
HTA Core Model[®] as a Value Assessment Framework
Perspective of a Global Healthcare Company

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Agenda



1. Background
2. Methods
3. Results
4. Conclusion

Background

EUnetHTA – Roche ToR

- Roche Pharma wanted to build a repository for sharing HTA evidence
- Because of the [apparent similarities in the intention and objectives](#) of the EUnetHTA HTA Core Model and the Roche Global HTA Evidence and Best Practice Sharing Repository, Roche has approached EUnetHTA to engage in a [joint project](#).
- Roche Pharma agrees to [explore the usefulness of the HTA Core Model](#) developed within EUnetHTA to both [guide the internal HTA evidence development process](#) and to [share HTA evidence](#) within a pharmaceutical company in order to optimally prepare for HTA submissions in the EU.

Potential Benefits to Roche Pharma



Adopting the EUnetHTA Core Model structure has the potential for Roche (and other HTA evidence contributors)

- to become **more efficient and effective in the global and local development of HTA evidence**
- To **efficiently exchange and utilize** HTA evidence as part of affiliate HTA submissions
- to align a **common and broader perspective on value**

The EUnetHTA HTA Core Model

Nine domains and 130 assessment elements

1 – Health Problem and Current Use of the Technology

2 – Description and Technical Characteristics of Technology

3 – Safety

4 – Clinical Effectiveness

5 – Costs and Economic Evaluation

6 – Ethical Analysis

7 – Organizational Aspects

8 – Social Aspects

9 – Legal Aspects

6 - Autonomy, respect for persons, justice/equity, ethical consequences of HTA

7 - Health delivery process, structure of health care system, management, culture

8 - Individual, major life areas

9 - Privacy of the patient, equality, IP, market regulation

The Usefulness of the HTA Core Model

How do you assess 130 HTA questions?



Assessors

- Representatives from 6 countries (Canada, France, Germany, Italy, Netherlands, UK)
- 4 Global Pricing and Market Access Colleagues

Questions

- The questionnaire was divided into 9 domains following the core HTA model
- Each domain was subdivided into topics (total 57 topics)
- For each topic we asked individual questions (total 130 elements)

The Usefulness of the HTA Core Model

Our two assessment criteria

Does it support a broad value concept for HTA?

- Important or unimportant information for
 - Payer/Decision Maker, e.g. for benefit assessments, pricing/reimbursement negotiation and or formulary listing
 - Demonstrating value proposition
- Anything redundant / missing / unclear

Will it enable efficient storing and sharing of HTA evidence?

