



EU REA adoption at national level

Project scope and main findings

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Agenda

- Project objectives and process
- Identification of barriers and potential solutions
- Conclusions

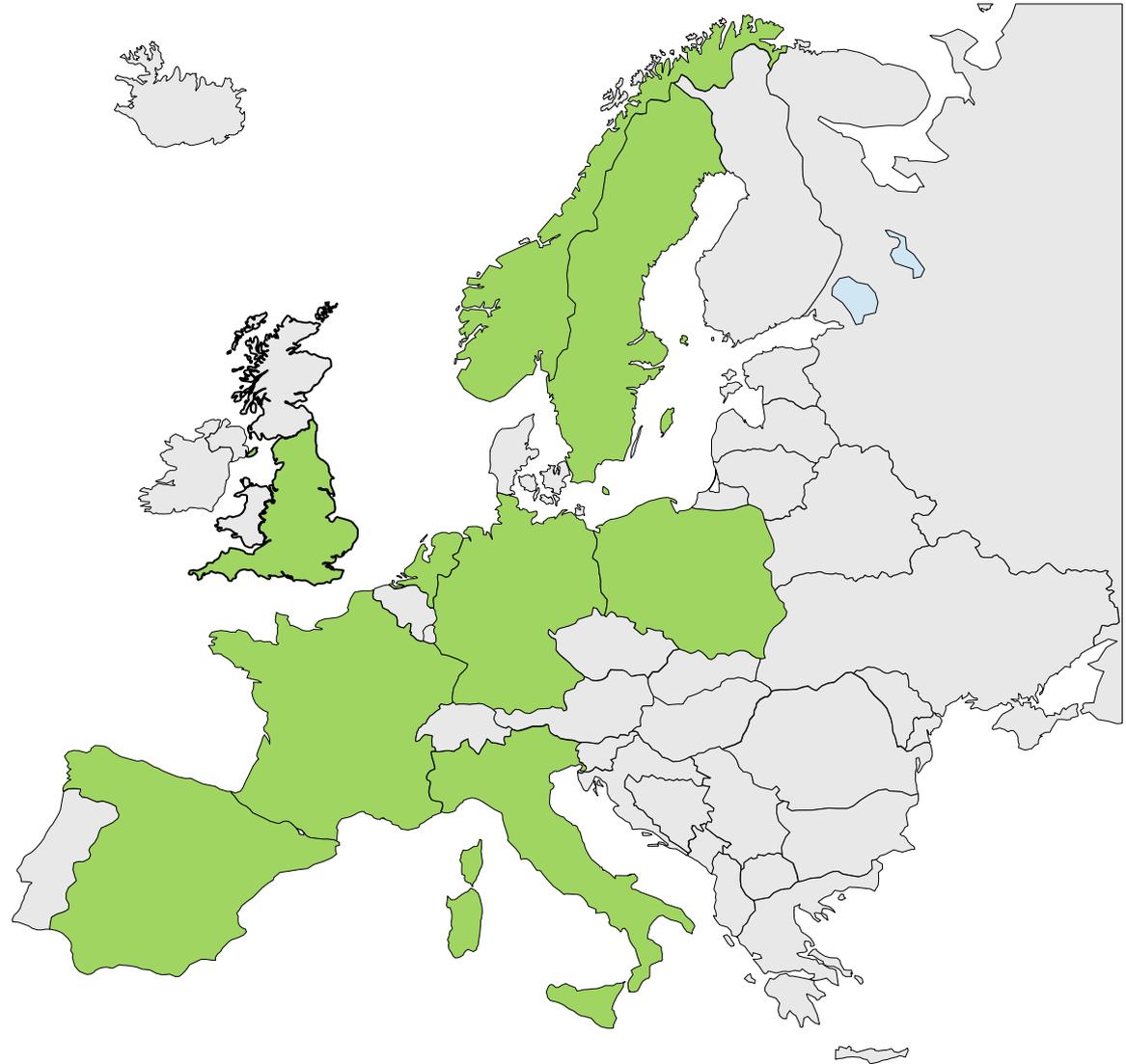
Project objectives

- The project had three steps:
 - **Step 1:** Develop materials to facilitate information sharing across national associations
 - Background material on EUnetHTA Joint Action 3
 - Structured template that guides national engagement on EU REA
 - **Step 2:** Provide support to EFPIA and national associations to share findings in a consistent way
 - Completion of the templates
 - Preparation of pre-workshop material
 - **Step 3:** Consolidate and analyse the completed templates for EFPIA identifying common barriers and drivers for national “adoption”
 - Preparation of pre- and after-workshop material

Wave 1 countries involved (9 countries in total)

Wave 1 countries

-  France
-  Germany
-  Italy
-  Netherlands
-  Norway
-  Poland
-  Spain
-  Sweden
-  England*



