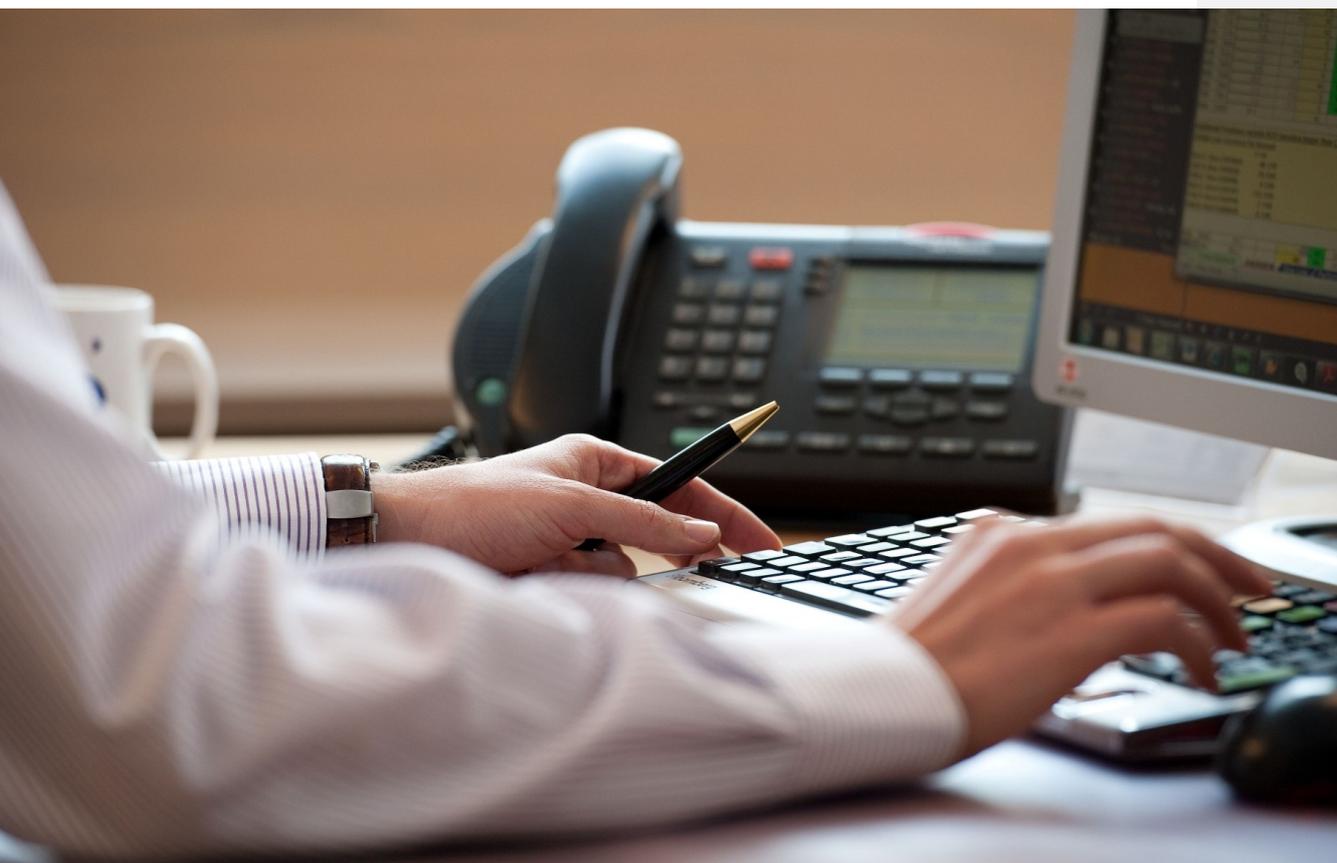




**EUnetHTA Core Model Questionnaire
Appendix 2**

*Unimportant Elements with Reasons by
individual country-not aggregated*



Unimportant Elements

1. Health Problem and Current Use of the Technology

Target condition

A0003	What are the known risk factors for the disease or health condition?
Country:	Reasons as to why it is not important:
UK	How a patient got to be diagnosed is not of relevance to decision makers.

