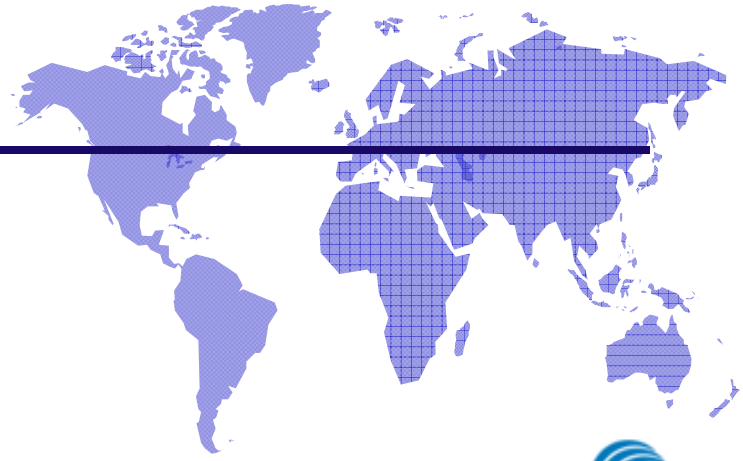
SWISSHTA

VALUE & VALUATION OF HEALTH TECHNOLOGIES

Presentation to 11th Annual HTAi Conference

Washington DC, June 16, 2014

Health Technology Assessment (HTA) in Switzerland



The SwissHTA Multi-Stakeholder Consensus

Value and Valuation of Health Technologies
(Guiding Principles)

Michael Schlander, Christian Affolter, Thomas B. Cueni, Heiner Sandmeier
on behalf of the SwissHTA Group

reporting on a Swiss consensus initiated by **santésuisse** und **Interpharma**
in cooperation with BAG, FMH and SAMW

FMH
Verbindung der Schweizer Ärztinnen und Ärzte
Fédération des médecins suisses
Federazione dei medici svizzeri
Swiss Medical Association

santésuisse

interpharma

INNOVAL HC
Institute for Innovation & Valuation in Health Care

A Multi-Stakeholder Approach

Project Team

- Christian Affolter (**santésuisse**)
- Thomas Cueni (**Interpharma**)
- Andreas Faller[1] (**BAG**)
- Pius Gyger (**Helsana**)
- Ansgar Hebborn / C. Cao (**Roche**)
- Daniel Herren[2] (**FMH**)
- Stefan Kaufmann (**santésuisse**)
- Heiner Sandmeier (**Interpharma**)
- Michael Schlander (**U of Heidelberg**)
- Peter Suter[1] (**SAMW**)

Scientific Steering Committee

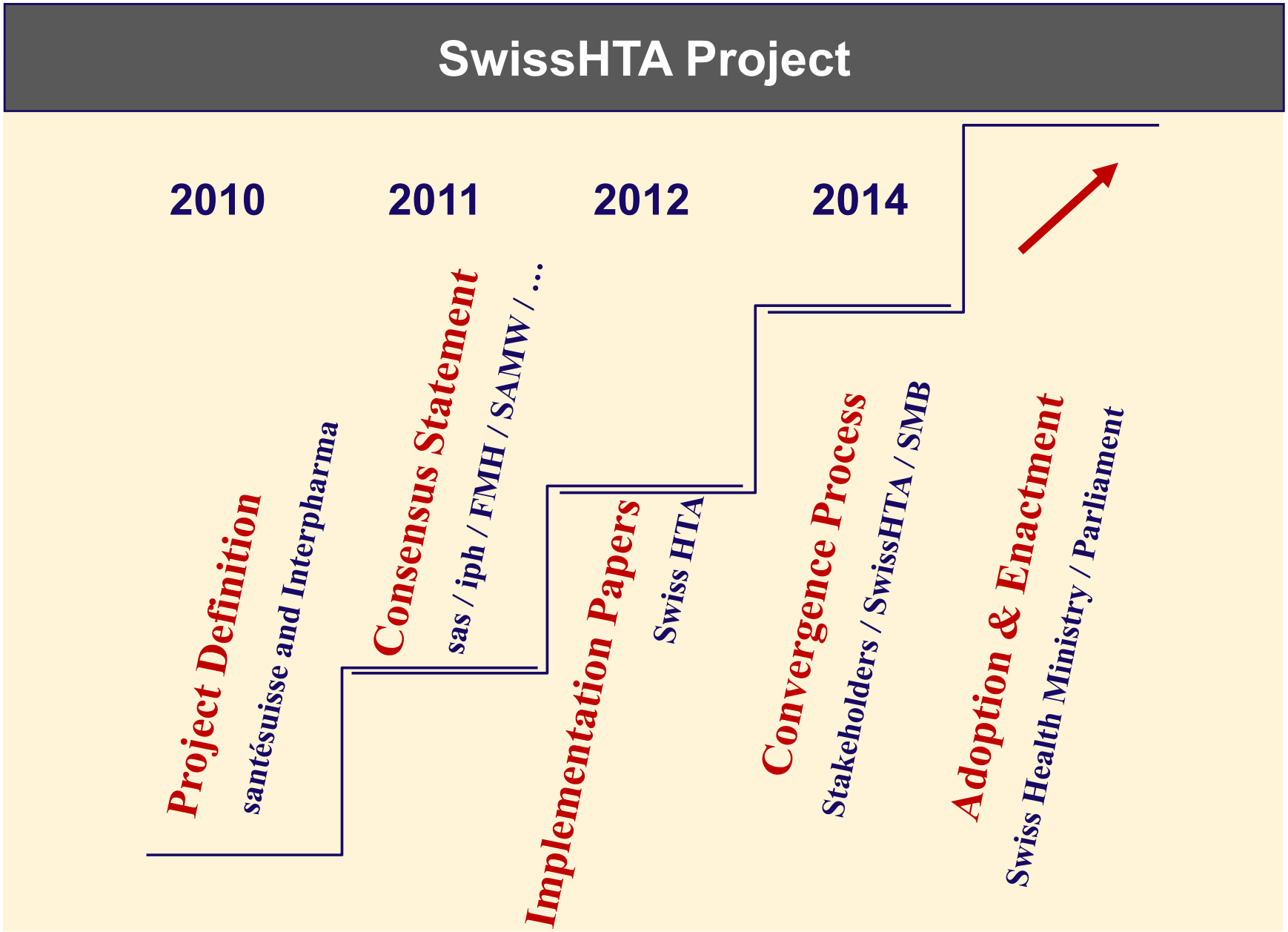
- **Professor Robert E. Leu**
  (University of Bern)
- **Professor Gérard de Pouvourville**
  (ESSEC, Paris)
- **Professor Michael Schlander**
  (University of Heidelberg
  & InnoVal^{HC}, Wiesbaden)