**HTA processes in Scotland and Wales are different from the process in England. While the ABPI is engaged to support EU REA adoption in all the UK countries, this analysis reports the findings for England only in order to avoid excessive complexity.*

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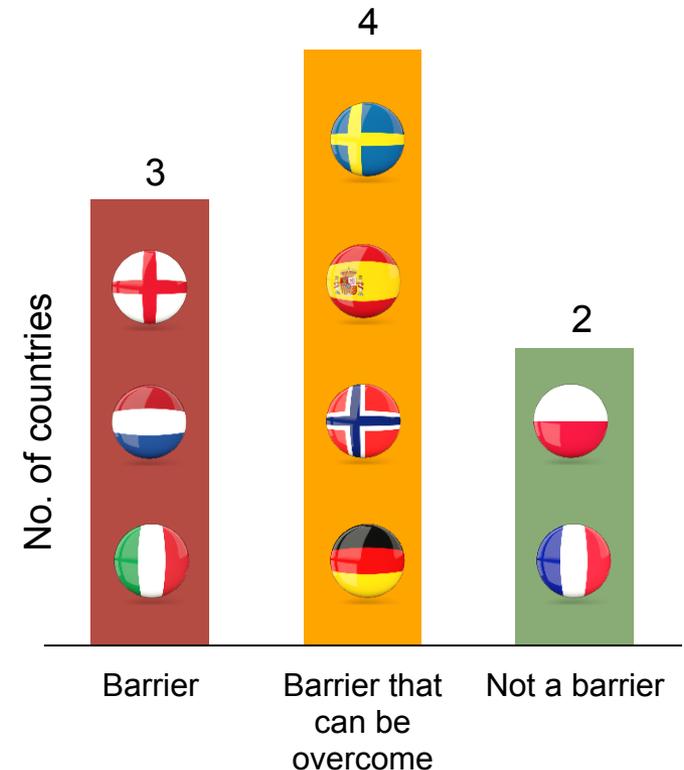
Analysis of the main findings

- The second step in the completed templates focused on:
 - The areas where EU REA has potential value
 - Barriers to adoptions of EU REAs
 - Possible actions to address these barriers at the national level and for the EUnetHTA process
- The analysis identified several potential barriers:
 1. Inconsistency between the EU REA and national HTA timelines
 2. Changes required in national laws and regulations
 3. Differences between EU REA and national HTA methodology
 4. Regionalisation of the HTA decisions
 5. Position of relevant stakeholders
- The analysis is based on the **currently available** information. In some countries, there are on-going assessments and dialogues which will provide additional information that will need to be incorporated.