1. Health Problem and Current Use of the Technology

Current management of the condition

A0018	What are the other typical or common alternatives to the current technology?
Country:	Reasons as to why it is not important:
Germany	The centre of the assessment is the comparison against the standard of care in the respective patient populations.

1. Health Problem and Current Use of the Technology

Utilization

A0012	What kind of variations in use are there across countries/regions/settings?
Country:	Reasons as to why it is not important:
France	Depends on epidemiology. This may be interesting, but the data are difficult to collect for some pathologies (regional level) due to the lack of registry
Germany	The use in the local market is considered relevant.

1. Health Problem and Current Use of the Technology

Utilization

G0009	Who decides which people are eligible for the technology and on what basis?
Country:	Reasons as to why it is not important:
Canada	In most cases, this data is not important, however we have examples where this data is required for reimbursement. For example, Erivedge was reimbursed with clear guidance on who the key actors were in deciding the use of the technology. In those instances, this would be a "4 = very important"

1. Health Problem and Current Use of the Technology

Utilization

B0003 What is the phase of development and implementation of the technology and the comparator(s)?

Country: Reasons as to why it is not important:

Canada This information is often used to demonstrate an additional value, for example if we change methods of administration, however, we are unsure of the value proposition from the payer's perspective.

Germany If a decision about an added benefit is limited for a certain period, this decision is based on the available data (or lack of data). "Innovation" in terms of new mechanisms of action etc. is not considered of relevance.

1. Health Problem and Current Use of the Technology

Utilization

F0001 Is the technology a new, innovative mode of care, an add-on to or modification of a standard mode of care or replacement of a standard mode of care?

Country: Reasons as to why it is not important:

Germany Whether the pharmaceutical is an add-on or a replacement to an established product is stated in the label. The SoC is derived from a review of approved substances and clinical guidelines/recommendations.

2. Description and technical characteristics of technology

Features of the technology

B0003b What is the phase of development and implementation of the technology and the comparator(s)?

Country: Reasons as to why it is not important:

Canada This information is often used to demonstrate an additional value, for example if we change methods of administration, however, we are unsure of the value proposition from the payer's perspective.

Germany please also see qB3.

2. Description and technical characteristics of technology

Investments and tools required to use the technology

B0007	What material investments are needed to use the technology?
Country:	Reasons as to why it is not important:
Canada	For most drugs, this information is not relevant. For drugs that are accompanied by companion diagnostics, this data would be very important.
Italy	not so relevant for pharma
UK	Unlikely to drive decision making

2. Description and technical characteristics of technology

Investments and tools required to use the technology

B0008	What kind of special premises are needed to use the technology and the comparator(s)?
Country:	Reasons as to why it is not important:
Canada	This information is only required in very rare instances where the drug requires this technology. We have not yet encountered this. Even still, this information more relevant at a local level, as opposed to a national/regional HTA level.
Germany	Usually the price of these facilities is not directly related to the drug.
Netherlands	Not required for national HTA However, could be helpfull/important hospital preparation
UK	Unlikely to drive decision making.

2. Description and technical characteristics of technology

Investments and tools required to use the technology

B0010	What kind of data and records are needed to monitor the use of the technology and the comparator?
Country:	Reasons as to why it is not important:
Canada	For most drugs, data and record monitoring is not required. Some rare occurrences, this may be required.
UK	Unlikely to drive decision making.

2. Description and technical characteristics of technology

Investments and tools required to use the technology

B0011	What kinds of registers are needed to monitor the use of the technology and comparator?
Country:	Reasons as to why it is not important:
Canada	For most drugs, data and record monitoring is not required. Some rare occurrences, this may be required.

