

The HTA Core Model : a useful framework for Roche to assess the value of a pharmaceutical product?

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Access to Healthcare

Roche's global commitment

Question for you

- On which basis would you assess a new oral therapy that would allow men to become women without surgery?

Effectiveness

Safety

Organizational aspects

Ethical aspects

Legal aspects

Cost implications



1. Background
2. The EUnetHTA HTA Core Model
3. The project
4. Results, conclusion and next steps

Background



eunetha

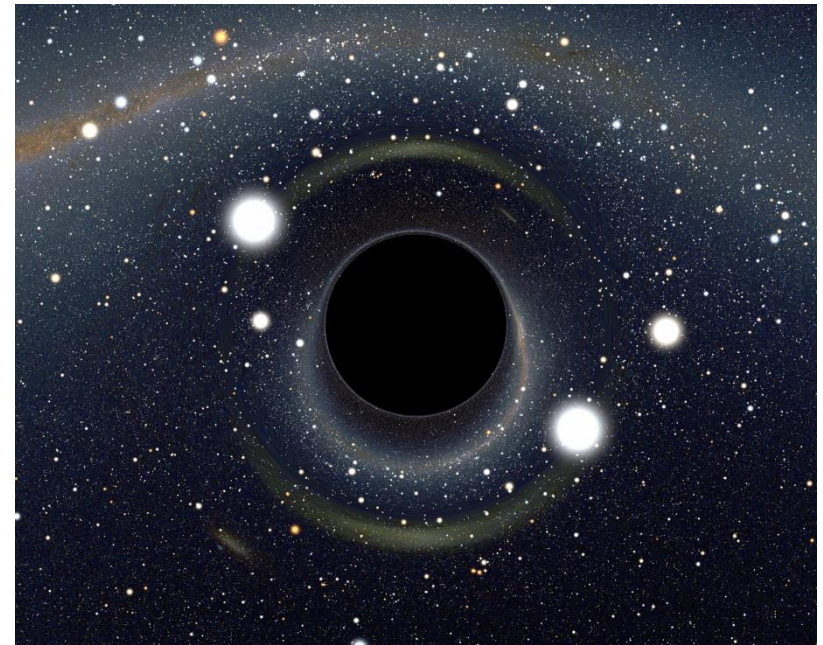
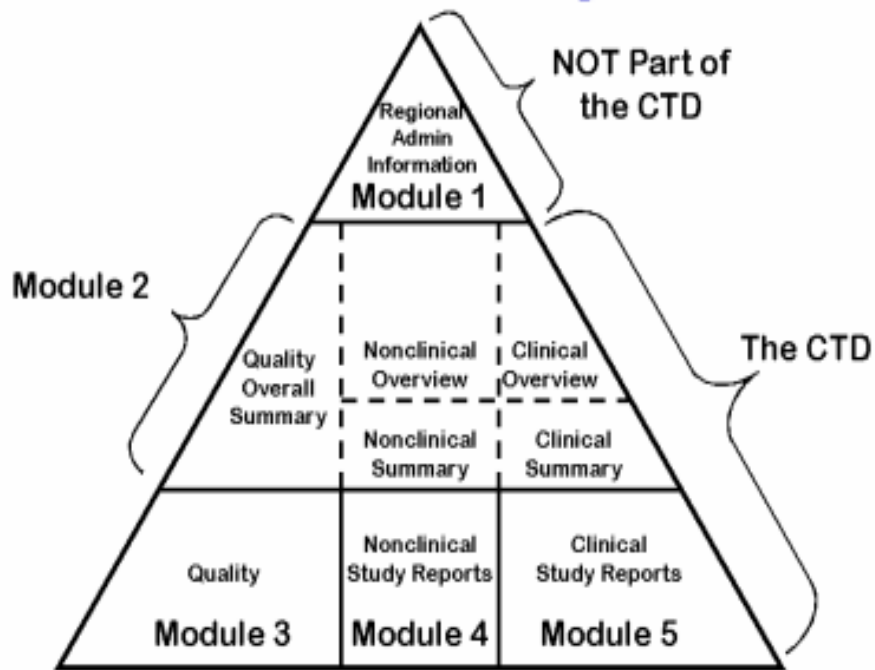
- What is
 - The European network for [Health Technology Assessment](#) (EUnetHTA) is a network for HTA across Europe
 - Government appointed organizations
 - Public national/regional HTA agencies,
 - Non profit organizations
 - Overall strategic objective of the network:
 - Enable an effective exchange of information
 - Support policy decisions by the Member States.
 - Including development of practical tools to provide reliable, transparent and transferable information to contribute to HTAs in the 28 members states.

Problem statement

- Regulatory

- HTA

The CTD Triangle



Objective

- Roche pharma is working on building a repository for sharing HTA evidence
- Because of the apparent similarities in the intention and objectives of the EUnetHTA HTA Core Model, Roche approached EUnetHTA to engage in a joint project.
- Roche agreed to [explore the usefulness](#) of the HTA Core Model developed by 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.

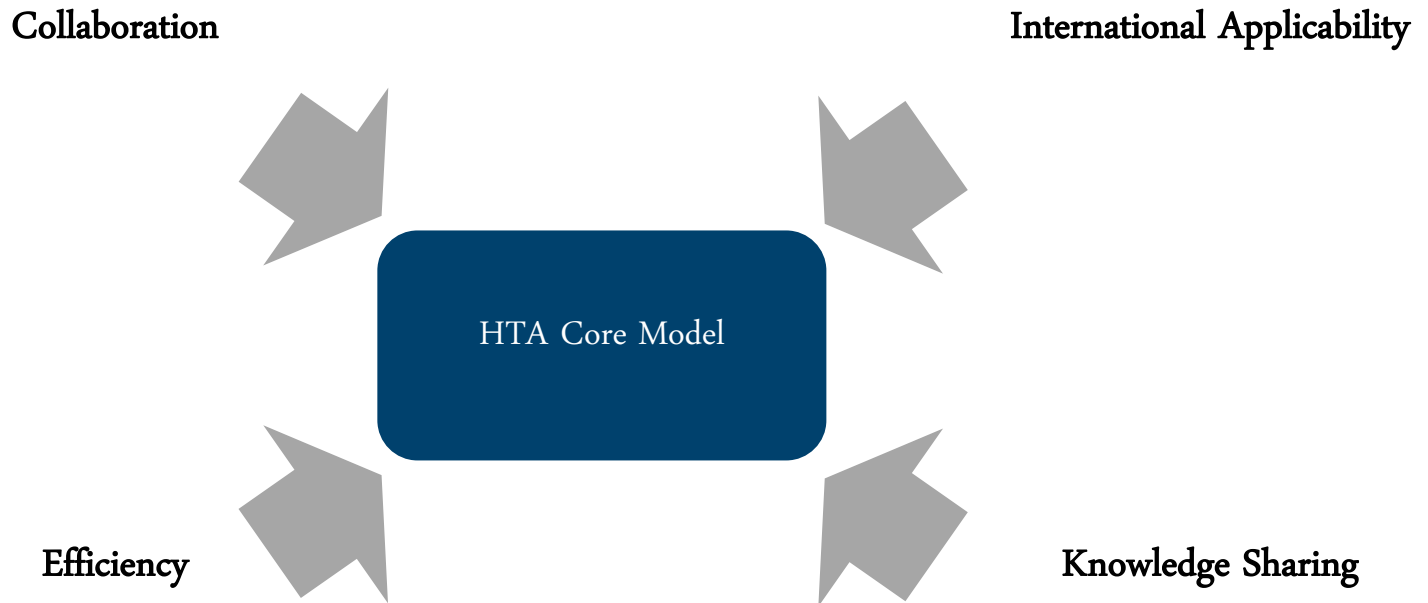
The HTA core model

EUnetHTA HTA Core Model

- What is EUnetHTA HTA core model?
 - The HTA Core Model is a methodological framework to facilitate the sharing of HTA information
 - The HTA Core Model divides HTA information into standardized assessment elements (questions)
 - It is structured in nine domains that emphasize the multidisciplinary nature of HTA

