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European Federation of Pharmaceutical Industries and Associations

Avoiding duplication – using European reports in national processes

Results of an EFPIA internal survey

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Disclaimer

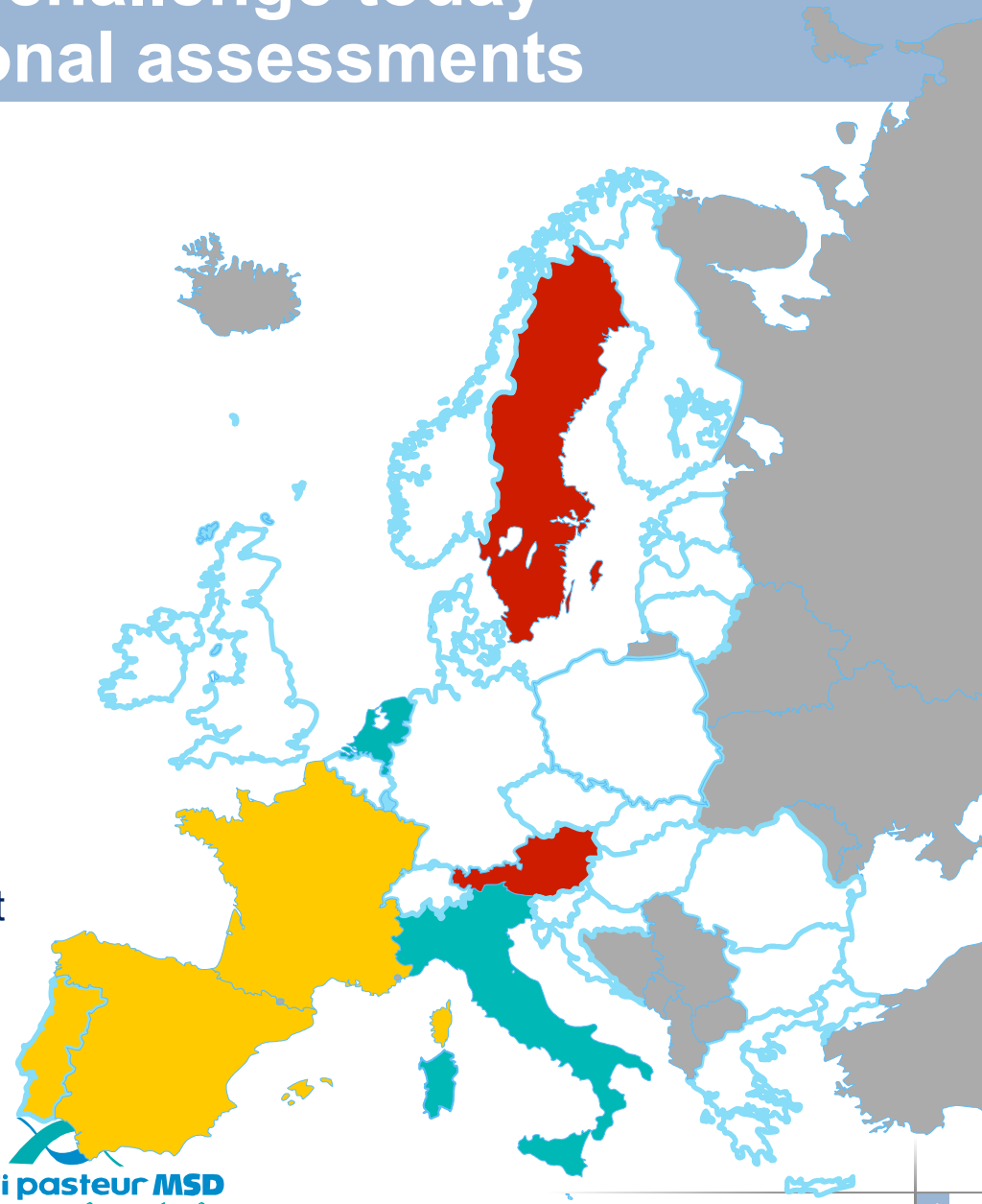
- The EFPIA survey is an internal exercise based on EFPIA national associations' input, summarised by the EFPIA secretariat.
- Although great care was taken to appropriately reflect the national situations, the results were not peer-reviewed. Some responses received were more detailed than others.
- The survey only includes information from a limited set of Member States; populous countries with advanced HTA systems (France, Germany, England), with regional systems (Italy, Spain), and mid-sized countries with advanced HTA systems (Belgium, Netherlands). The experience of smaller countries and those less experienced in HTA is not included.
- The survey was based on EFPIA's understanding of the EUnetHTA activities on joint REA. Therefore, any modification to the understanding of joint REA would lead to additional considerations as regards to re-use.