associated:

- **Professor Urs Brügger**
  (ZHAW & WIG, Winterthur)

[1]Government representative, observer status
[2]as of May 2011

Major Project Phases



Consensus Development Process: 7 ½ Retreats of Project Team, 2 Scientific Steering Committee Meetings, 3 Public Workshops

Retraite 1 (Muerren, January 27/28, 2011)
Retraite 2 (Hinterzarten, February 24/25, 2011)
Retraite 3 (Bern, April 26, 2011)
Retraite 4 (Brunnen, May 31 / June 01, 2011)
Retraite 5 (Solothurn, July 13, 2011)
Scientific Steering Committee (Wiesbaden, July 29, 2011)
Retraite 6 (Bern, August 19 / September 02, 2011)
Retraite 7 (Bern, October 19, 2011)

Deliberations by Project Team

Kartause **Ittingen**
November 05 / 06, 2010

Brunnen / Vierwaldstättersee
May 31 / June 01, 2011

Swiss Workshop 2:
Discussion of Interim Results with Stakeholders

Luzern / Vierwald-stättersee
September 28 / 29, 2011

Swiss Workshop 3
Discussion of Draft Consensus with Stakeholders

Expert Workshop 1:
Public Expectations & Societal Preferences; International Experience; Health Economic Evaluation Methods

Rules of Engagement for Project Team Members: Chatham House Rule

[Confidentiality and Openness]

"When a meeting, or part thereof, is held under the Chatham House Rule, participants are free to use the information received, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed."

Foundations: Fairness and Constructive Critique

"Wer am Wege baut, hat viele Meister"[1]

"A house built by the wayside

is either too high or too low."

[1] **Martin Luther (1530)**

Background of Project

Health Technology Assessment (HTA) in Switzerland:

- **EDI/BAG**: (Closed and open) **'Catalogue' of Health Insurance (OKP)** decisions of reimbursement, volumes, prices, and indications supported by expert commissions (since 1996)
- **SNHTA**: **Swiss Network for Health Technology Assessment** Network of Swiss HTA Stakeholders (since 1999)
- **GDK**: ‚Cost-Utility-Analyses'[1]; **Trägerverein „Medical Board"** (founded by FMH and SAMW in February 2011); predecessor, 'Zürich Medical Board' (since 2008)

*The dispersed existing HTA processes in Switzerland exhibited potential for improvement and **integration**.*

[1]vgl. Gesundheitsdirektion des Kantons Zürich: *Beurteilung medizinischer Verfahren. Methodischer Ansatz.*

SwissHTA: The Road to Consensus

Background: HTA at BAG (2011)