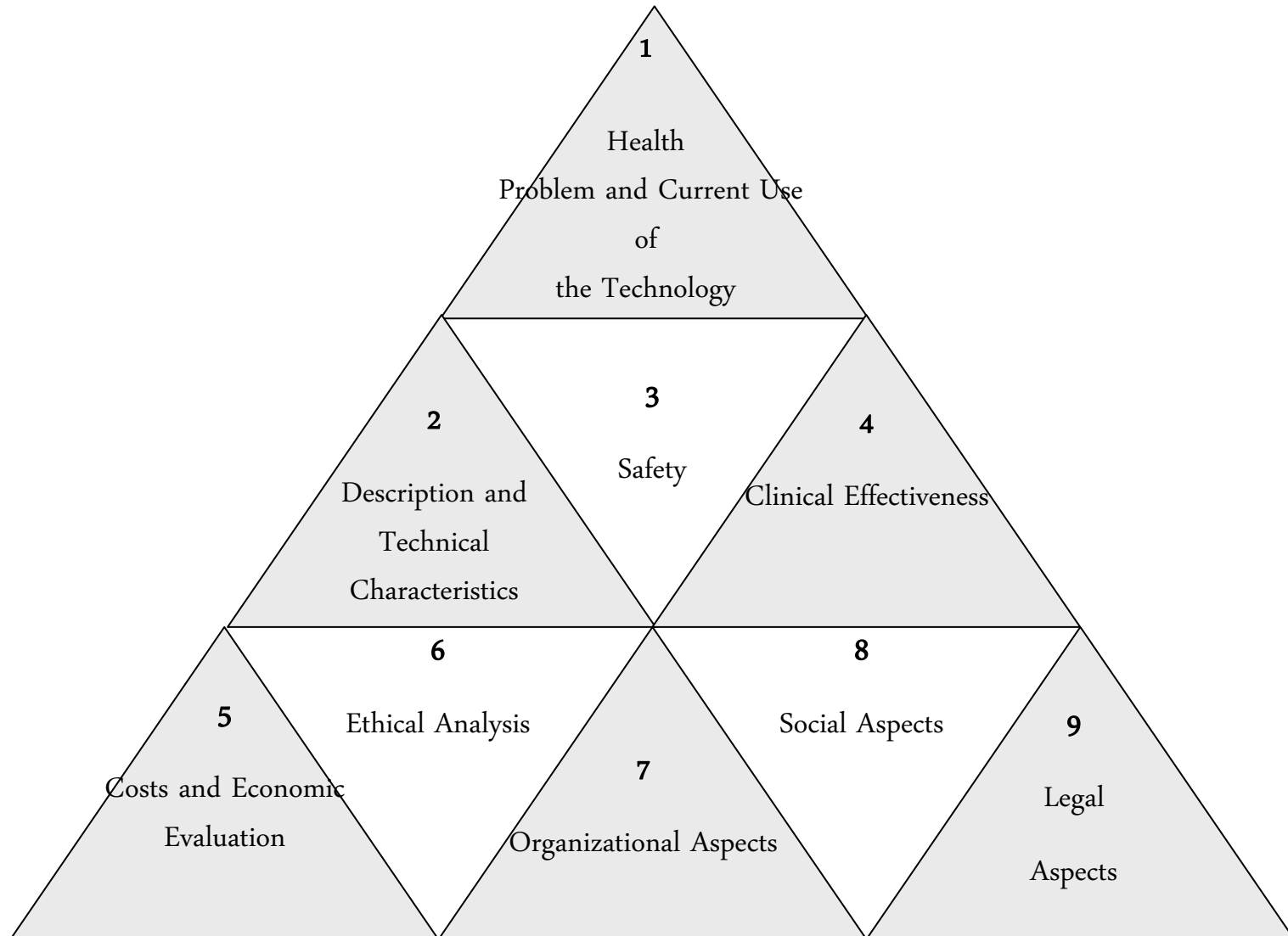
HTA Core Model

Drivers for EUnetHTA



HTA core model: the new CTD for HTA?

Nine domains and 130 assessment elements



HTA Core Model: Broad value Assessment?

Domains unfamiliar to Roche

6 – Ethical Analysis

7 – Organizational Aspects

8 – Social Aspects

9 – Legal Aspects

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

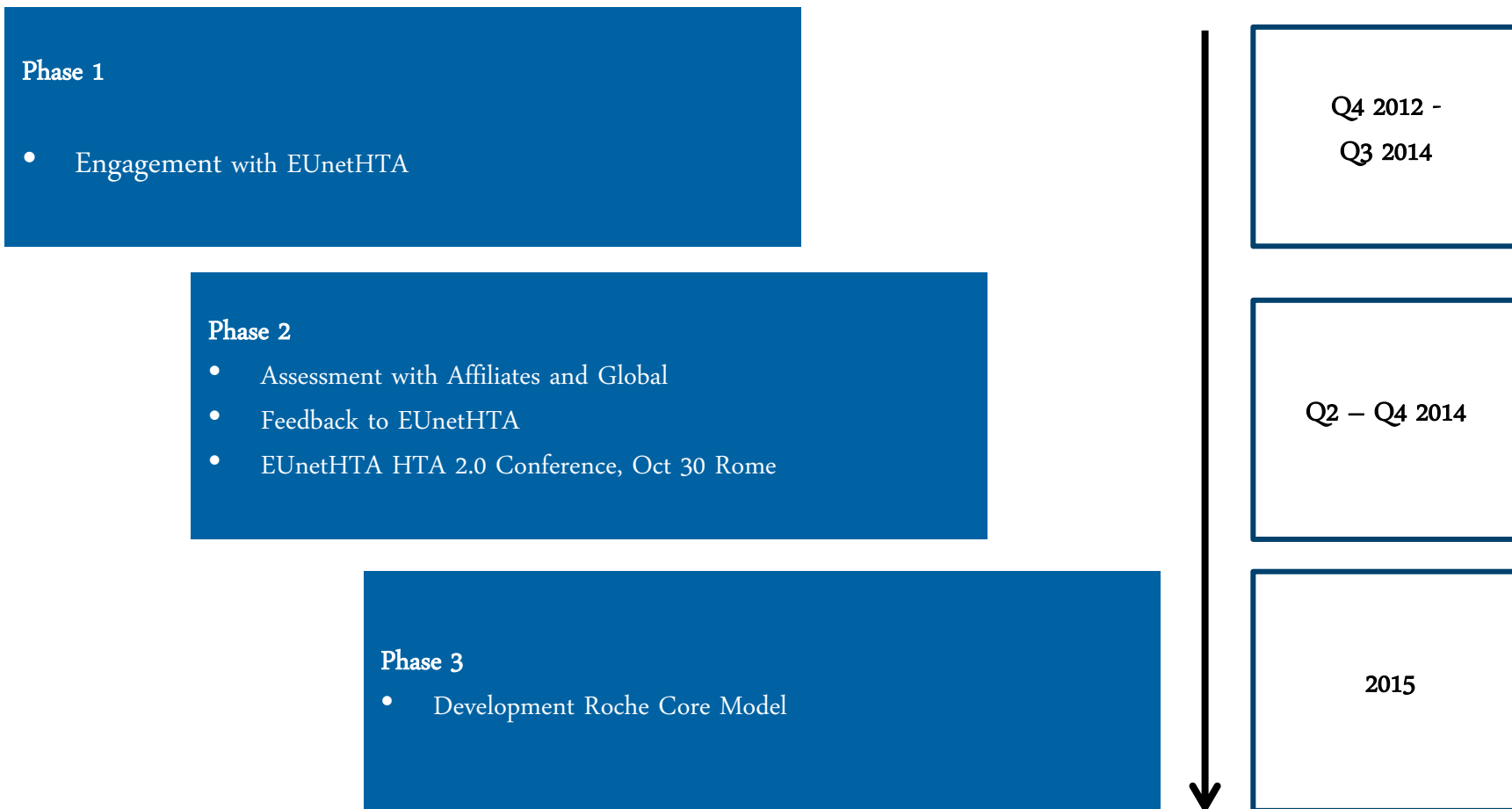
7 - Health delivery process, structure of health care system, management, culture

