Basic insurance package in the Netherlands

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Agenda

• Basic benefit package & drug reimbursement in the NL
• reimbursement decision making process
• Toothless tiger & recent turbulence
• Options for policy-making
• Uncertainty in policy making
• Conclusion and discussion
Basic benefit package NL

• Uniform for all citizens, compulsory to reimburse for competing health insurers
• Comprehensive for curative care
• Supplementary insurance for: optics, appliances, dental care, extensive physical therapy)
  (separate scheme for long term care)

• Medication: always assessment to get reimbursed;
• Other curative care: when physicians agree on use, simply in package, only when doubts in practice re-assessment might be started
The Netherlands system for medication

New medication

Non-hospital

"expensive"

Hospital

other
Expensive hospital drugs

CED = Coverage with evidence development
(= type of conditional reimbursement)

Reimbursement criteria t=0

- Therapeutical value expected
- Expected budget impact: > € 2.5 mln per year
- Expected cost-effectiveness
- Plan for outcomes research during t=0-4
  (collecting evidence from daily practice regarding appropriate care and cost-effectiveness)
- t=4 reimbursement advise
Criteria non-hospital drugs

- Therapeutical value
  - Equal value
    - Cluster price
  - Added value
    - Premium price
Sub-criteria therapeutical value

Efficacy & Safety

Effectiveness

Safety
Experience
Applicability
Ease of use

When posible, related to:
- Standard care or
- Usual care
Added value (premium price)

- Additional reimbursement criteria:
  - Budget impact (price x utilisation)
  - Cost-effectiveness since 2005 (only if BI > 2.5 mln €)

- 100% reimbursement for patient (no co-payment*)

Note:
* Added value -> premium price
* External price referencing (Germany, Belgium, France and UK)

* General co-payment first 300 € medical costs
Reimbursement decision making

System objectives

- Sustainability
- Quality of care
- Equity
Decision making on reimbursement

• positive list & central advisory/decision body; supply cases by pharma; case by case decision making.

Three phases:

• **Assessment:** pharmacotherapeutic value & pharmacoeconomic value of drug quantified & compared to available drugs.

• **Appraisal:** evaluating the societal value of drug by weighing the assessment outcomes and other (societal) criteria that reflect health system objectives.

• **Decision making:** value judgement of drug from a broader societal point of view, incl. health system objectives and non-health care-related outcomes.
Legitimacy (accountability for reasonableness, Daniels & Sabin 2002)

- **Transparency**: process must be transparent about rationale for a decision
- **Relevance**: the decision must rest on reasons that all stakeholders can accept as relevant to meeting health needs fairly given resource constraints
- **Revisability**: decisions should be revisable in light of new evidence and arguments
- **Enforcement/regulation**: must be regulation guaranteeing the three conditions described above.
Transparency

• formal stakeholder involvement in assessment and appraisal

• Documentation & motivation of the reimbursement decision is publicly available

• However, the decision making process is often not transparent

• Appraisal criteria often not transparent. NL has separate appraisal committee and list of criteria (no clear agenda setting)
Relevance

• NL has no formal hierarchy in decision criteria. But, therapeutic value most prominent (less/equal/added value);

• NL uses cost-effectiveness as a formal reimbursement criterion, but MoH does not want to use a CE threshold (range)-> role/weight CE not clear;

• Disease severity important: (more severe disease, reimbursement more likely), but operationalisation controversial;

• NL (as other countries) try to balance added therapeutic value, disease severity and costs. Reflects trade-off between system objectives: quality of care, equity and sustainability/efficiency.
Disease severity: efficiency vs equity: a proposal for NL

![Graph showing the relationship between severity of disease and cost per QALY]

- **Cost per QALY**
  - EURO 20,000 per QALY
  - Increasing threshold

- **Severity of disease (proportional loss of QALYs)**
Revisability

- Systematic reappraisals in NL (2011: only expensive hospital, non-hospital drugs since 2013);

- Systematic group-wise revisions only implemented in France and Sweden (improves consistency)

- Consequences revisions
  - No delisting NL (struggle with cancer and orphan drugs)
  - Modifications reimbursement levels: BE, FR
Cost-effectiveness in NL, a toothless tiger?