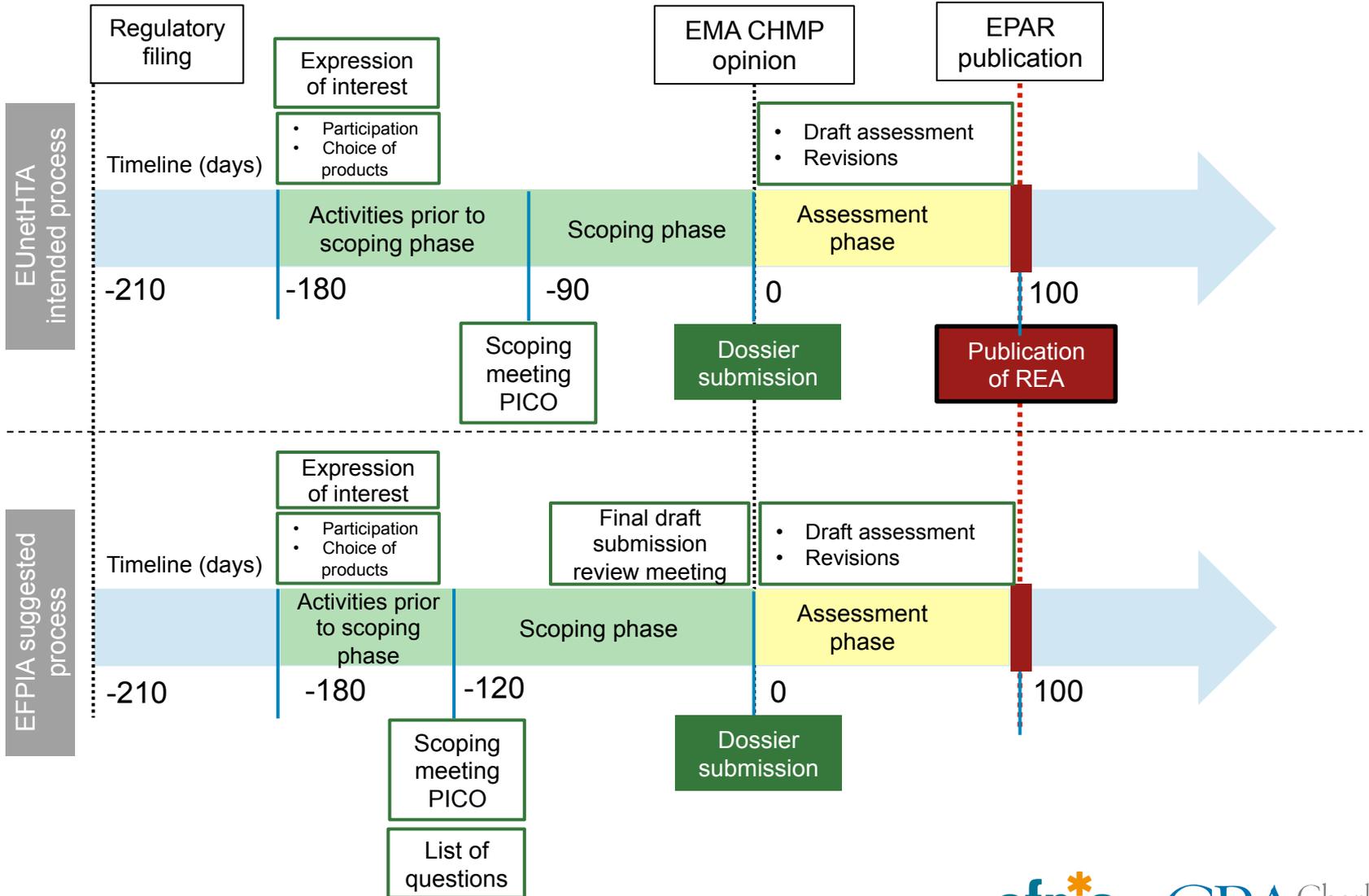
Inconsistency between the EU REA and national HTA timelines

Is the EUnetHTA timeline (i.e. publication of EU REA at the time EPAR is published) compatible with the national HTA processes?