Commissions using different processes and criteria

Kategorie[1]	Verordnung	Liste	Entscheid-instanz	Beratende Kommission
Leistungs-erbringer	KVV		Bundesrat	ELGK
Leistungen	KLV	KLV Anhang 1	EDI	ELGK
Mittel und Gegenstände	KLV	KLV Anhang 2 (MiGeL)	EDI	EAMGK
Analysen	KLV	KLV Anhang 3 (AL)	EDI	EAMGK
Konfektionierte Arzneimittel	SL	SL	BAG	EAK
Magistral-rezepturen	KLV	KLV Anhang 4 (ALT)	EDI	EAK

[1]Source: Felix Gurtner (13.06.2008)

Motivation: Potentials for Improvement

HTA at BAG:

Recommendations by GPK-N[1]

(with regard to the evaluation of physician services):

- Adequate Ressourcing (BAG and commissions)
- Definition and Operationalization of WZW Criteria of Swiss KVG
- Stronger Emphasis on 'Efficiency'
- Evaluation of Established Technologies

Stellungnahme des Bundesrates[2] (Auswahl):

- Process Improvement (incl. criteria for 'triage' of technologies)
- Evaluation of Alternative Organizational Arrangements
- Operationalization of WZW Criteria
- Need for Political Guidance (appraisals)

[1]Geschäftsprüfungskommission des Nationalrates (GPK-N): Empfehlungen vom 26. Januar 2009

[2]Bundesrat: Stellungnahme vom 24. Juni 2009

Motivation: Potentials for Improvement

HTA at Medical Board:

- Stakeholder Integration (in process development)
  as an inclusive, not exclusive process
- Incorporate International HTA Experience
  limitations of the 'logic of cost effectiveness'
- Incorporate International State of the Art
  in relevant scientific disciplines, incl. health economics
- Methodological and Implementation Issues
  examples: utility measurement,
  selection of technologies for evalation,
  differentiated approach to new and established technologies;
  institutional aspects: assessment , appraisal, and decision-making
- Guided by Expectations ("Social Preferences") of the Insured
  instead of reliance on quasi-utilitarian framework
- Linkage and Cross-Referencing to WZW Criteria of KVG
  definition and operationalization

Motivation: The Need to Act

- Bundesgericht (1): Urteil vom 23. November 2010 (Myozyme®)

  „Es können somit weder die therapeutische Wirksamkeit noch die **Wirtschaftlichkeit** je getrennt voneinander betrachtet werden in dem Sinne, dass die Frage nach dem hohen therapeutischen Nutzen mit einem kategorialen Ja oder Nein beantwortet werden könnte und bejahendenfalls die Kosten in beliebiger Höhe zu übernehmen wären."

  „Die Rechtsprechung hat ansatzweise versucht, anstelle der bisher auf politischer Ebene nicht festgelegten Kriterien die Kosten-/Nutzen-Beziehung zu beurteilen."

- Bundesgericht (2): Urteil vom 11. Juli 2011 (Champix®)

  „Nach der Verwaltungspraxis erfolgt die Beurteilung der **Zweckmässigkeit** aufgrund des Verhältnisses von Erfolg und Misserfolg (Fehlschlägen) einer Anwendung sowie der Häufigkeit von Komplikationen."

Objectives

HTA as 'Real World' *Decision Support*

HTA in Switzerland should

- provide effective support to health care decision makers in charge of reimbursement and pricing of interventions;
- include regular re-evaluation of any such decisions;
- identify evidence gaps and research needs;
- provide information supporting policies to ensure fair access of the Swiss health insured population to high quality, effective and economically sustainable health care interventions.

Objectives

Evaluation Criteria: Hierarchy of Objectives

1. **A Prior Normative Commitment**
   - Starting Point:: Swiss Legal Tradition
   - Human Rights / "Rights" or "Principles" -based Approach
     1. Personality, Integrity and Autonomy of the Individuum
     2. Principles of Nondiscrimination (Chancengerechtigkeit)
2. **Expectations of the Insured Population ("Social Preferences")**
   1. "Empirical Ethics"
   2. Research Need to close gaps in our understanding
3. **Operationalization of WZW Criteria**
   1. Wirksamkeit (Effectiveness)
   2. Zweckmässigkeit (Appropriateness)
   3. Wirtschaftlichkeit (Economic Viability)

A purely or primarily utilitarian evaluation approach would not be consistent with the Swiss legal tradition.

A Prior Normative Commitment

Starting Point:

- **Principle-Based Reasoning ('Rights' and 'Claims')**:
  personality, integrity and autonomy of individuum

- **Health as a 'Conditional Good'**
  a prerequisite to pursue life plans

  echoing the philosophical thinking
  of Immanuel Kant, Ronald Dworkin,
  John Rawls and Norman Daniels

  reflected in economic theory
  for example by Amartya Sen and Martha Nussbaum

A purely or primarily utilitarian evaluation approach would not be consistent with the Swiss legal tradition.

