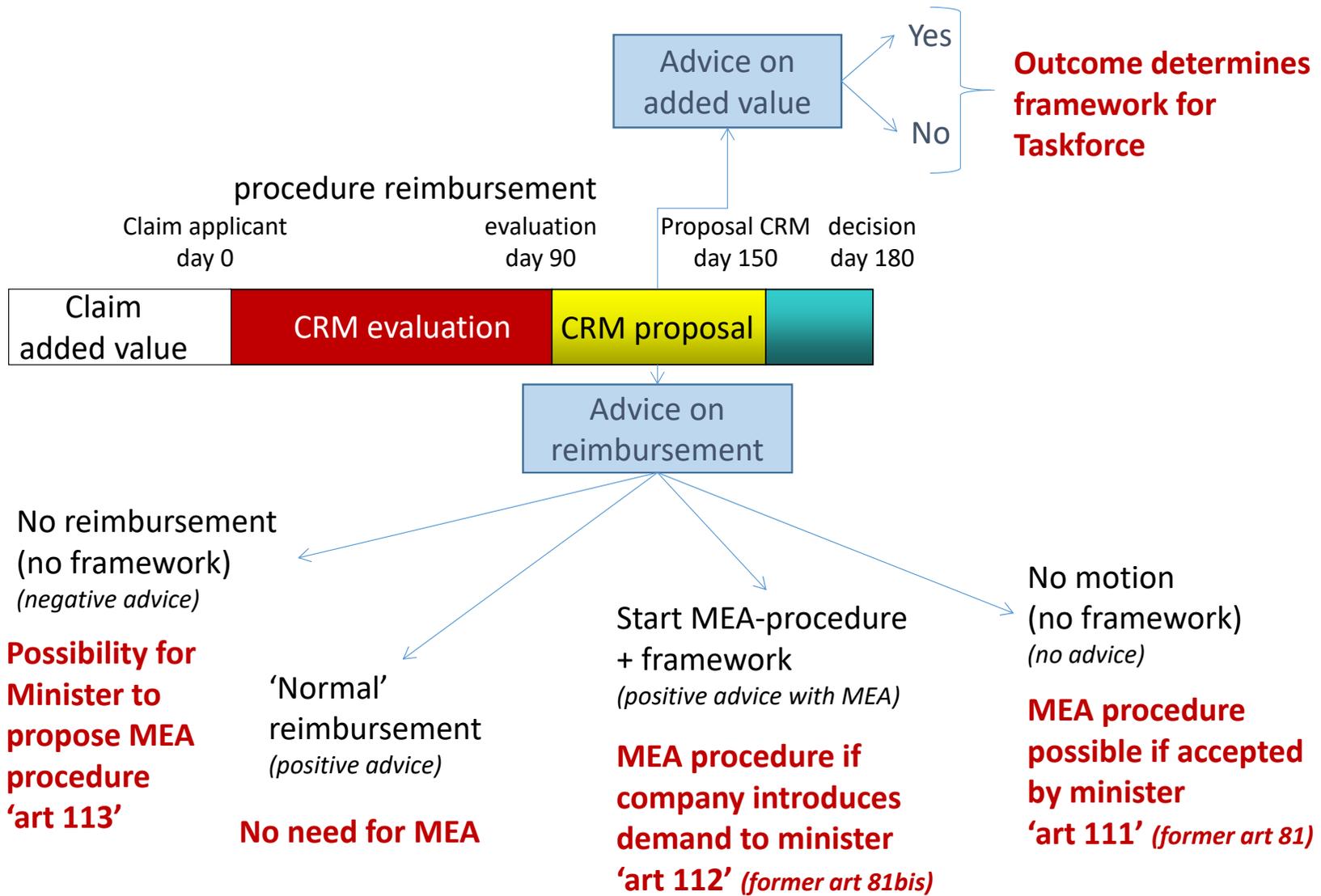


Negotiations are embedded in reimbursement legislation

No separate process

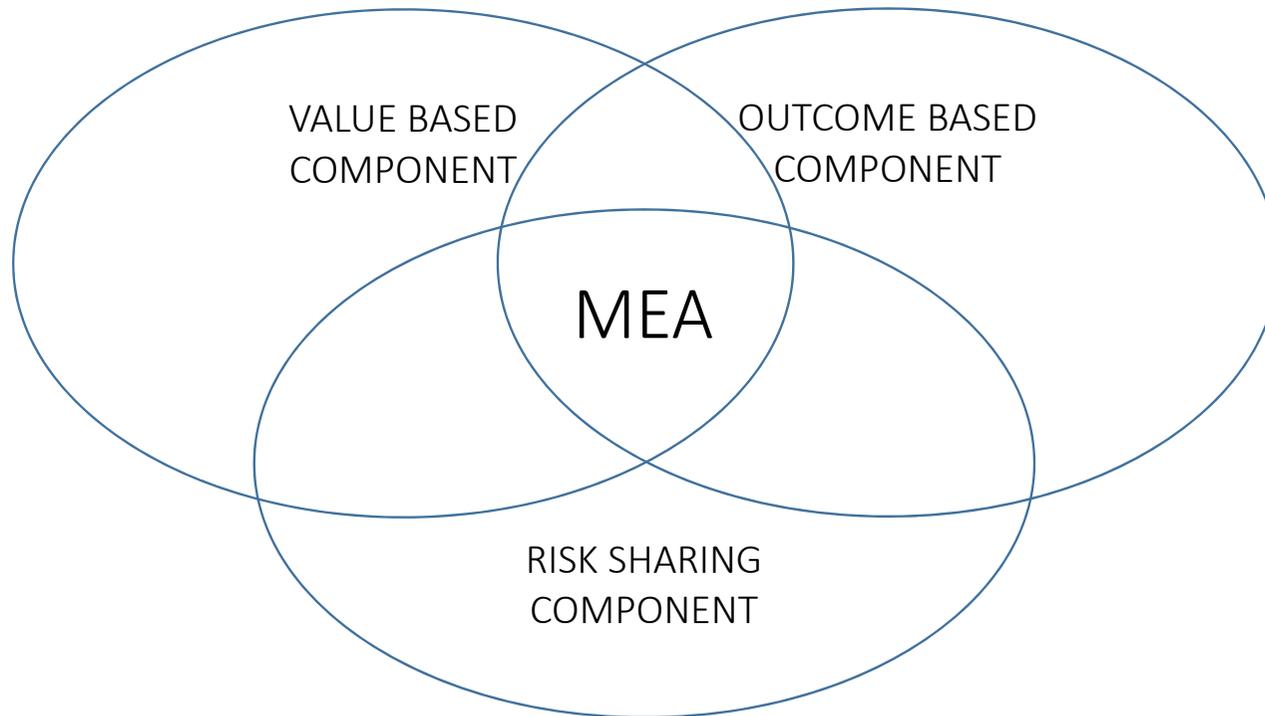


Decision tree



Managed Entry Agreements

Key Features and components



Managed Entry Agreements and 'applied Real World Evidence'

value/outcome/performance based reimbursement.. 'added value', based on hard evidence

risk sharing.. 'clinical trial evidence' versus 'real life treatments'..

willingness to pay (patient level).. if confirmed performance

willingness to pay (societal perspective).. taking into account budget limitations/allocations, prioritization, preferences,..

FLEXIBLE BUDGETING

Preferable simple one / not too complicated
Provide certainty over budget spent and cost/price paid

Cost reduction, but with original list price (eg rebate percentage of turnover)

Fixed amount per unit

Reduction price other drugs applicant (cross deal)

Budget cap

Price-Volume

Pay 4 performance scheme

Pay by Result (*'all or nothing'*)

Decrease of list price in combination with one of above

Compensation data collection

Other (e.g. combinations)

Collaboration Initiative on the reimbursement of medicines

 = Beneluxa
Initiative on Pharmaceutical Policy



BeNeLuxA– in practice..

proof of concept for the ‘coalition of the willing’

Main goal: **To ensure access to innovative drugs** at affordable cost

Cooperation is part of the policy-mix

- Information gathering on global markets benefits from joint approach

- National context determines course of action

- Joint negotiations only in select cases

What works?

- Setting clear, common goals

- Mutual benefit needs to be clear

- Pragmatic approach

 - Focus on desired outcomes

 - Lean organisational structure

BeNeLuxA– in practice..

‘coalition of the willing’ on 4 domains

Health Technology Assessment

Horizon Scanning

Exchange of information on pharmaceutical markets, prices and disease specific cross border registries

Pricing and reimbursement including joint negotiation

BeNeLuxA– in practice..

Joint Health Technology Assessment

Based on previous experience/expertise with MEDEV, EUnetHTA, JA2, informal collaboration,...