8 - Individual, major life areas

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

The project

Engagement with EUnetHTA and project phases



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

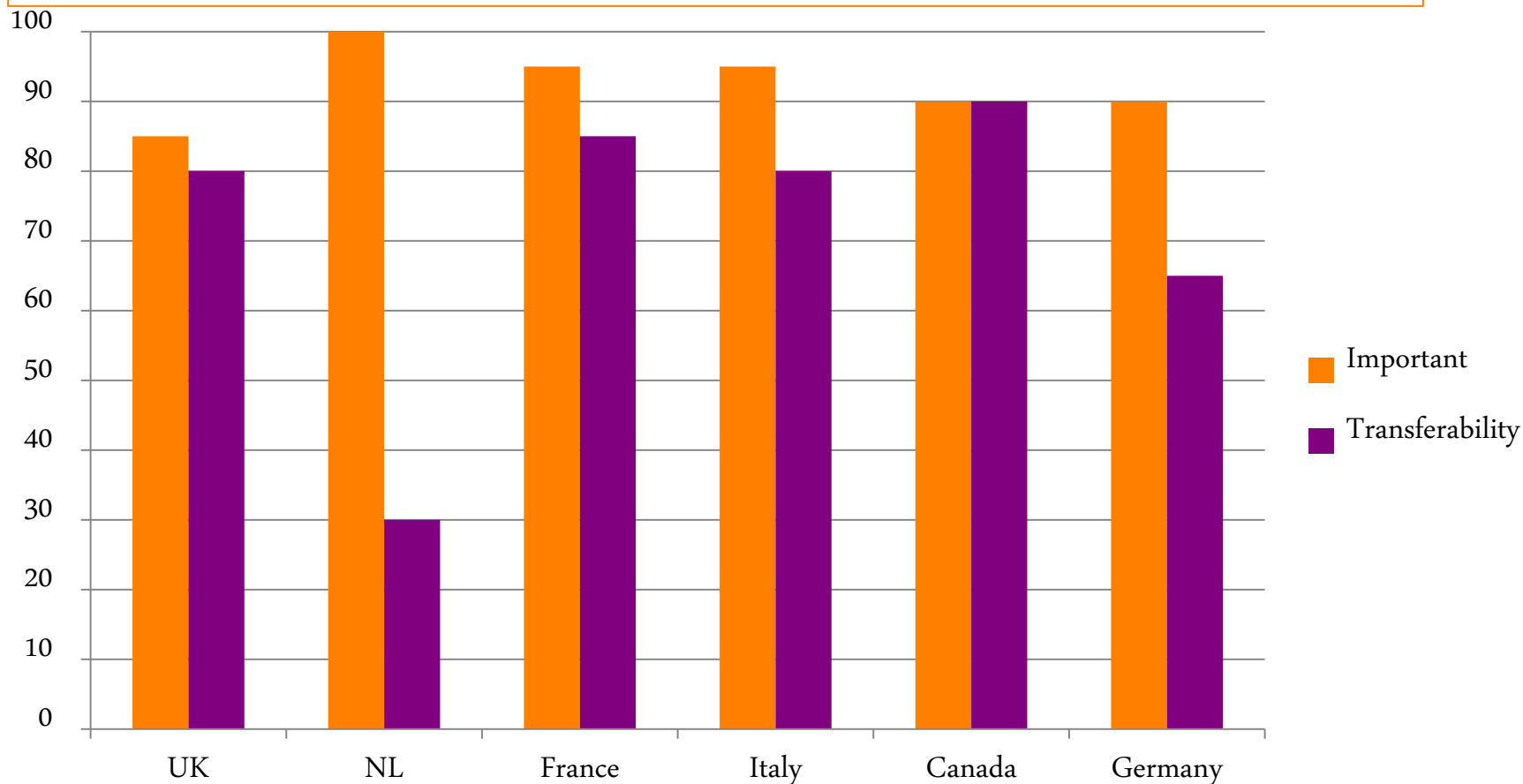
Results, conclusion and next steps

Domain 1:

Health Problem and Current Use of Technology is important in all countries



Topics include : target population, condition, current management, utilization, phase of development, regulatory status



Affiliate Importance Ranking: NL, F, ITA, CAN, GER, UK. Range from 100% to 85%

Affiliate Transferability Ranking: CAN, F, ITA, UK, GER, NL. Range from 90% to 30%

GPMA Importance Ranking: Range from 100% to 70%

Missing / Recommendation

- Include different types of market authorization eg conditional approval (should be expanded in A0020, Regulatory Status)

Unclear

- Need to improve element A0017 relating to differences in management of disease at different stages and include versus SoC.
- A0012 relates to variation in use of technology: need to clarify whether question includes competitors technology

Duplicated

- There are opportunities to cluster elements A0001, A0007,A0002, A0018. Also A0004 and A0005 could be merged.

Unimportant

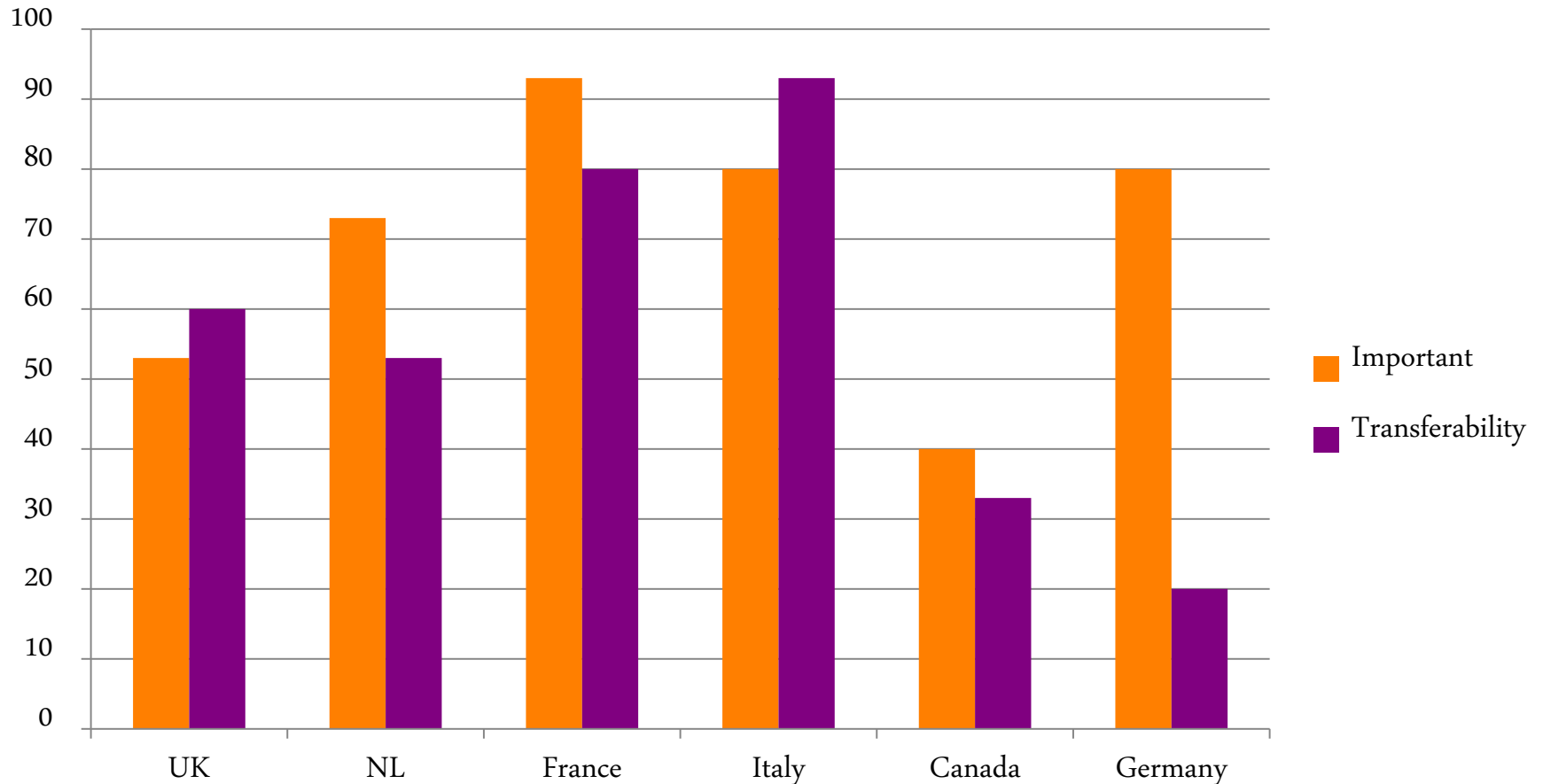
- There were no unimportant elements for 4 out of 6 countries

Domain 2: Description and technical characteristics of technology

Wide range of importance and transferability



Topics include: Features of the product vs comparator, indications, phase of development, who performs and administers it.