2. Description and technical characteristics of technology

Training and information needed to use the technology

B0012	What kind of qualification and quality assurance processes are needed for the use or maintenance of the technology?
Country:	Reasons as to why it is not important:
Germany	Not part of the assessment.
Italy	not so relevant for pharma
Netherlands	Not required for national HTA process
UK	Unlikely to drive decision making.

2. Description and technical characteristics of technology

Training and information needed to use the technology

B0013	What kind of training and information is needed for the personnel/carer using this technology?
Country:	Reasons as to why it is not important:
Germany	Not part of the assessment.
UK	Unlikely to drive decision making.

2. Description and technical characteristics of technology

Training and information needed to use the technology

B0014	What kind of training and information should be provided for the patient who uses the technology, or for his family?
Country:	Reasons as to why it is not important:
Canada	In some instances, we may provide this information to pre-emptively address any concerns the payers may have with regards to patient administration.
Germany	If a special training is necessary for the administration of the drug (as stated per label), the costs are added to budget impact calculation.
Netherlands	Not required for national HTA process However could be helpful for implementation in practice
UK	Unlikely to drive decision making.

2. Description and technical characteristics of technology

Training and information needed to use the technology

B0015	What information of the technology should be provided for patients outside the target group and the general public?
Country:	Reasons as to why it is not important:
Canada	We do not understand "outside the target group and the general public" - who would this be in reference to?
Netherlands	Not required
UK	Unlikely to drive decision making. Upside to business case.

3. Safety

Patient safety

C0004	How does the frequency or severity of harms change over time or in different settings?
Country:	Reasons as to why it is not important:
Canada	This issues is only important if the commercialized version being launched is not the same as the one from the clinical trial (eg. alk inhibitor and SLS-content)

3. Safety

Patient safety

C0007	Are there special issues in the use of the technology that may increase the risk of harmful events?
Country:	Reasons as to why it is not important:
Netherlands	Generally not included in national HTA submission, in specific cases we could include in our submission

3. Safety

Occupational safety

C0020	What kind of occupational harms can occur when using the technology?
Country:	Reasons as to why it is not important:
Canada	There are some rare exceptions where this data were very important - typically when there is extreme risk to the professional, however these drugs are rare.
Germany	Not part of the assessment.
Netherlands	Not included in national HTA process
UK	Unlikely to drive decision making.

3. Safety

Environmental safety

C0040	What kind of risks for public and environment may occur when using the technology?
Country:	Reasons as to why it is not important:
France	It doesn't seem to be important for most products. But it could be important for some products (no examples in mind).
Germany	Not part of the assessment.
Netherlands	Not required for national HTA process
UK	Unlikely to drive decision making.

3. Safety

Safety risk management

C0060 How does the safety profile of the technology vary between different generations, approved versions or products?

Country: Reasons as to why it is not important:

Canada Duplication of question C0004

3. Safety

Safety risk management

C0061 Can different organizational settings increase or decrease harms?

Country: Reasons as to why it is not important:

Canada Duplication of C0004

UK Unlikely to drive decision making.

3. Safety

Safety risk management

C0063 How can one reduce safety risks for professionals (including technology-, user-, and patient-dependent aspects)?

Country: Reasons as to why it is not important:

Germany Not part of the assessment.

Netherlands Not required for national HTA process

UK Unlikely to drive decision making.

3. Safety

Safety risk management

C0064 How can one reduce safety risks for environment (including technology-, user-, and patient-dependent aspects)?

Country: Reasons as to why it is not important:

Germany Not part of the assessment.

Netherlands Not required for national HTA process

UK Unlikely to drive decision making.

3. Safety

Safety risk management

C0062 How can one reduce safety risks for patients (including technology-, user-, and patient-dependent aspects)?

Country: Reasons as to why it is not important:

UK Unlikely to drive decision making.