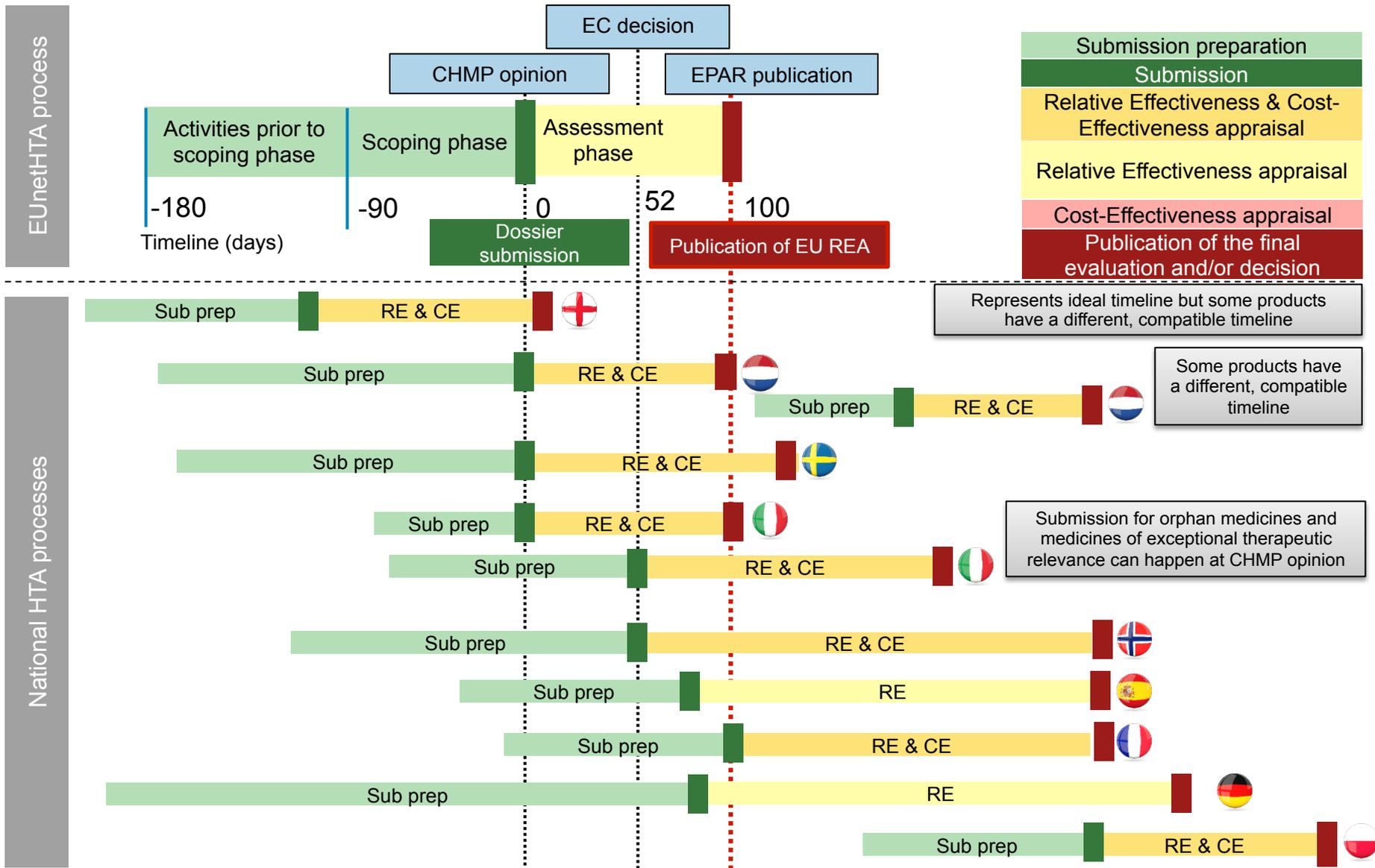
- Timeline appears to be a barrier in three countries [Italy, Netherlands, England], however, even here some products follow a different timeline, potentially compatible with the EUnetHTA process
- In some countries, EU REA could potentially replace national relative efficacy assessment, where timelines are compatible with the beginning of the national cost-effectiveness analysis [Norway, Sweden] or the national decision making process [Germany, Spain]
- In other countries, the national appraisal process begins after the publication of the EPAR [France, Poland]