- Language
- Clarity of questions
- Transferability of information

Perspectives taken by Roche Affiliates & Global



People involved

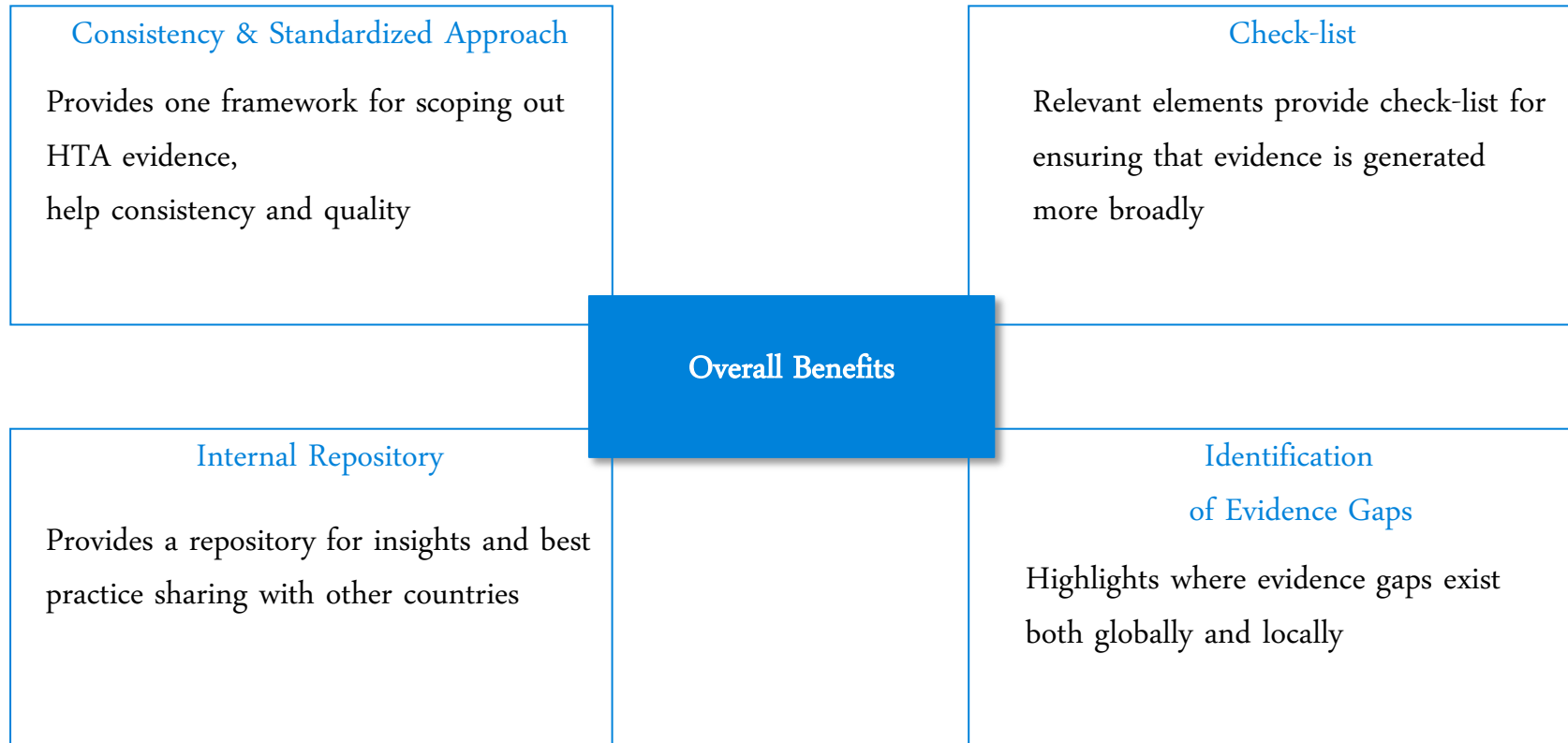
Perspective

Canada	4	Payers national & provincial
France	10	Payers national, local & broad
Italy	4	Payers national, regional, local payers, broad
UK	2	NICE, SMC, CDF
Holland	5	Payer, broad
Germany	6	IQWiG, G-BA
Global	4	Payer (across all countries), broad

Broad perspective refers to wide internal consultation and value to multiple external stakeholders.