4. Clinical Effectiveness

Function

D0014 What is the effect of the technology on work ability?

Country: Reasons as to why it is not important:

Germany Not part of the assessment.

Netherlands For clinical value assessment not important (not required), but for cost-effectiveness analysis national data on work absenteeism is mandatory (i.e. according to the guidelines a societal perspective should be used).

4. Clinical Effectiveness

Function

D0015	What is the effect of the technology on return to previous living conditions?
Country:	Reasons as to why it is not important:
Canada	This kind of information would need to be converted to a utility score to be used in a CUA. While this information may be important, it would have to be obtained in a scale that is recognized by our HTA bodies (i.e. EQ-5D, HUI-III, etc.)
Germany	Not part of the assessment.

4. Clinical Effectiveness

Function

D0016	How does use of the technology affect activities of daily living?
Country:	Reasons as to why it is not important:
Germany	An improvement in patient reported outcomes and HRQoL relative to the appropriate comparative therapy is an important aspect in the value proposition. However, for the demonstration of these benefits RCT-data is necessary.

4. Clinical Effectiveness

Mortality

D0002	What is the expected beneficial effect on the disease-specific mortality?
Country:	Reasons as to why it is not important:
Germany	Not part of the assessment. Only OS.

4. Clinical Effectiveness

Mortality

D0003	What is the effect of the technology on the mortality due to causes other than the target disease?
Country:	Reasons as to why it is not important:
France	Except for side effects
Germany	Not part of the assessment. Only OS.
Netherlands	Very unimportant as it is already an integral part of the overall survival measure (see: D0001)

4. Clinical Effectiveness

Change-in management

D0010	How does the technology modify the need for hospitalization?
Country:	Reasons as to why it is not important:
Germany	Not part of the assessment

4. Clinical Effectiveness

Change-in management

D0023	How does the technology modify the need for other technologies and use of resources?
Country:	Reasons as to why it is not important:
Germany	Not part of the assessment.
Italy	wrong domain (should be an organizational topic)

4. Clinical Effectiveness

Patient satisfaction

D0017	Was the use of the technology worthwhile?
Country:	Reasons as to why it is not important:
Germany	Only PRO, HRQoL considered relevant.
Netherlands	QoL is required, we assume 'patients' overall perception' is broader and is therefore not required.

5. Costs and economic evaluation

Resource utilization

E0001	What types of resources are used when delivering the assessed technology and its comparators (resource-use identification)?
Country:	Reasons as to why it is not important:
Germany	Additional costs of the intervention and the comparator (on the basis of the SmPC) are included in the calculation of the total budget impact and the price negotiation.

5. Costs and economic evaluation

Resource utilization

E0002	What amounts of resources are used when delivering the assessed technology and its comparators (resource-use measurement)?
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Country: Reasons as to why it is not important:

Germany Additional costs of the intervention and the comparator (on the basis of the SmPC) are included in the calculation of the total budget impact and the price negotiation.

5. Costs and economic evaluation

Resource utilization

E0009 What were the measured and/or estimated costs of the assessed technology and its comparator(s) (resource-use valuation)?

Country: Reasons as to why it is not important:

Netherlands We will use national unit prices of the resources to estimate total costs. Consequently, we are not interested in international cost data.

5. Costs and economic evaluation

Measurement and estimation of outcome(s)

E0005 What is (are) the measured and/or estimated health-related outcome(s) of the assessed technology and its comparator(s)?

Country: Reasons as to why it is not important:

Germany At the moment ICER is not part of the assessment.

Italy shouldn't it be included in the 4th domain?

5. Costs and economic evaluation

Examination of costs and outcomes

E0006 What are the estimated differences in costs and outcomes between the technology and its comparator(s)?

Country: Reasons as to why it is not important:

Germany At the moment ICER is not part of the assessment.

5. Costs and economic evaluation

Characterizing uncertainty

E0010 What are the uncertainties surrounding the costs and economic evaluation(s) of the technology and its comparator(s)?