• many EU countries: CE a formal reimbursement criterium, BUT: no country (except UK) has strict & transparant threshold (range) for acceptable cost per QALY

NL 2005-11: only 30% (19/63) of drugs that got premium price had pharmacoeconomic evidence!! (Franken et al 2013)

• Many exemptions: 24 orphan drugs, 7 HIV drugs (Scotland much stricter on PE evidence)

• 4 “insufficiently founded” econ. evaluations were reimbursed
Reimbursement dossiers (NL)

Pharmacoeconomic evidence in POSITIVE reimbursement advices (n=63)

- PE exempted due to orphan status: 24
- PE not available, other reasons: 7
- PE sufficiently founded: 10
- PE reasonably founded: 4
- PE moderately founded: 19
- PE exempted due to being a HIV drug: 3
- PE not available, reason not reported: 4

Pharmacoeconomic evidence in NEGATIVE reimbursement advices (n=26)

- PE not available: 14
- PE available, judged insufficiently founded, higher budget impact: 12
- Added therapeutic value: 5
- Similar therapeutic value: 7
Slower cost growth, lower prices (1)
(www.gipdatabank.nl)
Slower growth Dutch medication cost

Due to HTA? Often no EE, cost-effectiveness seldomly decisive

PRICE POLICY
• price law (= international reference pricing, since 1996)
• Price tendering for many generics since 2008
• patents ended -> more generics
• clawback

Savings in 2012: 3,1 bln euro (www.gipdatabank.nl)

Any impact HTA on efficiency?
Turbulence on ultra orphans 2012 in NL(1)

Press: “CvZ to delist 2 ultra-orphan drugs (Pompe/Fabry)”
Myozyme for classic Pompe = 300-700,000 € per QALY

Fueled discussion (“finally….”) =>
• Ethical to stop treatment?
• Ethical to value health monetarily?
• Ethical to deny the scarcity of resources?
• Better options to limit cost explosion?
• Why these orphan drugs so expensive?
• Negotiate on prices?
• R & D better financed publicly?

2013: MoH reimbursed drugs, lower price
Negotiated (confidential). CVZ now very cautious….
Turbulence on ultra orphans in NL (2)

Argument contra reimbursement:
• Cost per QALY very high
  *(too expensive..)*

Argument pro:
• For subgroup that benefits it is established
treatment for 5 years ("acquired right")

Lesson: maybe conditional reimbursement of
these drugs 5 years ago was unwise?
A proposal for ultra orphans in NL

Say: wtp/QALY for normal drugs up to 80,000 € per QALY,
Say: for ultra orphan drugs wtp = 300,000 € per QALY

For sub group that really benefits say a gain of 0.75 QALY per year

Given max WTP/QALY -> max drug costs per year:
= 225,000 € (as 225,000/0.75= 300,000).

Message of reimbursement authorities to producers:
“Don’t develop drugs with annual treatment costs of more than 225,000 €, we will not even allow conditional reimbursement”.
Reimbursement of orphan drugs in NL & EU

Ingredients:
- High WTP per QALY
- Often no cost-effectiveness data
- Often (very) weak effectiveness data
- Relatively low budget impact for 1 drug
- Very often reimbursement

- Cocktail: we pay a lot for a very uncertain, limited health gain, acceptable??
Options for policy making
### Passive or pro-active policy?