Questions submitted to EFPIA associations

- What could the joint REA report replace at national level?
- Which national context-specific information would still be needed?
- Which national committee conducts the national assessment and therefore should be involved in the joint REA report production?
- What is the assessment used for nationally (appraisal)?
- Would any legislative change be needed to allow for the use of the joint REA report at the national level?
- What impact would the use of the joint REA report have on national P&R timelines?
- Likelihood of political acceptance and other considerations

Company experience of first EUnetHTA pilot Zostavax REA : Biggest challenge today the effective use in national assessments

- **AUSTRIA** | partial translation & use (LBI)
- **DENMARK** | use as part of the scientific assessment
- **FRANCE** I no acceleration (partial use by HAS)
- **ITALY** I support to use some regional funding decisions (Veneto, Liguria, Sicilia)
- **NETHERLANDS** I *'pilot in the pilot'* – fails to address public health priority – positive CVZ/ZiNL advice but interference with ongoing reforms of the vaccines decision-making
- **PORTUGAL** I use for reimbursement (Infarmed)
- **SWEDEN** I duplication of clinical assessment and contradictory assessment of the public health need
- **SPAIN** I use as Therapeutic Positioning & vaccine eligibility for reimbursement but process on-hold
- **OTHERS** I low awareness & underuse



sanofi pasteur MSD
vaccines for life

Q: What could the joint REA report replace at national level?
A: Elements identified by EFPIA associations

	What	By whom	For what
England	Review of clinical effectiveness	Evidence Review Group (ERG - external academic group) Commissioned by NICE	ERG economic evaluation, feeding into NICE Appraisal Committee discussion
France	Internal assessment	Service Évaluation des Médicaments (SEM) of HAS (internal service)	Feeds into Transparency Committee discussion and ASMR rating
Germany	Parts of IQWIG/ GBA assessment of added therapeutic value	IQWIG/GBA Commissioned by GBA	GBA appraisal on added therapeutic value

Q: What could the joint REA report replace at national level?
A: Elements identified by EFPIA associations

	What	By whom	For what
Italy	Assessment	AIFA Technical Scientific Committee (composed of external experts)	Supporting discussion at Pricing Committee
Spain	Therapeutic Positioning Report	Spanish Medicines Agency Expert Committee, incl. representatives of regions	
Belgium	Review of medical evidence (clinical and safety part)	Internal evaluator of the INAMI (one of 12 INAMI staff, all members of the Reimbursement Commission)	For endorsement at the Reimbursement Commission, decision on ATV Yes/No
Netherlands	REA	Zorginstituut Nederland ZiNL WAR committee	

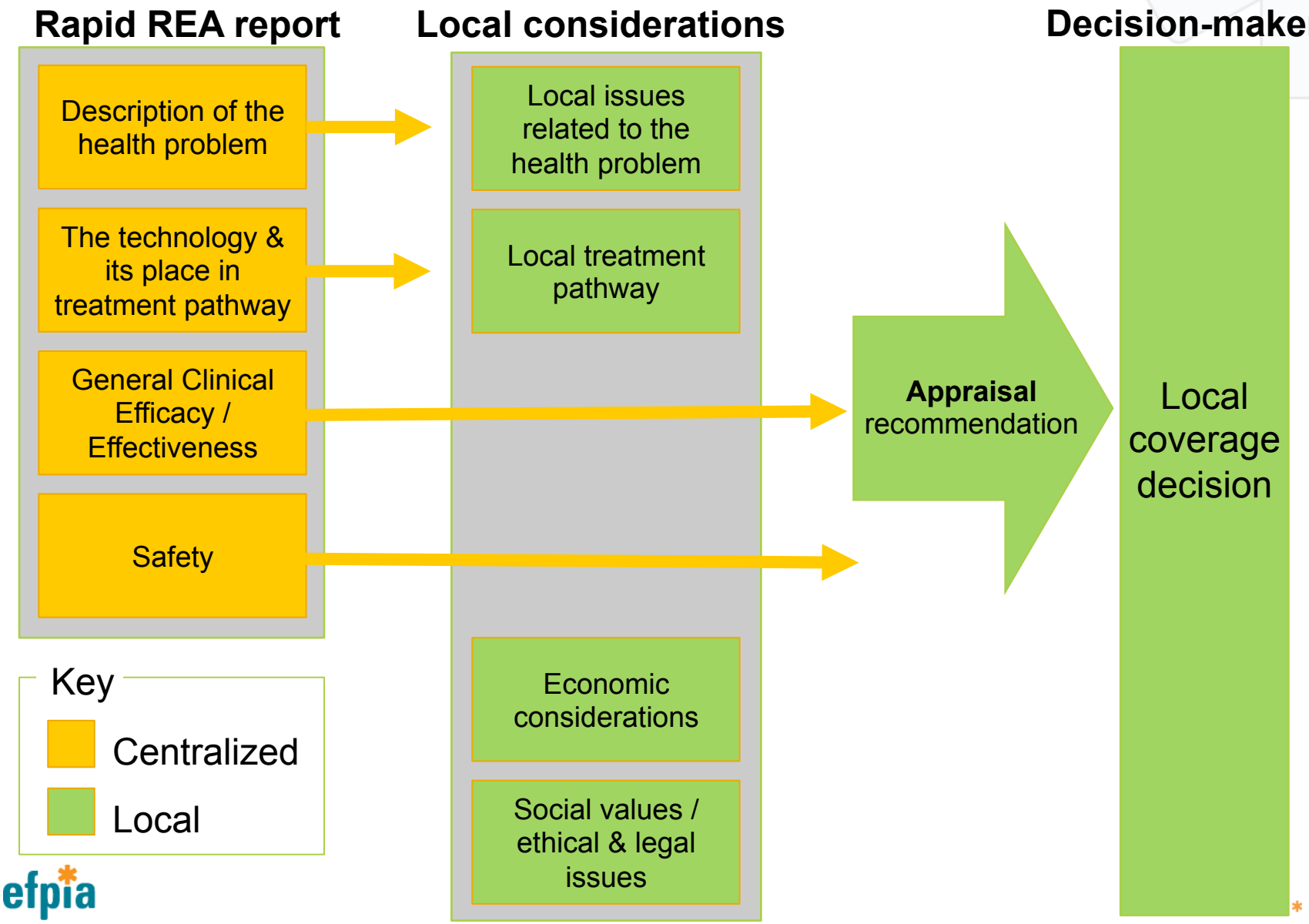
EFPIA associations also underline that national elements would be needed to complement the joint REA, e.g.

