

Inno-HTA: The Regulatory Perspective

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FORMERLY: AGES PharmMed – the Austrian Medicines Agency

FORMERLY: Main Association of Austrian Social Insurance institutions

Disclaimer

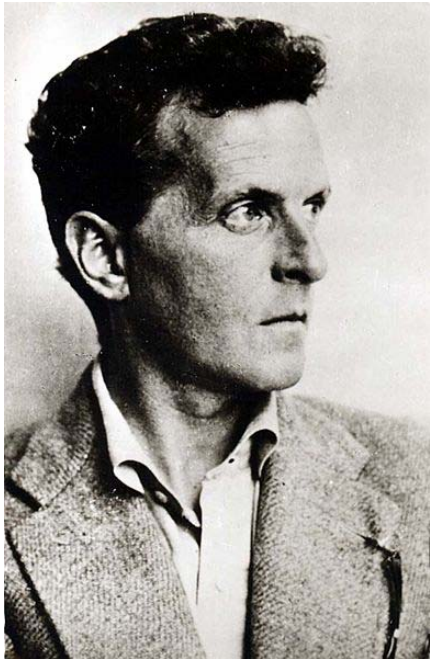
These are the presenters personal interpretations and opinions.

I do not work for an government institution anymore, and also when I did, I was NOT their spokes(wo)man.



The limits of my language mean the limits of my world.

Ludwig Wittgenstein
(26 April 1889 - 29 April 1951)



HTA

Fourth hurdle

Reimbursement

Relative Effectiveness

REGULATORY

....the trouble with definitions:

There is no truth, you have to see the
spectrum!

”CONTROLLED TERMINOLOGY”⁴ von 20

**What does
“regulatory”
mean?**

Regulating WHAT?

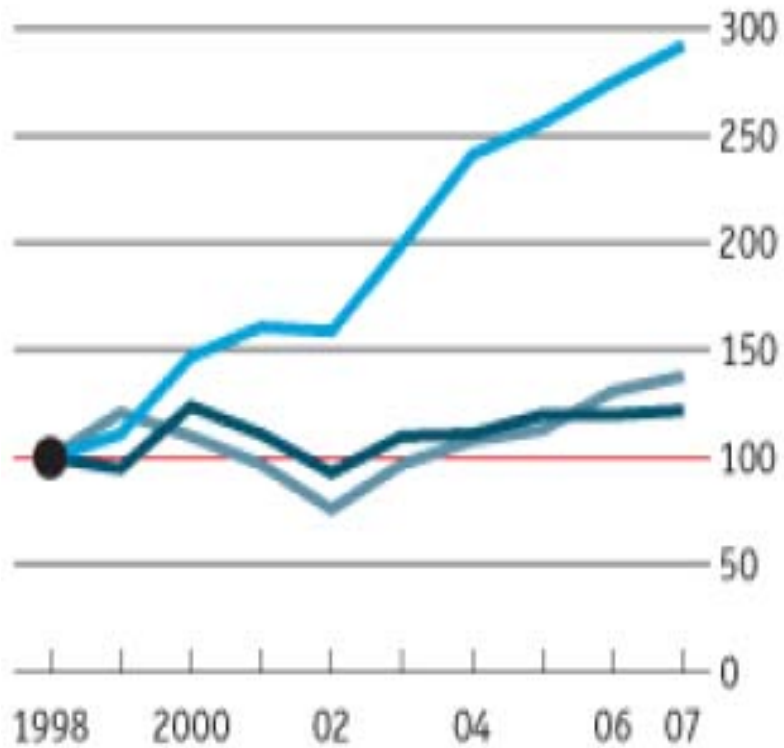
1. Medicinal Products (Pharmaceuticals)
2. Medical Devices
3. Medical Interventions
4. (Health Care Systems)

In general: decreasing (legal) regulation!