<table>
<thead>
<tr>
<th>Reimbursement NOW</th>
<th>FUTURE?</th>
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<tbody>
<tr>
<td>Authorities waiting for dossiers, also consider 6th ace–inhibitor</td>
<td>Needs assessment =&gt; drug list for which we want to pay premium price; (no 6th ace-inhibitor)</td>
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<tr>
<td>Decision case by case</td>
<td>Decisions simultaneously?</td>
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<tr>
<td>Many uncertainties at time of reimbursement =&gt; dilemma fast access vs value for money</td>
<td>Don’t accept <strong>avoidable uncertainty</strong> (low quality trials, no PE evidence) AND more uncertainty =&gt; lower price</td>
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<tr>
<td>Struggle with competing interests, trying to please all</td>
<td>Stricter, delist when no value for money</td>
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Uncertainty in policy making on reimbursement

- uncertainty is relevant for policymakers (risk averse).

- Types of uncertainty:
  - Clinical uncertainty:
    - Effectiveness (endpoints vs surrogate outcomes)
    - Safety (number/seriousness adverse events)
    - Quality of life
  - Cost-effectiveness
  - Budget impact (no of patients, price per patient)
  - Technical uncertainty (modelling disease and treatment)
Uncertainty & reimbursement (1)

Conditional with evidence development (CED)
NL: final decision after 4-6 years, based on cost-effectiveness in daily practice and appropriate drug use (extended in 2013);

• Quite comfortable arrangement for producers: 4 years a high price (t=0-4, risk for payer);

• 2012: frustration CvZ/VWS on poor t=4 data (Omalizumab):
  – financial penalty for poor data collection?
  – 2014: many t=4 reports still to be discussed….  

• 2013 Ipilimumab t=0: 84K pp py, 120,000 €/QALY..
Uncertainty & reimbursement (2)

- Price-volume-agreements (France ea, NL recent)
- sales < Y price P1; sales > Y lower price P2

Advantages:
- less uncertainty on budget impact
- industry can cover R & D costs (P1*V1)
- surplus for producers and consumers

Disadvantages:
- does not address value for money
- negotiations and price not transparent
- more strategic (gaming) conduct
Price-Volume agreement revisited (1)

November 2012: PV agreement in NL on dabigatran & rivaroxaban (new oral anti-coagulants)
-> cost reduction (> 10 mln €), but price not transparent

A proposal (Steenhoek & Koopmanschap):
• R&D cost new drug 1 bln € (probably much lower)
• Market of 2 bln consumers world wide
• EU report: R&D 17% of sales (marketing 23%)

Manufacturers want to earn back investment:
NL: 17 mln inh./2 bln -> 8.5 mln € R&D -> cumul sales 50 mln €
Volume-price agreement revisited (2)

So after cumulative sales 50 mln € (NL),

price might be lowered, with: 40%

as R&D (17%) earned back and marketing (23%) is not necessary anymore (drug showed its added value)

Of course a rough exercise, but advantage is the transparency of the price reduction and its timing

NL in 2011: 20 drugs with cumulative sales > 50 mln €
Price reduction -> cost reduction 244 mln € in 2011
(2006-2011 about 800 mln €)
Uncertainty & reimbursement (3)

- Contract: reimbursement depends on treatment success (outcomes based risk sharing, PfPO)
- August 2012 CVZ omalizumab (after 4 years CED)

Advantages:
- “no cure, no pay” => value for money
- application on best patient sub groups
- after contract new decision possible

Disadvantages:
- transaction costs contract
- clear outcome indicator crucial (QALY?)
- cost of monitoring/registration
Conclusion and discussion

- Reimbursement criteria: (cost) effectiveness, budget impact, disease severity important -> *Struggle for clarity*

- Uncertainty crucial:
  - Many uncertainties at reimbursement decision
  - Better research, conditional reimbursement, link uncertainty-price?

- Re-evaluation of reimbursement decisions: not systematically done, if so reimbursement price not often reconsidered.

- HTA potentially influential, but not easy recipe for more value for money (thus far more impact of price policy)
Take home…

NL health care, only medication systematically assessed

New drugs always value for money?  
*HTA research well developed in NL, but taken seriously…?*

*In practice a struggle for policy, due to uncertainty and lobbies*