Affiliate Importance Ranking: F, ITA, GER, NL, UK, CAN. Range from 93% to 40%

Affiliate Transferability Ranking: ITA, F, UK, NL, CAN, GER. Range from 93% to 20%

GPMA Importance Ranking: Range from 100% to 20%

Missing / Recommendation

- Recommendation: Move some topics which relate to Training and Information to Domain 7: Organisational Aspects.

Duplicated

- There is overlap between Domain 1 and Domain 2.
- Cluster B0011,B0010 and B0012
- B0003 an B0003B are duplicated

Unimportant

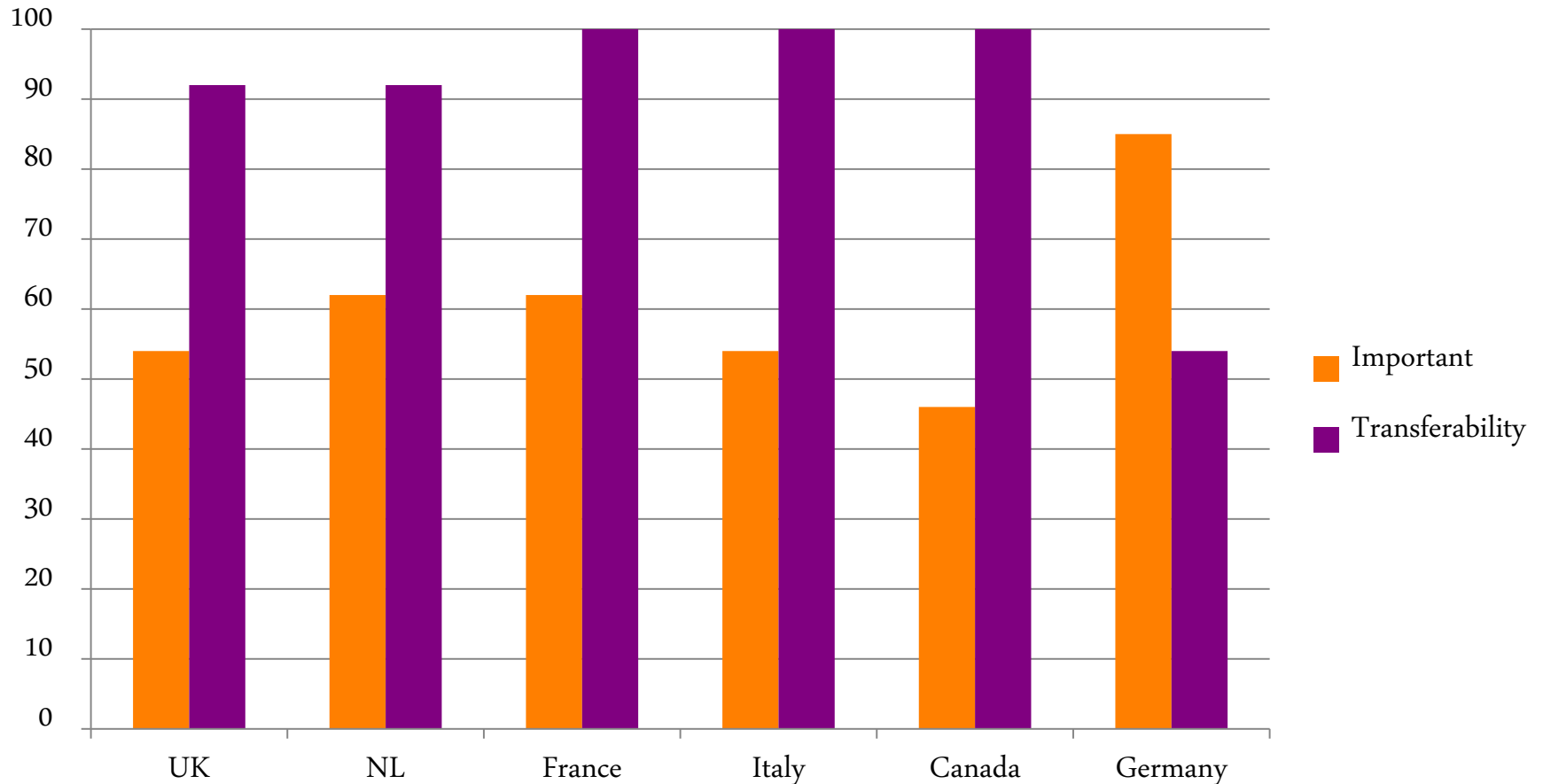
- There were two unimportant elements for 4 out of 6 countries.
 - B0012: what kind of qualification and quality assurance processes are needed for the use or maintenance of the technology.
 - B0015: What information of the technology should be provided for patients outside the target group and the general public.

Domain 3:

Safety-similar levels of importance and transferability



Topics include: Patient safety, occupational safety, environmental safety and safety risk management.



Affiliate Importance Ranking: GER, NL, F, ITA, UK, CAN. Range from 85% to 46%

Affiliate Transferability Ranking: F, ITA, CAN (100%), NL & UK (92%), GER (54%). Range from 100% to 54%

GPMA Importance Ranking: Range from 100% to 23%

Missing / Recommendation

- There is duplication between Regulatory requirements and this domain, therefore it should be reduced.
- Reduce elements relating to occupational and environmental safety which were ranked low.

Duplicated

- There were a large number of duplicated elements.
 - For example: cluster elements C0020, 40,60 and 61 together. Also cluster C0063,64 and 62

Unimportant

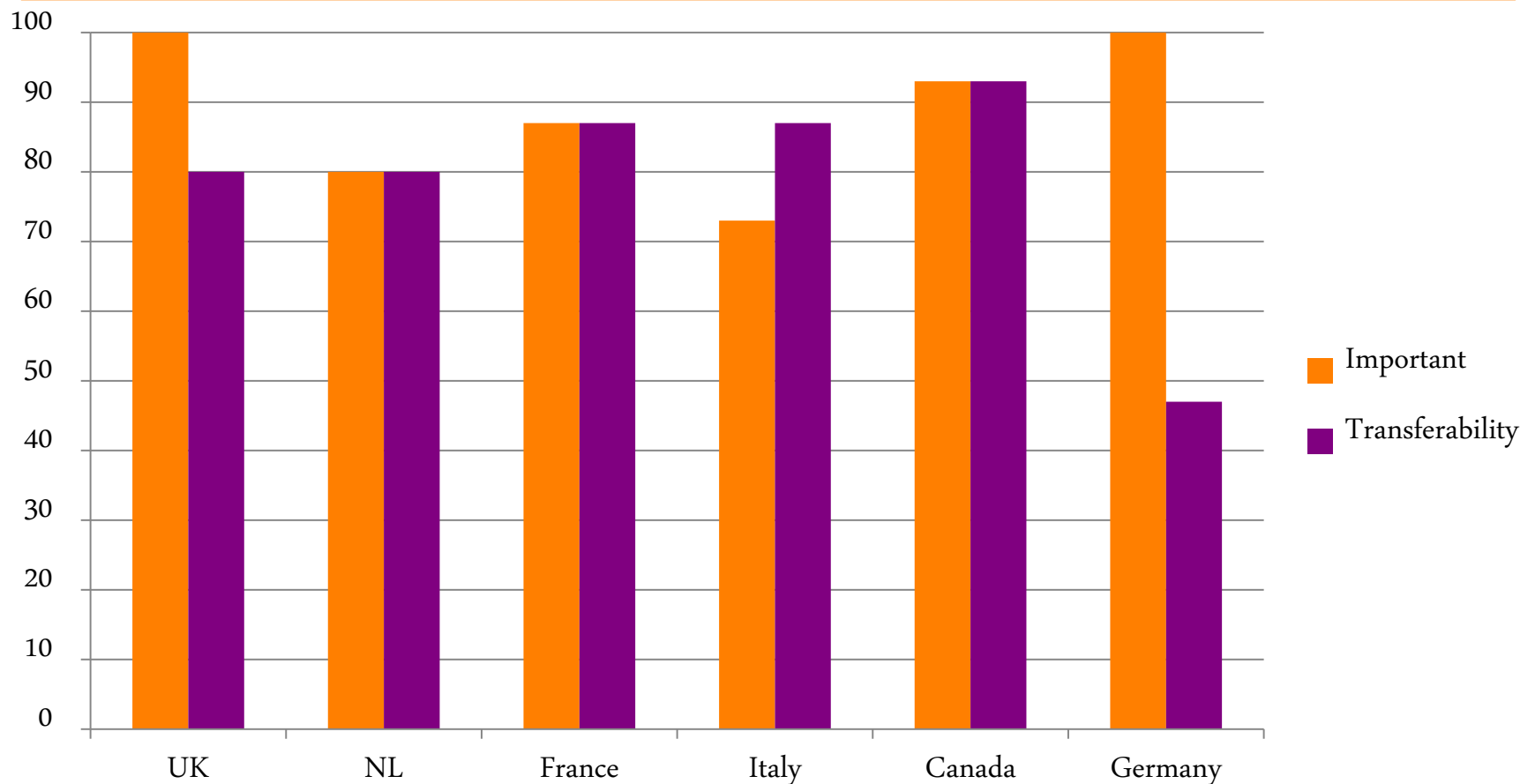
- There were three unimportant elements for 4 out of 6 countries.
 - C0040: What kind of risks for public and environment may occur when using the technology.
 - C0063: How can one reduce safety risks for professionals
 - C0064: How can one reduce safety risks for the environment