A Prior Normative Commitment

Federal Constitution of the Swiss Federation:

- **Principle of Equality** (Article 8)

  1: Every person is equal before the law.
  2: No person may be discriminated against […]
  3: The law shall provide for the elimination of inequalities that affect persons with disabilities. .

- **Protection of Children and Young People** (Article 11)

  1: Children and young people have the right to the special protection of their integrity and to the encouragement of their development.

- **Right to Assistance When in Need** (Article 12)

  Persons in need and unable to provide for themselves
  have the right to assistance and care,
  and to the financial means required for a decent standard of living.

A New Interpretation of the Swiss WZW Criteria

1. **Effectiveness (*Wirksamkeit*)**
   1. Starting Point (1): **Added Benefit**
      (always) comparative effectiveness evaluation;
      degree of confidence in available evidence
   2. Starting Point (2): Relevance of available clinical evidence for Swiss health care, given the **Swiss Standard of Care**
2. **Appropriateness (*Zweckmässigkeit; 'social desirability'*)**
   1. Starting Point (3): Prior **Normative Commitment**
   2. Starting Point (4): **Social Preferences** of the Insured
3. **Economic Viability (*Wirtschaftlichkeit*)**
   1. Starting Point (5): **Budgetary Impact**
   2. Starting Point (6): **Efficiency**;
      Incremental Cost Effectiveness Relation

[1]Opportunitätskosten aus Systemperspektive

Wirksamkeit: **Individual Value Perspective** Driven by Clinical Effectiveness

"Levels of evidence"

in line with principles of evidence-based medicine (EBM):

Reasonable Evidence Expectations

incentives for providers to produce evidence to the extent and quality that can "reasonably" be expected given the specifics of a technology in a given phase of its life cycle;

Expected Level of Evidence

application of the principles of EBM should be pragmatic in order to appropriately accommodate situational aspects inevitably influencing the level and quality of evidence of effectiveness that can be reasonably expected from a provider of a technology at a given time in the technology life cycle;

Full range of demonstrated health-related benefits

will be evaluated from an individual's perspective. Outcomes will be rated based on relevance and magnitude of the effects observed.

Judgments on the degree of confidence

in the health-related benefits found in studies will primarily depend on the available level and quality of evidence. As a reference level for grading, *Swiss HTA* defines the best possible level of evidence that can be expected in a given context.

Social Value Assessment[1]

Zweckmässigkeit: **Social Value** (Empirical Ethics)

- **Severity and Urgency**
  of initial health problem
- **"*Fair Innings*"**
  interventions for children and young people who have not had an opportunity to pursue their individual life plans (=> *"conditional good"*)
- **Nondiscrimination or Fairness**
  fair chance of access to effective health care even if condition is rare or intervention is expensive
- **"*Bagatellen*"**
  exclusion or low priority for minor self-limiting health problems and 'affordable' interventions[2]
  ('affordability determined from a patient's out-of-pocket perspective)
- **Fast Access to Real Innovation**[3]

[1]Hypothesen; es besteht erheblicher Forschungsbedarf;
[2]durch die Versicherten

[3]"echt" i.S. von belegbarem Mehrnutzen;
"möglichst unbehindert" i.S. von allgemein und rasch

Wirtschaftlichkeit: **Economic Viability**

1. **Budgetary Impact**
   Opportunity costs from a decision makers' perspective are defined by the overall budgetary impact of funding a specific health technology. The aim of these analyses is to establish transparency on the short, medium, and long term consequences of a decision from the perspective of payers.