Total shareholder returns by industry

1998=100

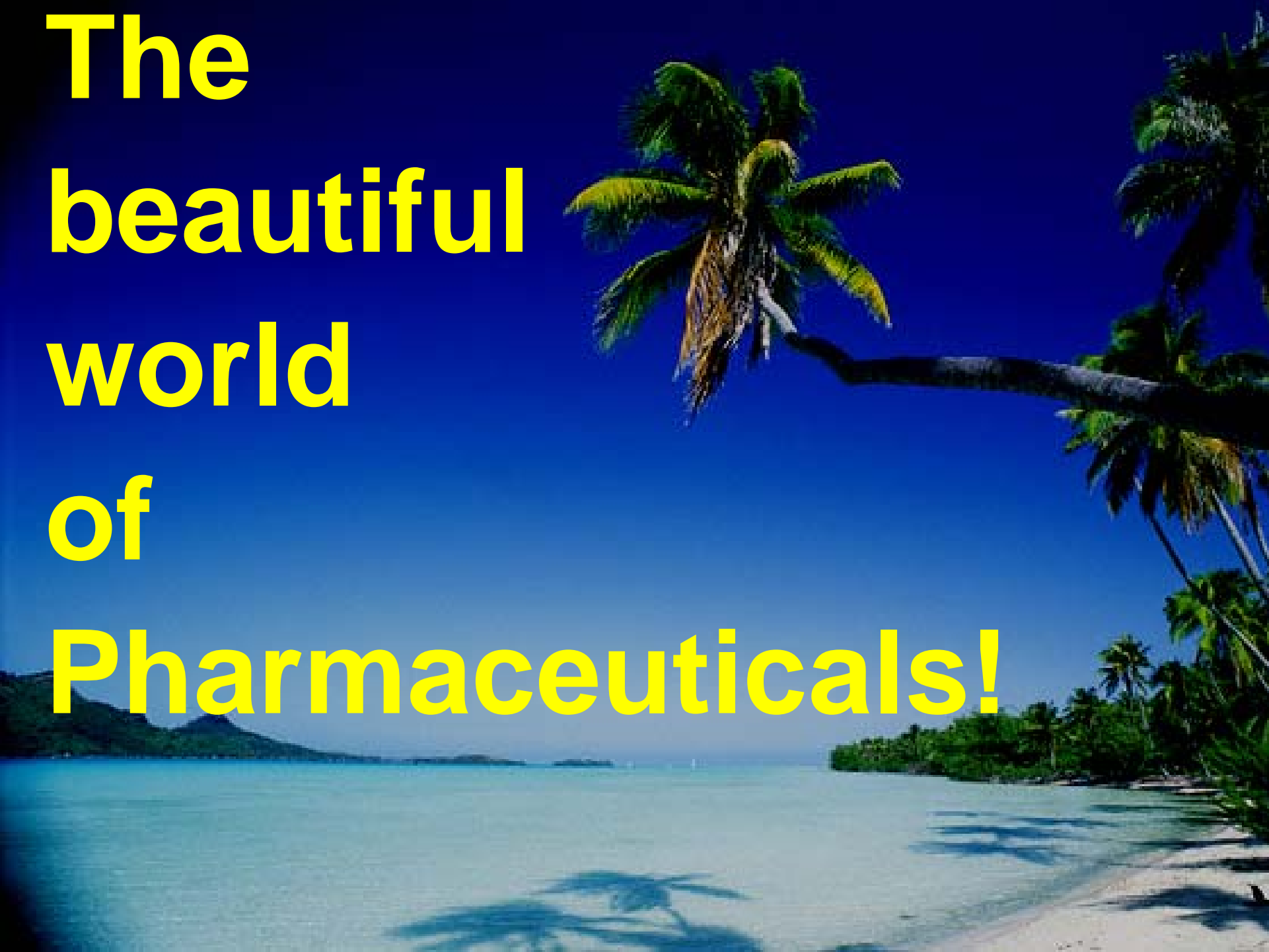
— Medical devices — Pharmaceuticals
— S&P 500



Source: BCG ValueScience Center

From the magazine „The Economist“

**The
beautiful
world
of
Pharmaceuticals!**



EU legislation

Regulation 2309/93



...authorization of such medicinal products should be based on the objective scientific criteria of the **quality**, the **safety** and the **efficacy** of the medicinal product concerned **to the exclusion of economic or other considerations**; ...

The provisions of this Regulation **shall not affect the powers** of the Member States' authorities as regards the price setting of medicinal products or their **inclusion in the scope of the national health systems of the Member States' authorities or their inclusion in the scope of the social security schemes** on the basis of health, economic and social conditions. ...

Legal basis

Pharma legislation:

http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/eudralex_en.htm

General EU law Database:

<http://eur-lex.europa.eu/de/index.htm>

EU legislation:

1. Directives
2. Regulations




A close-up photograph of a person's muscular lower leg and foot on a track. The person is wearing a red and white athletic shoe. The background shows a track with blue and white hurdles. The text "The 'fourth hurdle'" is overlaid in a red-bordered box in the upper left.

The "fourth hurdle"

Stupid term!

The „life“ of a drug

“The fourth hurdle”:

1. Quality
 2. Safety
 3. Efficacy
 4. **“Shall we pay for it?” (fourth hurdle)**
- Regulatory Agencies  Market approval
- Note: A red bracket groups items 1, 2, and 3, pointing to the text 'Regulatory Agencies'.*

Pricing & Reimbursement

Two Hurdles! Two regulators?

One or two types of „regulators“:

1. Market authorisation agencies (regulator)

EMA together with 40 National Agencies in the 27 EU Member States

Common legal basis

2. Payers (some call them regulators as well)

Very heterogeneous - National law mostly

Exception: Transparency Directive

Often a combination of institutions (e.g. NICE) and/or Social Security Institutions and/or Ministries of Health

Different perspectives and common approaches

Are reimbursement decisions just about money?



Efficacy versus Effectiveness



Efficacy



Effectiveness

Three schools of thought:

- 1. Spectrum within RCTs**
- 2. From Trial data to Real Life data**
- 3. Modelling (e.g. Cost-effectiveness)**

Anatomy of a decision



Analysis of evidence



Value judgement

Where does Inno-HTA fit in?

Some of it on both levels, but most of it on the “second regulatory level” namely payment or reimbursement decisions.

The **validity** versus **relevance** concept from the **Inno-HTA** project is of high value to understand and communicate differences between Market approval and Reimbursement

References:

- 1) Reflections On Science, Judgment, And Value In Evidence-Based Decision Making: A Conversation With David Eddy. Health Affairs - Web exclusive. DOI 10.1377/hlthaff.26.4.w500
- 2) D.M. Eddy, "Clinical Decision Making: From Theory to Practice—Anatomy of a Decision," Journal of the American Medical Association 263, no. 3 (1990): 441–443.



Thank you
for your kind attention!