Country: Reasons as to why it is not important:

Germany At the moment ICER is not part of the assessment.

5. Costs and economic evaluation

Characterizing heterogeneity

E0011 To what extent can differences in costs, outcomes, or 'cost effectiveness' be explained by variations between any subgroups using the technology and its comparator(s)?

Country: Reasons as to why it is not important:

Germany At the moment ICER ist not part of the assessment.

5. Costs and economic evaluation

Validity of the model(s)

E0012 To what extent can the estimates of costs and outcomes or from economic evaluation(s) be considered as providing valid descriptions of the technology and its comparator(s)?

Country: Reasons as to why it is not important:

Germany At the moment ICER ist not part of the assessment.

6. Ethical Analysis

Beneficence/nonmaleficence

F0100 What is the severity level of the health condition that the technology is directed to?

Country: Reasons as to why it is not important:

UK This is already provided in an earlier domain

6. Ethical Analysis

Beneficence/nonmaleficence

F0011 What are the benefits and harms of the technology for other stakeholders (relatives, other patients, organizations, commercial entities, society etc.)?

Country: Reasons as to why it is not important:

Canada This type of information is something we can use to develop our value proposition, but whether or not our HTA bodies will accept it is uncertain. -That is why we decided it is somewhat unimportant.

6. Ethical Analysis

Beneficence/nonmaleficence

F0003 Are there any other hidden or unintended consequences of the technology and its applications for different stakeholders (patients/users, relatives, other patients, organizations, commercial entities, society etc.)?

Country: Reasons as to why it is not important:

Canada Bio-ethics is rarely a focus from our HTA bodies. Some advocacy groups may use this information but not for our submission purposes.

UK Unlikely to drive decision making.

6. Ethical Analysis

Autonomy

F0005 Is the technology used for patients/people that are especially vulnerable?

Country: Reasons as to why it is not important:

Netherlands Local legislation and label decides whether or not it can be used in these groups of people.

6. Ethical Analysis

Autonomy

F0004 Does the implementation or use of the technology affect the patient's capability and possibility to exercise autonomy?

Country: Reasons as to why it is not important:

Canada This is not of concern for our HTA bodies.

UK Unlikely to drive decision making.

6. Ethical Analysis

Autonomy

F0006 Is there a need for any specific interventions or supportive actions concerning information in order to respect patient autonomy when the technology is used?

Country: Reasons as to why it is not important:

UK Unlikely to drive decision making.

6. Ethical Analysis

Autonomy

F0007 Does the implementation or withdrawal of the technology challenge or change professional values, ethics or traditional roles?

Country: Reasons as to why it is not important:

Netherlands Not formally assessed, but may influence use in daily practice. Important that technology will be included in guidelines.

UK Unlikely to drive decision making.

6. Ethical Analysis

Respect for persons

F0008 Does the implementation or use of the technology affect human dignity?

Country: Reasons as to why it is not important:

UK Dignity is not a protected characteristic in the UK.

Comment [BK1]: Wording?

6. Ethical Analysis

Respect for persons

F0009 Does the implementation or use of the technology affect the user's moral, religious or cultural integrity?

Country: Reasons as to why it is not important:

Netherlands Will not be assessed by payers.

6. Ethical Analysis

Justice and Equity

F0012 How does implementation or withdrawal of the technology affect the distribution of health care resources?

Country: Reasons as to why it is not important:

UK Implied within CE thresholds

6. Ethical Analysis

Justice and Equity

F0013 How are technologies with similar ethical issues treated in the health care system?

Country: Reasons as to why it is not important:

Netherlands Will not be assessed.

6. Ethical Analysis

Justice and Equity

H0012 Are there factors that could prevent a group or person from gaining access to the technology?

Country: Reasons as to why it is not important:

Netherlands Not applicable.