Domain 4:

Clinical Effectiveness is important in six countries and highly transferable



Topics include: Patient, ability to work, QoL, activities of daily living, benefit/harm, mortality, morbidity, need for other resources, patient satisfaction.



Affiliate Importance Ranking: UK & GER (100%), CAN, F, NL, ITA (73%). Range from 100% to 73%

Affiliate Transferability Ranking: CAN (93%), F, ITA, NL, UK, GER (47%). Range from 93% to 47%

GPMA Importance Ranking: Range from 100% to 73%

Domain 4: Clinical Effectiveness

Missing /
Recommendation

- Recommendation: Re-name Domain 4, to “Clinical efficacy & effectiveness”
 - Clinical efficacy addresses RCT and clinical effectiveness includes real world evidence and indirect treatment comparisons.
 - Indirect Treatment Comparisons including MTCs

Unclear

- D0003 “what is the effect of the technology on the mortality due to causes other than the target disease.”
- D0017: “Was the use of the technology worthwhile”(patient satisfaction.) Relates more to PROs.

Duplicated

- Combine assessment elements which relate to HRQoL and Disease specific QoL.
- Combine elements relating to overall mortality and disease specific mortality.

Unimportant

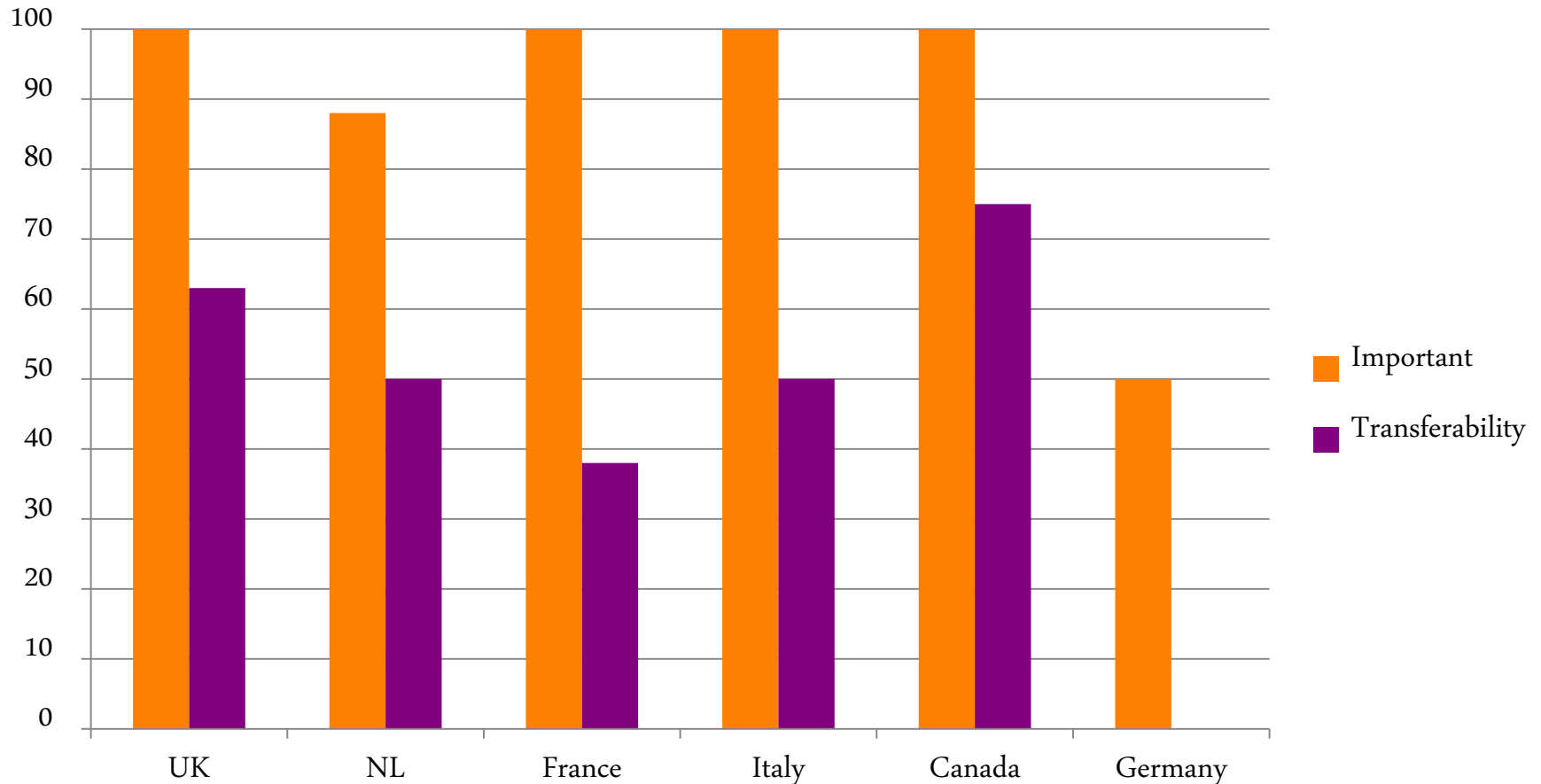
- There were no unimportant elements for 4 out of 6 countries

Domain 5:

Costs and economic evaluation-important in UK, France, Canada, Netherlands,Italy and less important in Germany



Topics include: resource utilisation, costs and outcomes,uncertainties & model validities



Affiliate Importance Ranking: UK, F, ITA & CAN (100%), NL, GER (50%). Range from 100% to 50%

Affiliate Transferability Ranking: CAN (75%), UK, NL, ITA, F, GER (0%). Range from 75% to 0%

GPMA Importance Ranking: Range from 100% to 87%

Duplicated

- Combine assessment elements E0012 and E0010 which relate to characterizing uncertainty and the validity of the model