Coherent and compatible with Joint Action 3

‘testing’ models for implementation:

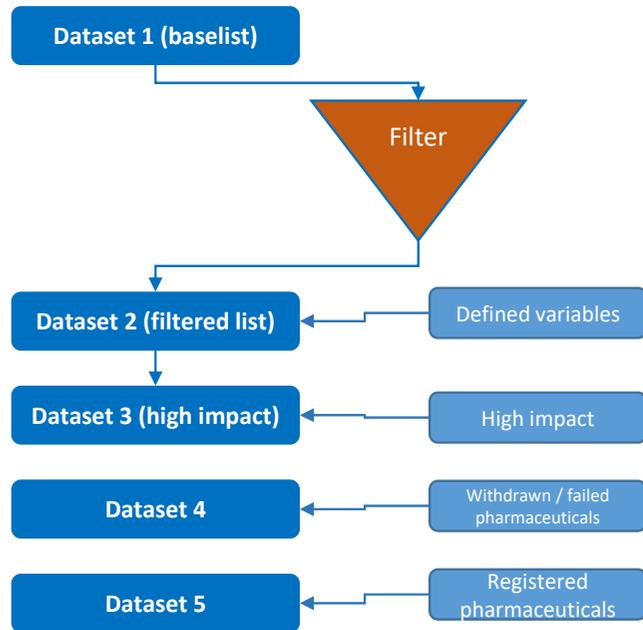
Mutual recognition of Assessments (operational)

Joint ‘writing’/editing (operational)

Sharing expertise (operational), eg. Dutch ‘Wetenschappelijke AdviesRaad’ of ZIN acts as external expert in Belgian reimbursement procedure

BeNeLuxA– in practice..

Joint Horizon Scanning deliverables



High impact reports

Priority Area 02: Cancer

| Topics | High-Impact Potential |
|--|---|
| 1. Afatinib (Gilotrif) for treatment of advanced head and neck cancer | No high-impact potential at this time |
| 2. Anamorelin for treatment of cancer-related cachexia/anorexia | No high-impact potential at this time |
| 3. * Blinatumomab (Blincyto) for treatment of acute lymphoblastic leukemia | Lower end of the high-impact-potential range |
| 4. Cabozantinib (Cometriq) for treatment of renal cell carcinoma | No high-impact potential; archived November 2015 on basis of experts' comments |
| 5. Capsule endoscopy (PillCam Colon 2) for colorectal cancer screening | No high-impact potential; archived September 2015 on basis of experts' comments |
| 6. * Crizotinib (Xalkori) for treatment of ROS1-positive nonsmall cell lung cancer | Lower end of the high-impact-potential range |
| 7. * Daratumumab (Darzalex) for treatment of multiple myeloma | Moderately high |
| 8. Denosumab (Xgeva) for treatment of refractory hypercalcemia of malignancy | No further potential for high impact; archived November 2015 on basis of being broadly diffused |
| 9. * Dinutuximab (Unituxin) for treatment of neuroblastoma | Lower end of the high-impact-potential range |
| 10. * Elotuzumab (Empliciti) for treatment of multiple myeloma | Moderately high |

Real time database



*AHRQ high impact report 2015

<https://effectivehealthcare.ahrq.gov/sites/default/files/cancer-horizon-scan-high-impact-1512.pdf>

BeNeLuxA– in practice..

Joint Horizon Scanning

IHSI

International Horizon Scanning Initiative



www.ihsi-health.org

BeNeLuxA– in practice..

Information Sharing

Drug consumption

Prevalence and burden of disease

Best practices in (health budget) management (e.g. hep. C approach, reference pricing, generic policy, biosimilar policy,..)

Post marketing evidence gathering (e.g. registries)

Policy questions (e.g. KCE-ZIN Study 2013-03-HSR_on drug pricing scenarios)

BeNeLuxA– in practice..

Pricing and Reimbursement, including joint negotiations

By structural exchange of information and testing through pilots of procedures or scenarios for joint negotiations that lead to financial arrangements and contracts

That are compatible with and respect national legislation and competence and responsibility of the different stakeholders in the decision making process

That respect confidentiality of the commonly negotiated financial details (..nothing changes compared with today..)

THIS IS NOT JOINT PROCUREMENT

THIS IS NOT LIMBO DANCING.. *how low can you go..*

thank you

francis.arickx@riziv-inami.fgov.be