6. Ethical Analysis

Legislation

F0016 Can the use of the technology pose ethical challenges that have not been considered in the existing legislations and regulations?

Country: Reasons as to why it is not important:

UK Unlikely to drive decisions. Only ethics considered in terms of equalities legislation.

6. Ethical Analysis

Ethical consequences of the HTA

F0102 Does the economic evaluation of the technology contain any ethical problems?

Country: Reasons as to why it is not important:

Italy not linked to this domain

7. Organizational aspects

Health delivery process

G0001 How does the technology affect the current work processes?

Country: Reasons as to why it is not important:

Canada Some of the data would be useful at the local level (i.e. hospitals and institutions) but our HTA bodies (federal and regional) do not focus on this.

7. Organizational aspects

Health delivery process

G0002 What kind of involvement has to be mobilized for patients/participants and important others?

Country: Reasons as to why it is not important:

UK Unlikely to drive decision making

7. Organizational aspects

Health delivery process

G0003 What is the process ensuring proper education and training of the staff?

Country: Reasons as to why it is not important:

UK Unlikely to drive decision making

7. Organizational aspects

Health delivery process

G0004 What kind of co-operation and communication of activities have to be mobilized?

Country: Reasons as to why it is not important:

UK Unlikely to drive decision making

7. Organizational aspects

Health delivery process

G0012 How is the quality assurance and monitoring system of the new technology organized?

Country: Reasons as to why it is not important:

Netherlands Quality assurance is important, but will not be assessed by the payer but by the local registration authorities.

UK Unlikely to drive decision making.

7. Organizational aspects

Structure of health care

G0005 How do decentralization or centralization requirements influence the implementation of the technology?

Country: Reasons as to why it is not important:

UK Unlikely to drive decision making.

7. Organizational aspects

Structure of health care system

G0101 What are the processes ensuring access to care of the new technology for patients/participants?

Country: Reasons as to why it is not important:

Canada We may be able to use geographical information.

7. Organizational aspects

Process-related costs

G0006	What are the processes related costs for purchasing and setting up the new technology?
Country:	Reasons as to why it is not important:
Canada	Cost of testing (i.e. a companion diagnostic) may be relevant in the future but currently, our HTA bodies do not explicitly evaluate this added cost.
UK	Unlikely to drive decision making.

7. Organizational aspects

Management

G0008	What management problems and opportunities are attached to the technology?
Country:	Reasons as to why it is not important:
Netherlands	Not formally assessed, but of course important with regard to uptake,

7. Organizational aspects

Management

G0009b	Who decides which people are eligible for the technology and on what basis?
Country:	Reasons as to why it is not important:
Canada	May be important in rare cases.

7. Organizational aspects

Culture

G0011	How are the other interest groups taken into account in the planning / implementation of the technology?
Country:	Reasons as to why it is not important:
UK	Unlikely to drive decision making.

8. Social aspects

Individual

H0100	What kind of changes do patients or citizens expect?
Country:	Reasons as to why it is not important:
Netherlands	Will not be assessed.
UK	Unlikely to drive decision making

8. Social aspects

Individual

H0003	What kind of support and resources are needed for the patient or citizen as the technology is introduced?
Country:	Reasons as to why it is not important:
UK	Unlikely to drive decision making

8. Social aspects

Individual

H0004	What kind of changes may the use of the technology generate in the individual's role in the major life areas?
Country:	Reasons as to why it is not important:
Canada	This is only important if it is incorporated into a quality of life survey to elicit utilities

8. Social aspects

Individual

H0006	How do patients, citizens and the important others using the technology react and act upon the technology?
Country:	Reasons as to why it is not important:
Canada	Is only factored in a fullsome QoL analysis
France	Depend on the disease (mental disease) Important if we consider the patient's preference for the use of a technology (eg subcutaneous product vs IV) but the clarification doesn't seem to take it into account.

8. Social aspects

Individual

H0012b Are there factors that could prevent a group or persons to participate?