Unimportant

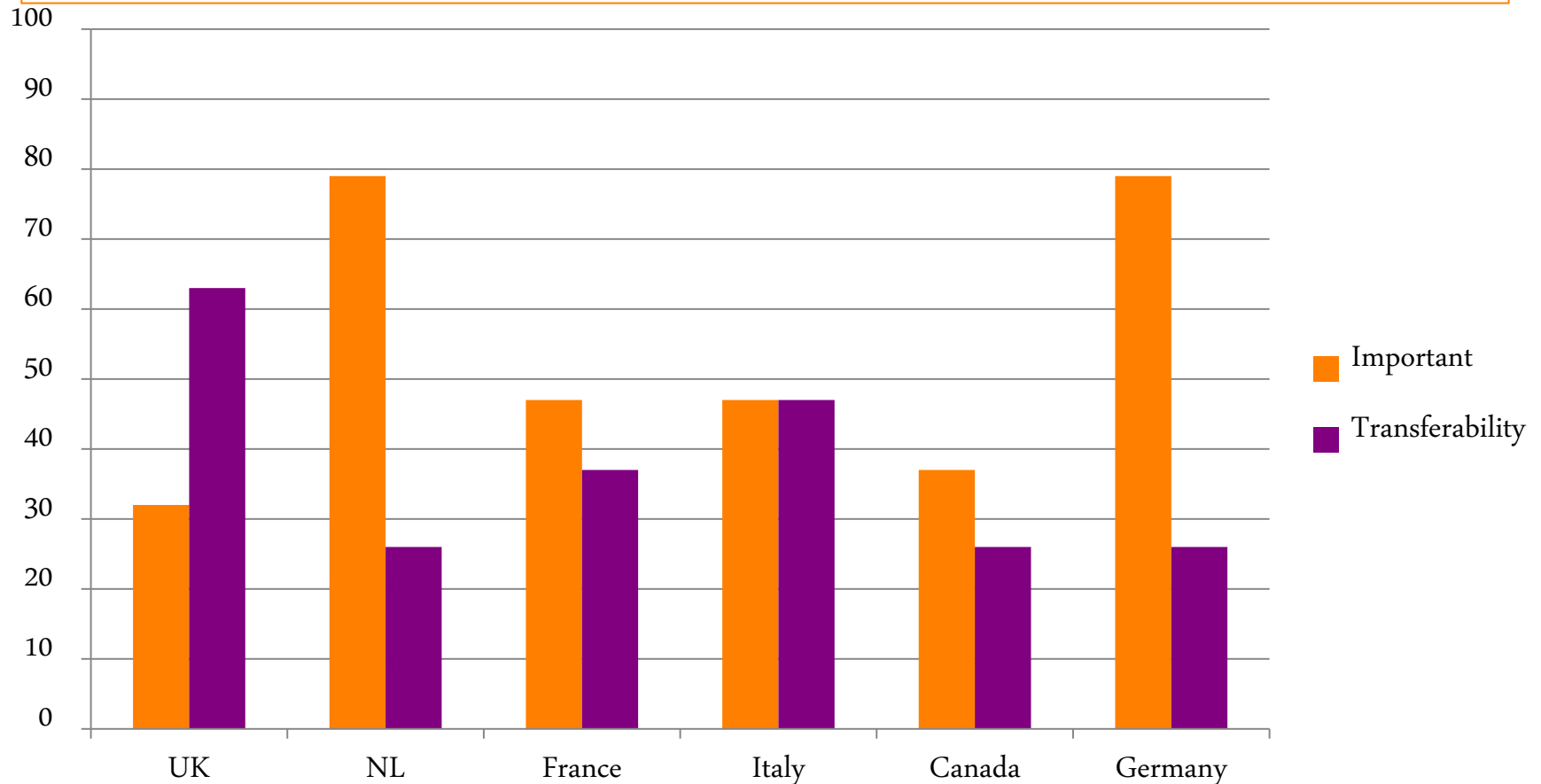
- There were no unimportant elements for 4 out of 6 countries

Domain 6:

Ethical Analysis is important in Germany and Netherlands



Topics include: benefit versus harm to patient and other stakeholders, vulnerable patients' autonomy, human dignity, respect for persons, equity, non-discrimination.



Affiliate Importance Ranking: NL & GER (79%), ITA, F, CAN, UK (32%). Range from 79% to 32%

Affiliate Transferability Ranking: UK (63%), ITA, F, NL & CAN & GER (26%). Range from 63% to 26%

GPMA Importance Ranking: Range from 100% to 42%

Domain 6: Ethical Analysis

Comments

- This domain is hard to measure quantitatively
- Roche lacks the capabilities internally to address some of the ethical elements.
- Germany would like to have a statement from an ethical committee relating to certain trial designs e.g. cross-over studies

Unclear

- Many elements were unclear for example:
- F0014 “basic human rights” are not well defined
- F0101 “Does the technology invade the sphere of privacy of the patient or user.?”

Duplicated

- This domain could be reduced to fewer questions

Unimportant

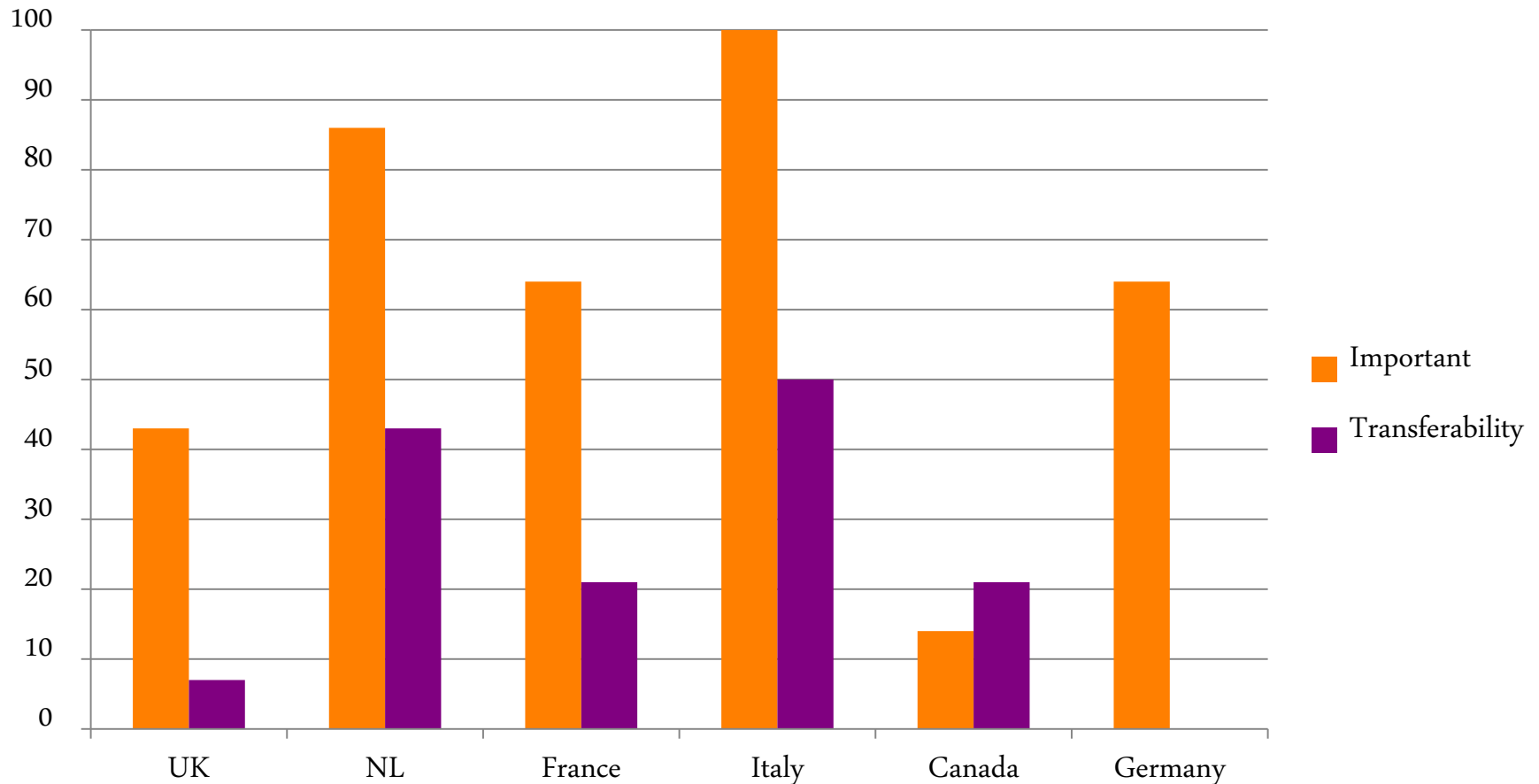
- There were three unimportant elements for 4 out of 6 countries.
 - F0007 Autonomy: Does the implementation or withdrawal of the technology challenge or change professional values, ethics or traditional roles
 - F0009 Respect for persons: Does the implementation or use of the technology affect the user’s moral, religious or cultural integrity
 - F0013 Justice and Equity: How are technologies with similar ethical issues treated in the health system

Domain 7:

Organizational aspects are important in Italy, Netherlands, Germany and France



Topics include: current work processes, patient flow, training & education, quality assurance, access to care, process related costs and management issues.