	Complement in description	Complement in economics and HC syst. org.
England		Cost-utility analysis
France	Target population, place in therapeutic strategy, impact on public health, severity of disease	
Germany	Size (prevalence) of theoretical population (per subgroup), quality demands regarding use	Cost of therapy and comparator(s)
Italy		Impact on Health Budget and on healthcare organization
Spain		Pharmacoeconomic evaluation and budget impact analysis
Netherlands	Position in therapy, comparator, nat. guidelines, specific patient (sub) groups, doctors input	Budget impact, criteria for clustering
Belgium	Some parts of the clinical review	Budget Impact & Health Economic evaluation

Some associations underlined that a joint REA can only work if:

- There is upfront agreement on key features such as
  - Comparator
  - Endpoints
  - Patient population
  - Study design
- This can be discussed in a scoping meeting
- But a more effective way to address these issues could be to discuss upfront, during development, through scientific advice involving the relevant assessment bodies; ideally this would be achieved in a joint scientific advice process, involving regulators and HTA bodies

EFPIA understanding of joint REA versus local information



Q: Would any legislative change be needed to allow for the use of the joint REA report at the national level?
Q: Which national committee conducts the national assessment and therefore should be involved in the joint REA report production?

- 4 out of 7 countries considered that a review of guidelines could ensure use of joint REA at the national level
- Germany, Italy, Spain indicated legislative change would be needed
- Relevant agencies/assessors not always aware of or aligned with European debate
  - Some agencies included to date, which have no role in the national 'access pathway'
  - Some relevant agencies do not involve national assessors in the European exercise

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Q: What impact would the use of the joint REA report have on national P&R timelines?

- In order not to lead to delays, a joint REA should be available quickly:
  - Before MA in UK, Netherlands
  - Within 4-6 weeks after MA in France, Germany
  - Others unclear

Q: Likelihood of political acceptance and other considerations

- Interest yes, commitment no
- Scientific advice considered necessary prerequisite in a number of countries
- Political positive statements, not always followed by scientific and technical commitments
- In some countries, awareness of discussion is very low
- All countries agree that appraisal and final decision always need to remain at a devolved level

Key learnings

- Direct incorporation possible, if relevant institution/ committee is involved
- For some systems, use of European reports will be easier than for others, given the structure of their access pathways
- In some countries, the need for legislative change to integrate European reports might act as a barrier
- Timing is a key issue: if not available early enough, European reports would delay processes and therefore patient access
- In countries where regional level heavily involved in determining access to medicines, interface with European and national levels more difficult to define

Who should be involved in the process moving forward? Key national functions identified

- France: Head of HAS Service Évaluation des Médicaments
- Germany: GBA Head of Medicine Department
- England: Director of the Centre for Health Technology Evaluation at NICE or Chair of NICE Appraisal Committee
- Italy: President of AIFA Technical Scientific Committee
- Spain: Head of Department of Human Medicines in the Spanish Medicines' Agency
- Belgium: Head of Department of INAMI internal evaluators
- Netherlands: Secretary of ZiNL WAR

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A European process should take the best of national experiences

- At a European level
  - Scoping meeting is key
  - Regular interactions with manufacturer to clarify outstanding questions and discuss submission are needed
- Involvement of industry in appraisal step remains a national issue

How can the HTA Network help re-use

- Reflect on European legislation to speed up things at the national level
- Identify and involve institutions and individuals responsible for national assessment within ‘access pathway’
- Develop and define a joint scientific advice process involving regulators and HTAs, to agree on key assessment elements upfront

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Q&A

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