HTA Core Model

Overall positive internal reaction

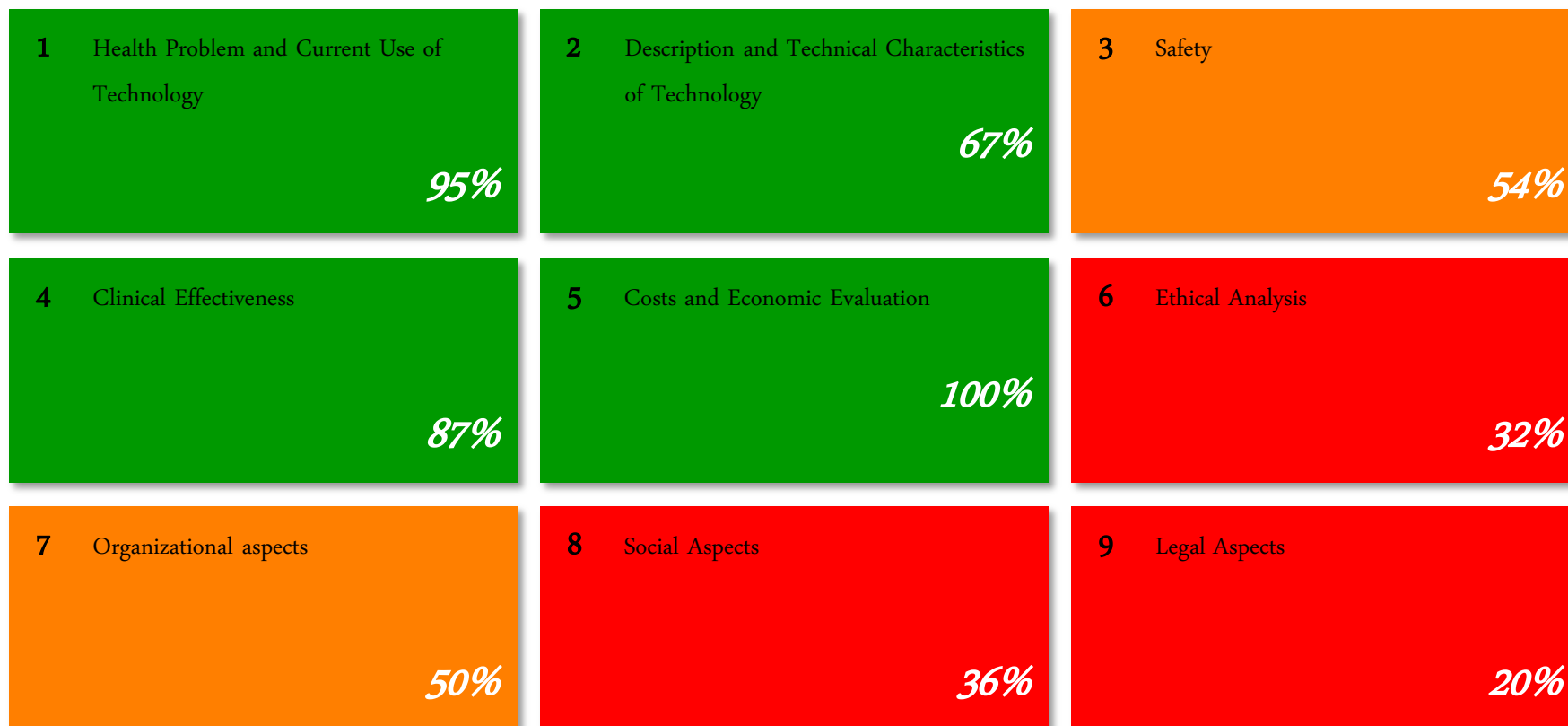


Helps drive a broad concept of value!

Importance of Domains

At least four out of six countries agree strongly with the importance of Domains 1, 2, 4 & 5

However, all domains were important (green) in at least one country



Roche Adaptation is in Early Stages

Clearer plans during Q1-2/2015

Evidence Generation

Each domain and topic will be discussed within cross-functional teams.

Assessment elements will be replaced by key words.

A prioritization of topics and key words will occur.

An agreed global evidence plan will be derived.

Specific local data will be developed separately, outside of the HTA model.



When could it be used?

- Evidence plan for Phase 2-3
- Preliminary value story Phase 2-3
- Information for reimbursement dossier
- Providing additional information for improving value story at launch and post -launch



How could it be used?

- Check-list for gathering HTA information
- Repository for storing and sharing evidence for HTA submissions
- To support the overall value of the product

Conclusions

- EUnetHTA Core Model [useful, comprehensive framework](#)
- Roche Pharma considers [all domains](#) to be [important](#)
 - Domains 1-5 currently critical for pricing & reimbursement submissions
 - Domains 6-9 address number of value elements which are often not considered sufficiently
- Roche Pharma exploring adapting the [HTA Core Model for internal use](#)
- Both Roche Pharma and external stakeholders need to [consider value more broadly](#)
 - Provides ability to adequately demonstrate value potential of a health technology

Potential things to consider for EUnetHTA...