Affiliate Importance Ranking: ITA (100%), NL, F, GER, UK, CAN (14%). Range from 100% to 14%

Affiliate Transferability Ranking: ITA (50%), NL, CAN, F, UK, GER (0%). Range from 50% to 0%

GPMA Importance Ranking: Range from 64% to 36%

Recommendations

- Consider moving some of the assessment elements to Domain 5 eg: structure of health care and process related costs elements.
- EUnetHTA to consider inviting broader stakeholders to review and populate different Domains.
 - For example Clinicians could contribute towards Domain 7.
 - Patient associations could contribute towards Domain 8 and Regional and Local

Unimportant

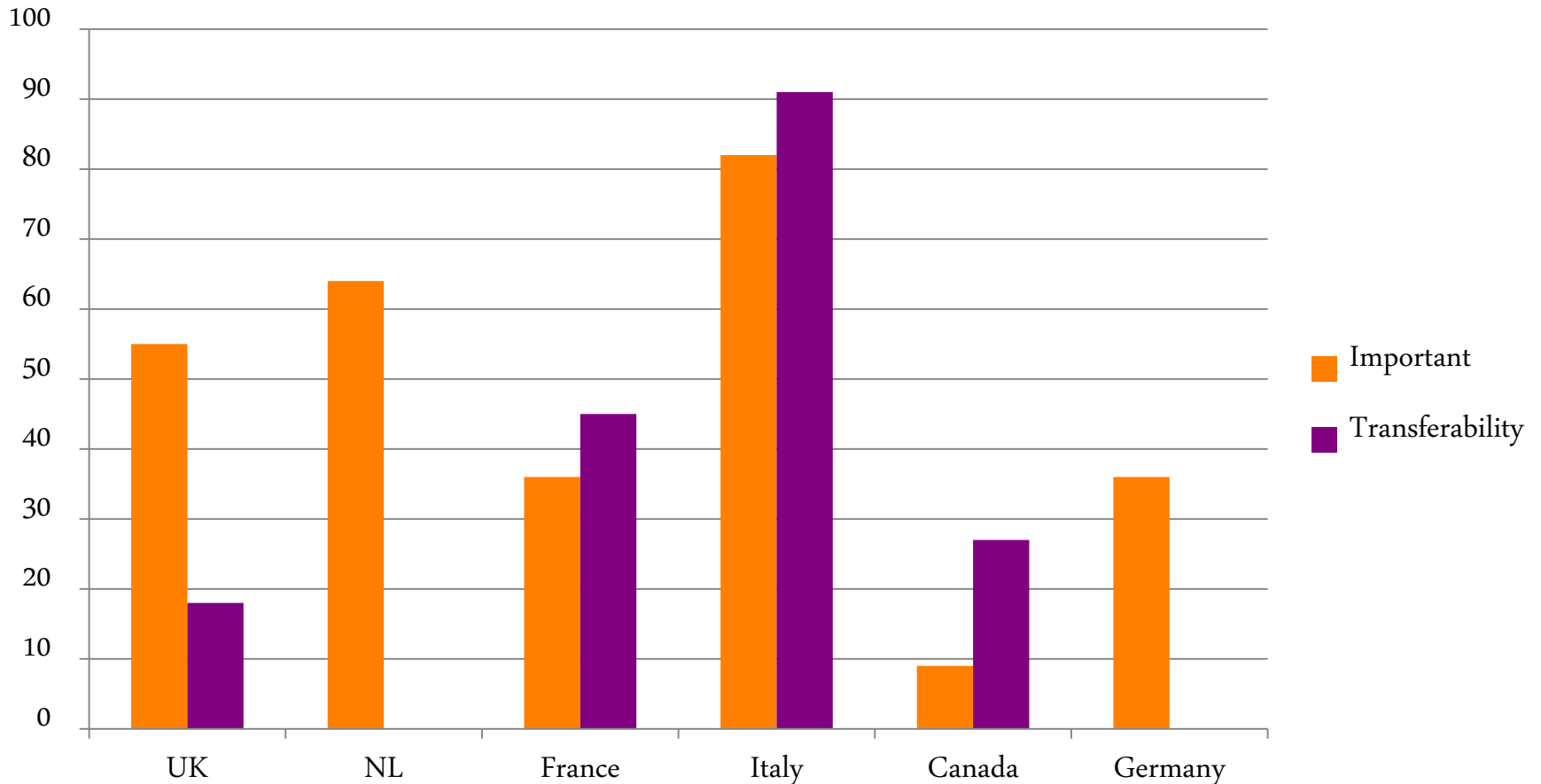
- There is one unimportant element for 4 out of 6 countries.
 - G0012 Health Delivery Process: How is the quality assurance and monitoring system of the new technology organized.

Domain 8:



Social aspects are important in Italy, Netherlands and UK

Topics include: patient support, resources, impact on patient's lives, broader social impact



Affiliate Importance Ranking: ITA (82%), NL, UK, GER, F, CAN (9%). Range from 82% to 9%

Affiliate Transferability Ranking: ITA (91%), F, CAN, UK, GER & NL (0%). Range from 91% to 0%

GPMA Importance Ranking: Range from 100% to 27%

Recommendations

- Rename this Domain to Patient/Caregiver and Society
- Consider moving Patient assessment elements to one domain.
- Data could be captured beyond HRQoL to capture caregiver data.

Unclear

- H0004: it is not clear which “major life areas” are being considered.

Duplicated

- Many patient related elements are already captured in Domain 4.

Unimportant

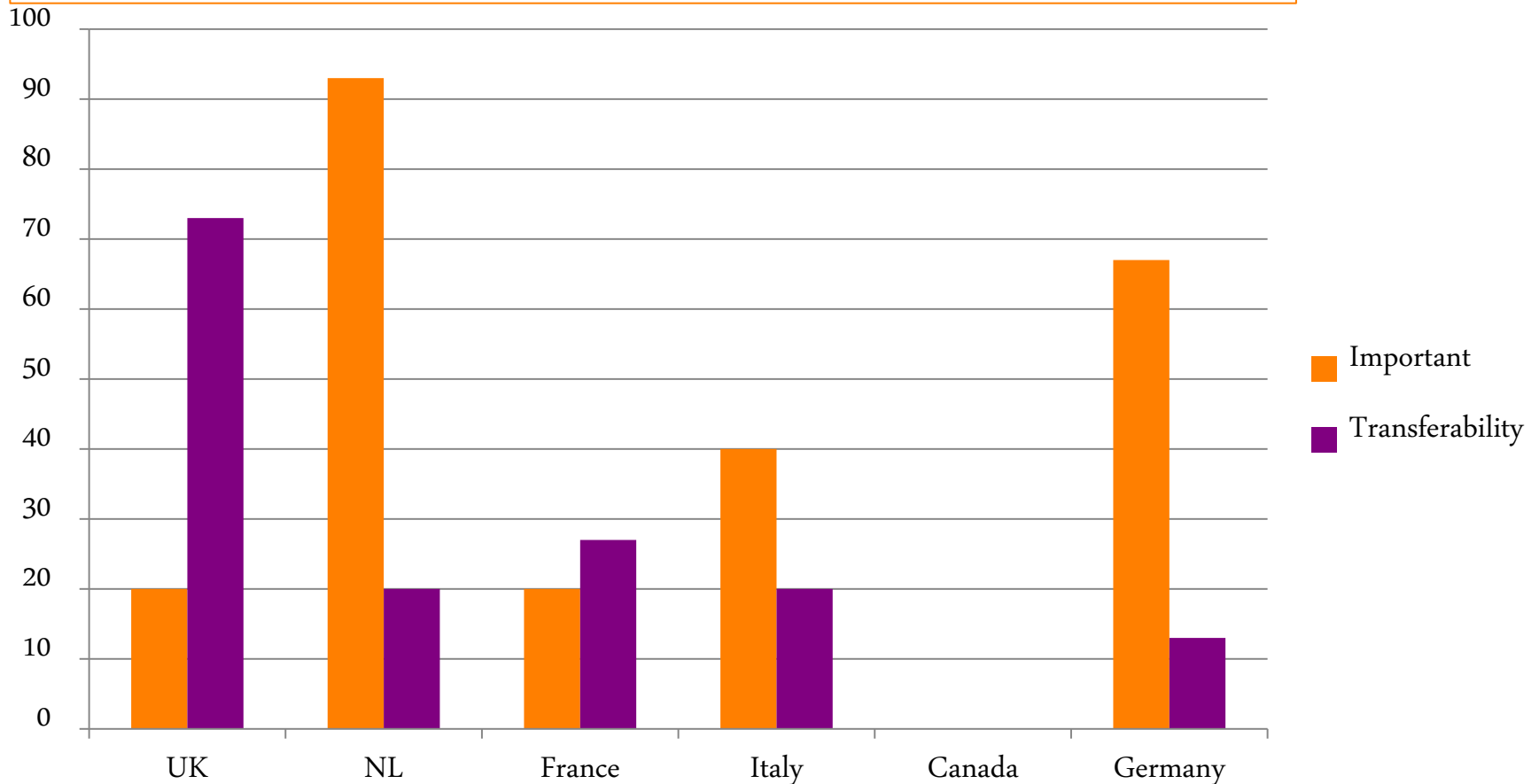
- There were three unimportant elements for 4 out of 6 countries.
 - H0011 Major life areas: What kinds of reactions and consequences can the introduction of technology cause at the overall society level.
 - H0007: Information exchange: What is the knowledge and understanding of the technology in patients and citizens?
 - H0013: Information exchange: What are the social obstacles or prospects in the communication about technology