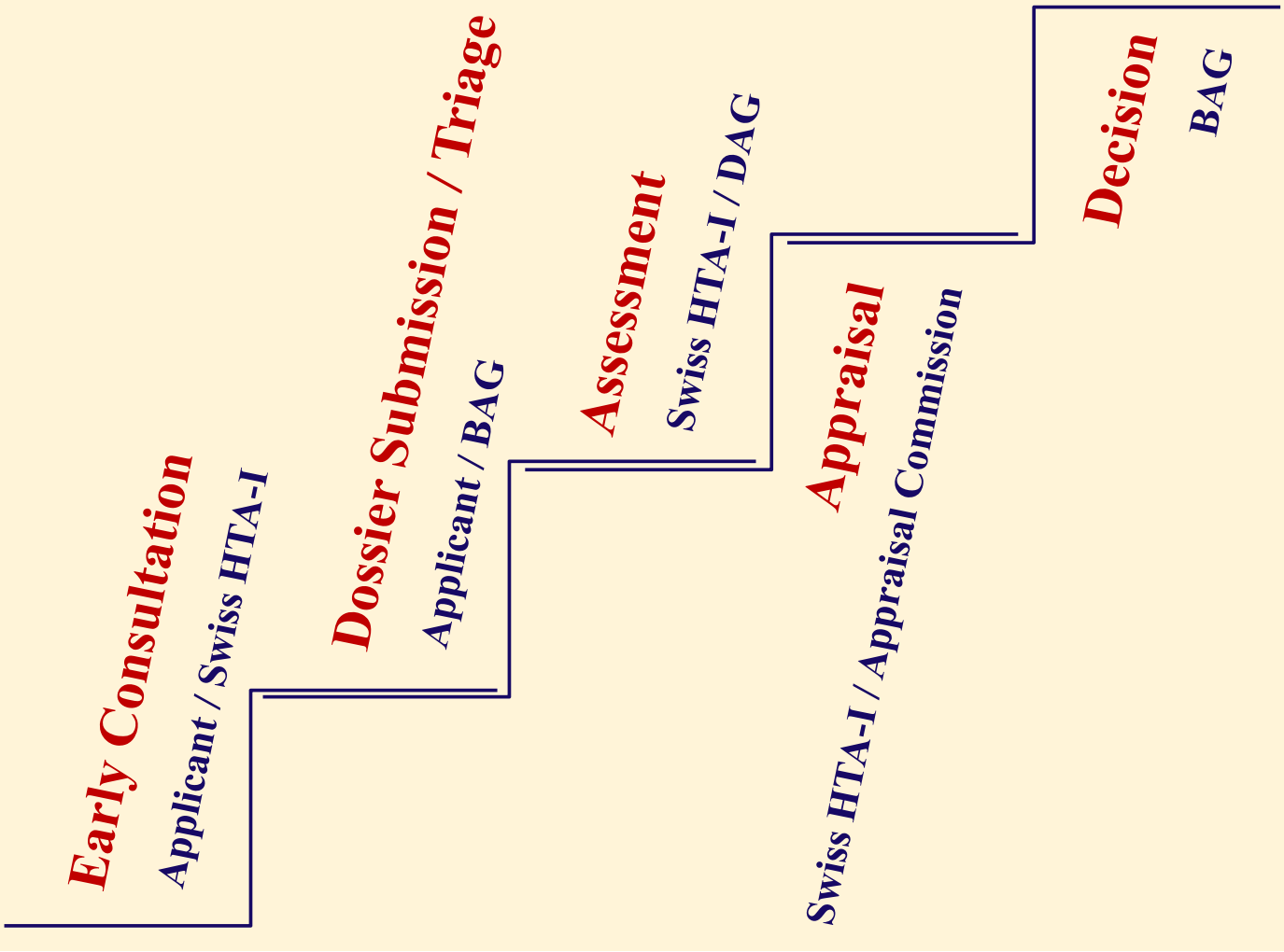
2. **Cost Benefit Evaluations**
   are considered most useful for technologies with a high budgetary impact, especially when there is reason to believe that social benefits conferred by their use are small or moderate only.

3. **Technical and Allocative Efficiency**
   The evaluation of relative cost benefit ratios ("efficiency") should, for the time being, focus on issues of "*technical efficiency*", i.e., compare alternative ways to achieve the same clinical objective. Accordingly, the most appropriate evaluation method (cost minimization, cost effectiveness, cost utility analysis, etc., will depend on the specific research question. In other words, *Swiss HTA Consensus* recommends "*methodological pluralism*".

4. *SwissHTA* recognizes that the results of conventional cost benefit evaluations can be positively unethical when judged against the prior normative commitment.
   ***Swiss HTA* rejects the idea of uniform cost per QALY benchmarks.**