Country: Reasons as to why it is not important:

Canada Only thing of concern for us is a geographic aspect.

8. Social aspects

Major life areas

H0001 Which social areas does the use of the technology influence?

Country: Reasons as to why it is not important:

France It could be used for the value proposition at regional level but it is not a major criteria

8. Social aspects

Major life areas

H0011 What kinds of reactions and consequences can the introduction of the technology cause at the overall society level?

Country: Reasons as to why it is not important:

Netherlands Will not be assessed.

8. Social aspects

Major life areas

H0009 What influences patients' or citizens' decisions to use the technology?

Country: Reasons as to why it is not important:

Netherlands Will not be assessed.

UK Does not determine outcome of HTA but does determine level of access - likely to be country specific.

8. Social aspects

Information exchange

H0007	What is the knowledge and understanding of the technology in patients and citizens?
Country:	Reasons as to why it is not important:
UK	Does not determine outcome of HTA but does determine level of access - likely to be country specific.

8. Social aspects

Information exchange

H0013	What are the social obstacles or prospects in the communication about the technology?
Country:	Reasons as to why it is not important:
Netherlands	Will not be assessed.
UK	Does not determine outcome of HTA but does determine level of access - likely to be country specific.

9. Legal aspects

Autonomy of the patient

I0002	What kind of legal requirements are there for providing appropriate information to the user or patient?
Country:	Reasons as to why it is not important:
France	Regulatory aspects
UK	Patients are required to receive detailed information (pharmacy) relating to a medicine.

9. Legal aspects

Autonomy of the patient

I0005	What kind of legal requirements are there to obtain informed consent from the user or patient?
Country:	Reasons as to why it is not important:
France	Regulatory aspects
UK	Patients are required to receive detailed information (pharmacy) relating to a medicine and medicines are prescribed after patients are aware of benefits and harms.

9. Legal aspects

Autonomy of the patient

I0034	Who is allowed to give consent for minors and incompetent persons?
Country:	Reasons as to why it is not important:
France	The decision of consent is not an HTA concern
UK	Does not drive decision making

9. Legal aspects

Privacy of the patient

I0009	What do laws/ binding rules require from appropriate measures for securing patient data?
Country:	Reasons as to why it is not important:
France	It is the responsibility of the regulator
UK	Does not drive decision making.

9. Legal aspects

Equality in health care

I0011	What do laws/ binding rules require from appropriate processes or resources to guarantee equal access to the technology?
Country:	Reasons as to why it is not important:
UK	Does not drive decision making.

9. Legal aspects

Authorization and safety

I0017	What are the legal requirements for safety of the technology and are they fulfilled in practice?
Country:	Reasons as to why it is not important:
UK	Does not drive decision making.

9. Legal aspects

Ownership and liability

I0019 What should be known about the intellectual property rights and potential licensing fees?

Country: Reasons as to why it is not important:

UK Does not drive decision making

9. Legal aspects

Ownership and liability

I0021 What should be known of the legal or binding rules about the width, depth and length of the manufacturers guarantee?

Country: Reasons as to why it is not important:

France Not applicable for drugs

UK Does not drive decision making.

9. Legal aspects

Regulation of the market

I0024 What kind of regulations are there for acquisition and use of the technology?

Country: Reasons as to why it is not important:

UK Does not drive decision making.

9. Legal aspects

Regulation of the market

I0025 What legal restrictions are there for marketing the technology to the patients?

Country: Reasons as to why it is not important:

UK Does not drive decision making.

9. Legal aspects

Regulation of the market

I0026 What should be known about the legal issues in cases of new technologies where the current legislation is not directly applicable?

Country: Reasons as to why it is not important:

France Regulatory aspects

UK Would not be considered by HTA

9. Legal aspects

Regulation of the market

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

Country: Reasons as to why it is not important:

UK Does not drive decision making.