Domain 9:

Legal aspects are important in Netherlands and Germany and moderately important in Italy



Topics include: patient consent, privacy, equality in healthcare, ownership and liability, market regulation, Intellectual property



Affiliate Importance Ranking: NL (93%), GER, ITA, UK, F, CAN (0%). Range from 93% to 0%

Affiliate Transferability Ranking: UK (73%), F, ITA & NL, GER, CAN (0%). Range from 73% to 0%

GPMA Importance Ranking: Range from 100% to 7%

Domain 9: Legal Aspects

Comments

- It is not clear how the legal assessment elements fits into the discussion with the payers.
- There is a capability gap within Roche relating to some of the assessment elements in the legal domain for example: patient privacy.

Unclear

- I0027: Regulation of market: Are there relevant concerns of conflicts of interest concerning the preparation of binding rules and their implementation?

Duplicated

- I0002 & I0005 could be clustered together as they relate to “autonomy of the patient.”
- **Move to Domain 2:** “What authorizations and register listings does the technology have? “(I0015)
“What are the legal requirements for the safety of the technology and are they fulfilled in practice”(I0017)

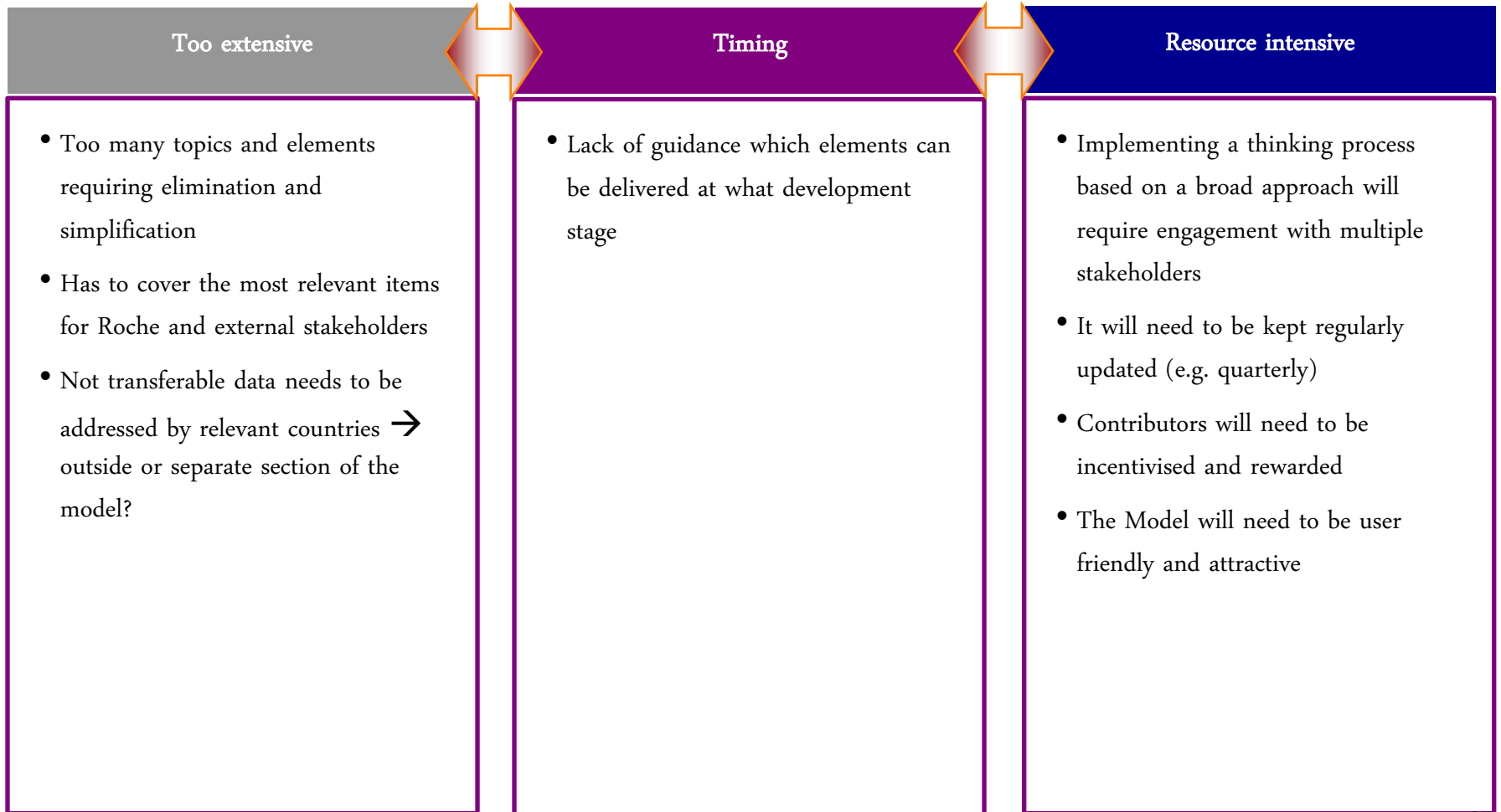
Unimportant

- There were six unimportant elements for 4 out of 6 countries.
- They related to ownership and liability and regulations of the market

Affiliates' suggestions for Roche Core Model

- Roche Core Model could be a living, regularly updated document, which should provide evidence and rationale along the product life-cycle for:
 - guidance on the payer and pricing strategy
 - Preparing for HTA submission and benefit assessments
 - P&R negotiations at national level and sub-national level
 - Engagement with broader stakeholders (payers, physicians, policy makers, patients)
 - Enable broader thinking relating to value message development
- Information needs to be referenced and clearly explained
- Key messages & information for each domain could be developed
- Market Access/Payer Strategy could be addressed in a separate document

The current EUnetHTA Core Model has challenges for internal adoption



Conclusions

- The HTA Core Model is a [useful, comprehensive framework](#)
- Roche 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 not considered sufficiently
 - Domains 5 -9 involve local data/activities – less transferrable
- Roche is exploring adapting the [HTA Core Model for internal use](#)
- Both Roche and external stakeholders need to [consider value more broadly](#)
 - Provides ability to adequately demonstrate value potential of a health technology
- Roche suggested some changes on the core model to EUnetHTA

Potential Benefits of implementing an adaptation of the HTA Core Model in Roche



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

- To become more efficient in global and local planning towards the **development of HTA evidence**
- To **exchange and use** HTA evidence as part of affiliate HTA submissions in a systematic framework
- To align a common and **broader perspective on value**

Roche is considering adapting the HTA Core Model

Plans are in their Early Stages & will evolve during 2015



Evidence Generation

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

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

Doing now what patients need next