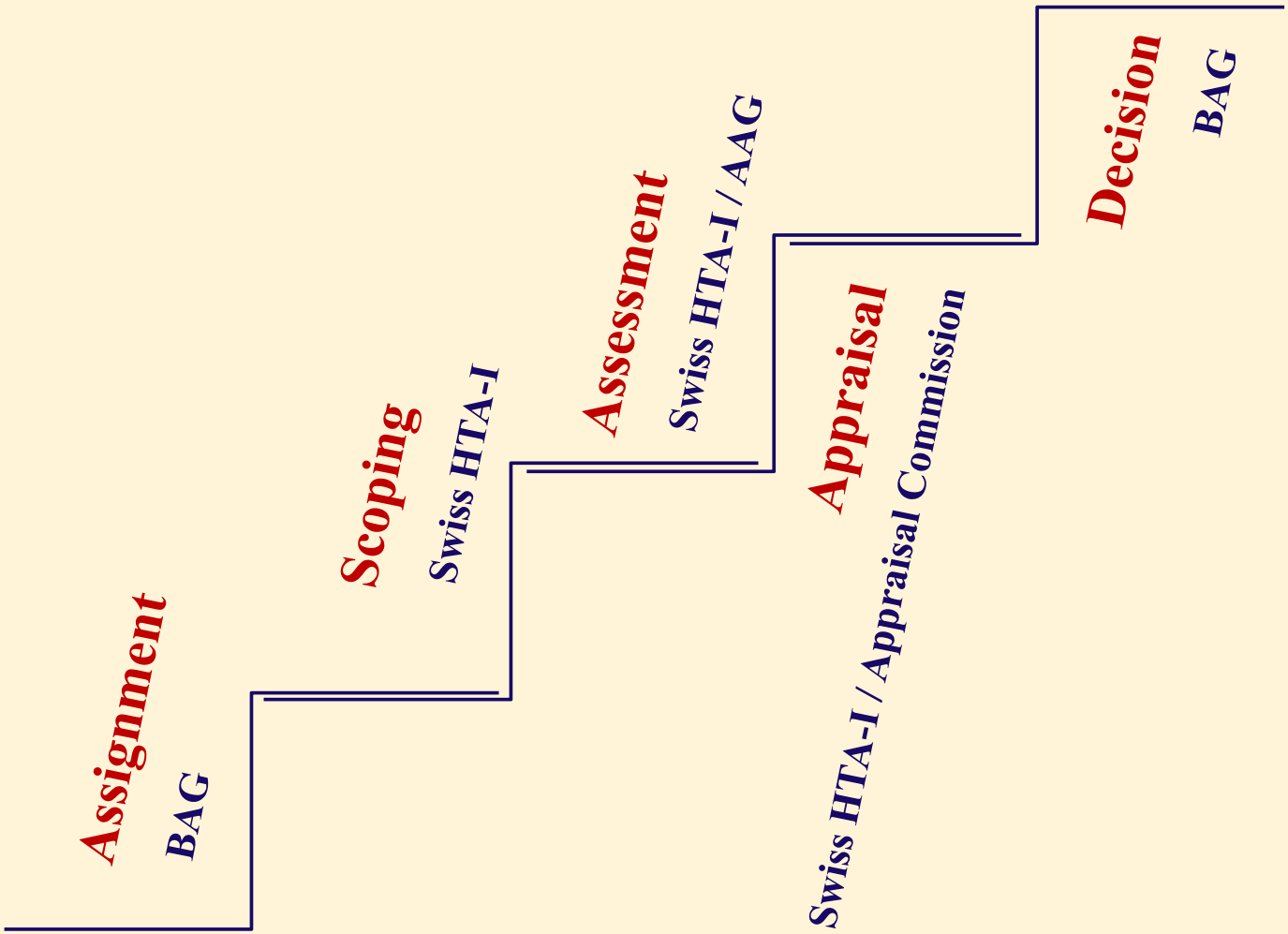
Evaluation Processes (1)

Rapid HTA Process ("rHTA")



Evaluation Processes (2)

Complete HTA Process ("cHTA")