- Re-name EUnetHTA HTA Core Model to “Value Assessment Framework”
- Rename domains 4 and 8 (suggestions given)
- Some assessment elements are not clearly written (details given)
- Redundant and missing elements (details given)
- Simplify language and illustrate with examples (details given)

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Doing now what patients need next

Backup



HTA Core Model

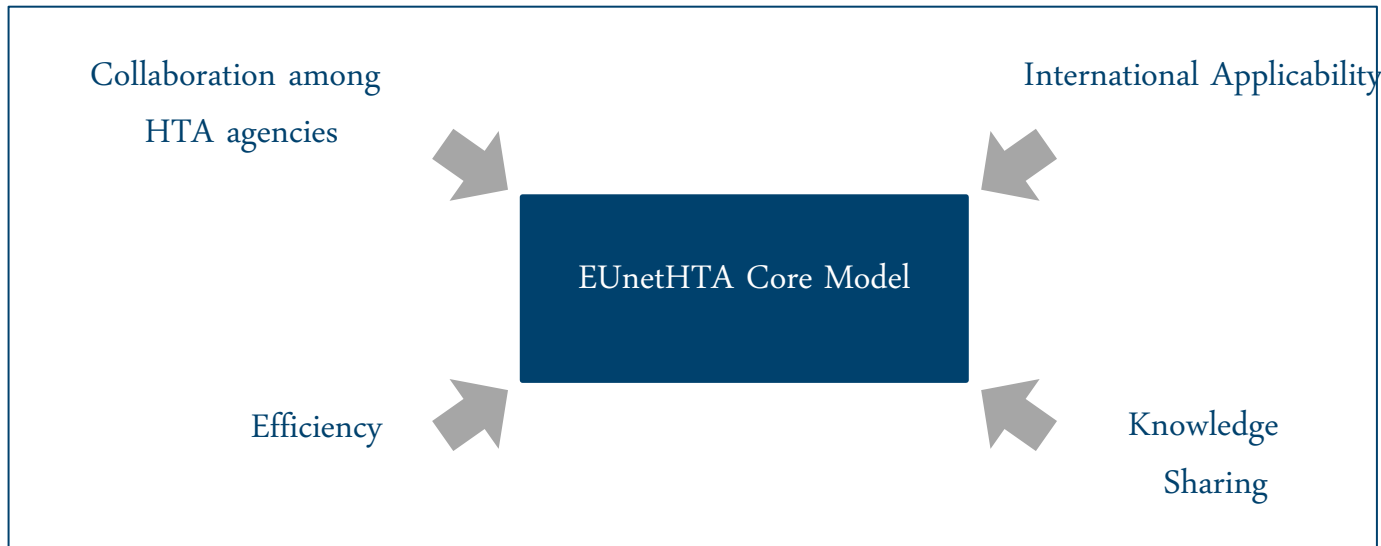
EUnetHTA remit and drivers

Objective

Put into practice an effective and sustainable HTA collaboration among agencies in Europe that brings added value at the European, national and regional level

Tools

EUnetHTA Core Model, Relative Effectiveness, Adaptation toolkit



Core Selection

Using different levels of agreement

Agreement	Important	Important and transferable	Unimportant
All 6 countries	38	15	2
At least 5 countries	58	31	6
At least 4 countries	78	50	23
At least 3 countries	105	69	44
At least 2 countries	118	87	68
At least 1 countries	127	117	91

Roche key HTA principles

- Health technologies cover products and services including but not limited to pharmaceuticals, devices, and diagnostics as applied in healthcare and prevention.
- Assessments of health technologies should be conducted in an open dialogue with all relevant stakeholders.
- Assessments of health technologies should be objective and transparent to the involved parties.
- Assessments of health technologies should be based on a broad value concept taking into account all relevant parties and effects.
- Assessments of health technologies should consider all available data and evidence.

Roche key HTA principles

- Assessments of health technologies should be based on scientifically sound and adequate methodologies.
- Assessments of health technologies should handle remaining uncertainty in a rational manner.
- Value should be recognized and rewarded.
- Decisions should reflect the needs and values of the population.
- The rationale of decisions should be made explicit.
- Positive decisions should lead to access.
- Decisions should be reconsidered when new evidence becomes available.

Doing now what patients need next