SwissHTA Output & Outlook

Project Output

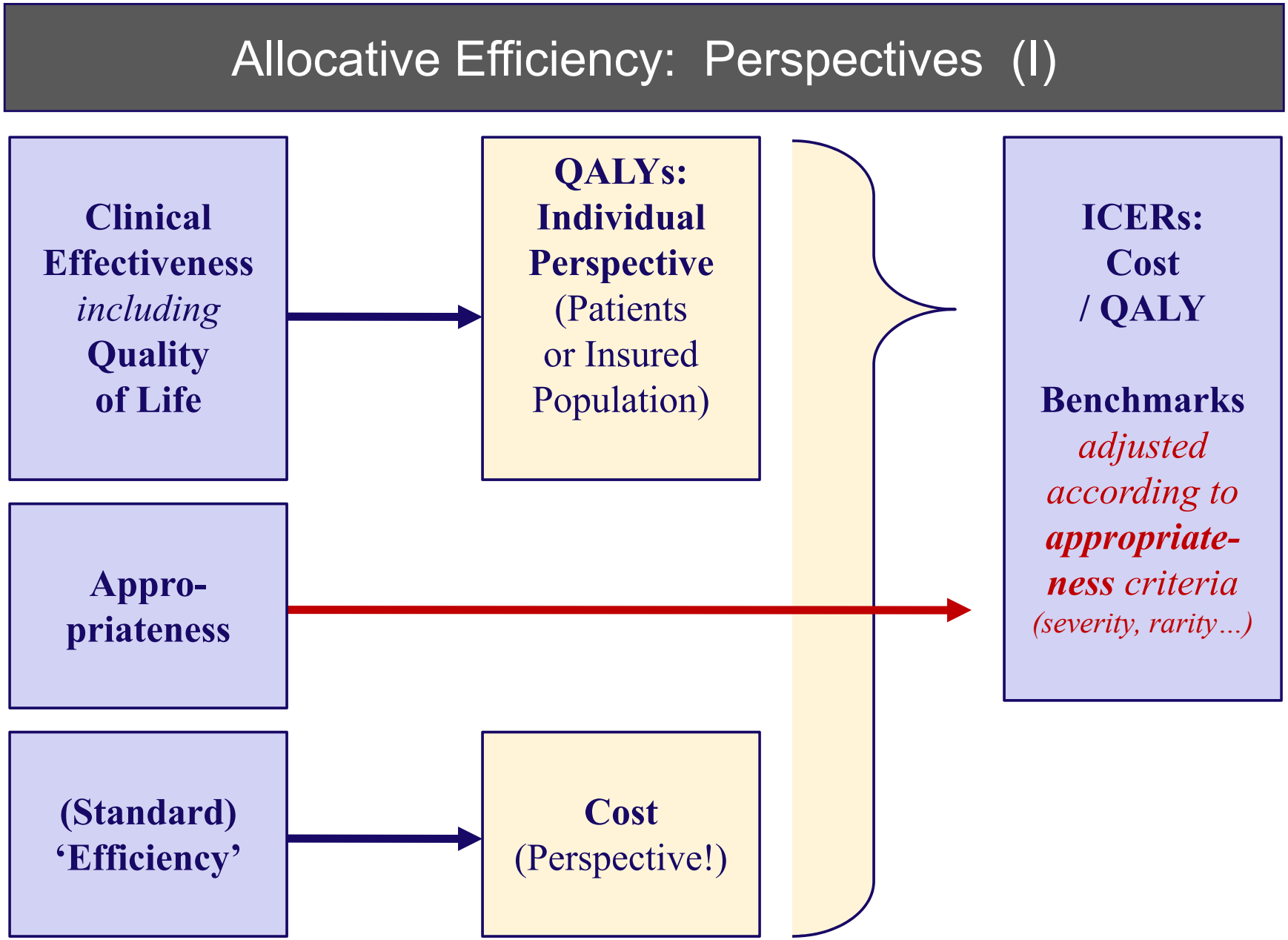
1. **Consensus Statement**
2. **Appendix to Consensus Statement: Development Options**
3. **Full Documentation of Consensus (222 pages)**
4. **SwissHTA: Guiding Principles**
5. **Implementation Paper 1** (Institutional & Organizational Considerations)
6. **Implementation Paper 2** (Rapid HTA Process)
7. **Implementation Paper 3** (Full HTA Process)
8. **Implementation Paper 4** (New WZW Criteria)
9. **Implementation Paper 5** (Benefit Evaluation)
10. **Implementation Paper 6** (Economic Evaluation)

Project Outlook

Convergence Process: SMB, SwissHTA, Stakeholder Groups & BAG

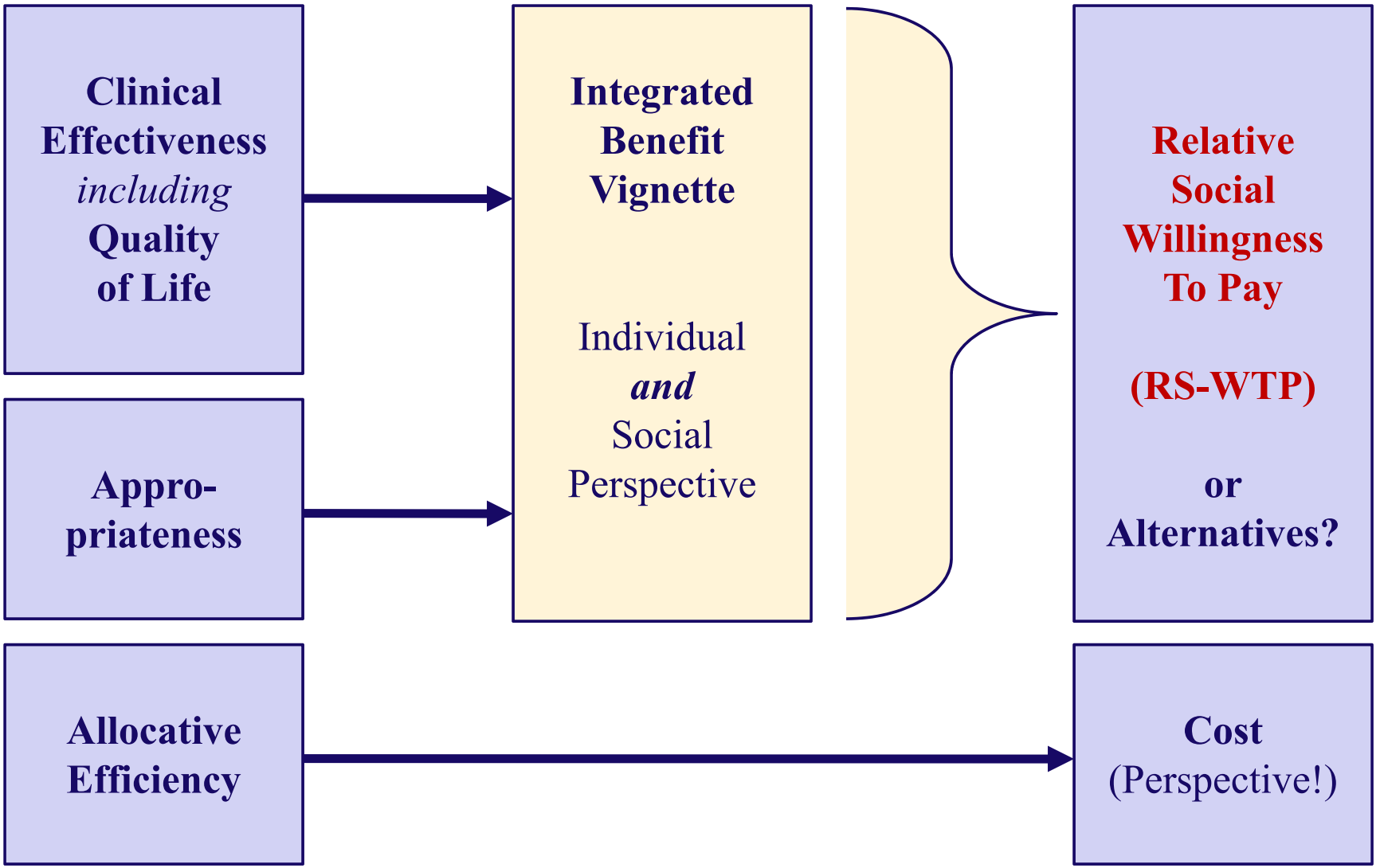
APPENDIX

Appendix. Evaluations Methods: Further Development



Appendix. Evaluations Methods: Further Development

Allocative Efficiency: Perspectives (II)



Appendix. Implementation

Quality Assurance: Process Quality

Criteria:

1. Realize
   ex ante identified **potentials for improvement**

2. Meet the criteria of
   "**Accountability for Reasonableness**"

3. Meet the criteria of
   "**Good HTA Practice**"

Appendix. Quality Assurance

Process Quality: "Accountability for Reasonableness"

Accountability for Reasonableness (A4R) Criteria:

(nach Norman Daniels und James Sabin, 1998)

1. Publicity Condition:

"Decisions regarding coverage for new technologies (and other limit-setting decisions) and their rationales must be publicly accessible."

2. Relevance Condition:

"These rationales must rest on evidence, reasons, and principles that all fair-minded parties (managers, clinicians, patients, and consumers in general)
can agree are relevant to deciding how to meet the diverse needs of a covered population under necessary resource constraints."

3. Appeals Condition:

"There is a mechanism for challenge and dispute resolution regarding limit-setting decisions, including the opportunity for revising decisions in light of further evidence or arguments."

4. Enforcement Condition:

"There is either voluntary or public regulation of the process to ensure that the first three conditions are met."

Appendix. Quality Assurance

Process Quality: "Good HTA Practice"

Principles (from Michael F. Drummond et al., 2008;
cf. Peter J. Neumann et al., 2010; cf. also Charles River Associates Analysis, 2011)

1. HTAs should have explicit and relevant goals and scope
2. HTAs should be unbiased, rigorous and transparent
3. HTAs should include all relevant technologies
4. HTAs should have a clear system for setting priorities
5. HTAs should incorporate appropriate methods for assessing costs and benefits
6. HTAs should consider a wide range of evidence and outcomes
7. HTAs should consider a full societal perspective
8. HTAs should explicitly characterise uncertainty surrounding estimates
9. HTAs should consider and address issues of generalisability and transferability
10. HTAs should actively engage all stakeholder groups
11. Those undertaking HTAs should actively seek all available data
12. The implementation of HTA findings needs to be monitored
13. HTAs should be timely but separate from other regulatory review
14. HTA findings need to be communicated appropriately to different decision makers
15. The link between HTA and decision making processes needs to be transparent and clearly defined

SWISSHTA

VALUE & VALUATION OF HEALTH TECHNOLOGIES

Swiss HTA Consensus:

M. Schlander, C. Affolter, H. Sandmeier, U. Brügger, C. Cao, T. Cueni, G. de Pouvourville, A. Faller, P. Gyger, A. Hebborn, D. Herren, S. Kaufmann, R. Leu, P. Suter:
Bewertung medizinischer Interventionen in der sozialen Krankenversicherung. Dokumentation zum Thesenpapier (Eckpunkte des Schweizer Konsensus).

Basel, Bern, Solothurn and Wiesbaden, October 19, 2011.
Accessible at **www.swisshta.ch** and www.innoval-hc.com.

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