Comparison between EUnetHTA intended process and EFPIA suggestion



Stylised comparison between EUnetHTA and national HTA timeline



Inconsistency between the EU REA and national HTA timelines

Potential barriers

- In some countries, the HTA process is completed before the publication of the EPAR (for some products)



- In some countries, the relative efficacy analysis begins before the publication of the EPAR



- In one country, the HTA appraisal starts with some considerable delay with respect to the publication of the EPAR – in this case the evidence in EU REAs may need to be updated



Possible solutions

- EUnetHTA and national processes could be coordinated (and this would require internal coordination by national HTA agencies staff and industry staff with the EU REA authors)
- Immediate adoption of EU REA would be possible for the products that do not follow the “major” HTA process. When the process for “non-standard” products is under development and EU REA process needs to be built into this process
- Adoption of EU REA would be compatible with national timelines if local adaption of EU REAs can be completed before the national relative efficacy analysis is usually completed to feed into cost-effectiveness appraisal. The incorporation of EU REAs in the national process depends on how it is structured
- It is rare that there are significant changes in the evidence over a period of one year, however there could be several solutions if this results to be a barrier

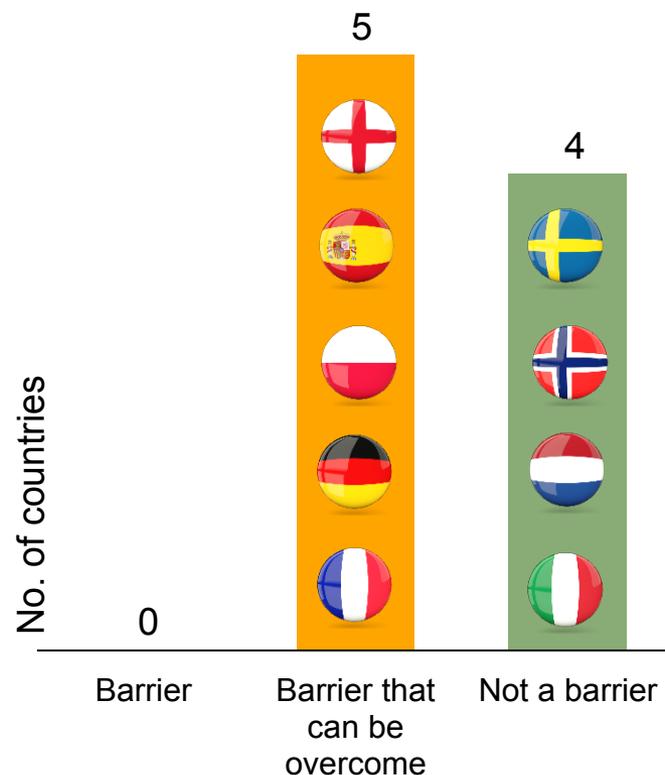
Type of products that can use the EU REA

Type of product		FRA 	DEU 	NOR* 	POL 	ESP 	SWE 	NLD 	ENG 
All	Including vaccines	✓		✓	✓	✓	✓		
	Except vaccines		✓						
Specific products	Medicines evaluated by regional committees								✓
	Orphan and specialised commissioning medicines								✓
	Hospital drugs (not in the 'Sluis') for which ZIN wants to do an assessment after the product is already (temporary) reimbursed on the market							✓	
<p><i>*Note: For Norway, all medicines assessed by NoMA.</i></p>									

Changes required in national laws and regulations

Are there any laws or regulations dictating the process and methodology of HTA/market access processes that need to be changed in order to adopt EU REA?

- This is a potential barrier in five countries [France, Germany, Poland, Spain, England]
- EU REAs need to be mandatory to be used in practice [Germany, Poland, Spain]
 - This can be particularly important where HTA agencies do not recognise the value or the quality of EU REAs [Germany, Poland]
 - If EU REA is not mandatory and not replacing the national process, the national HTA agency could ignore it if it disagrees with the methodology and/or outcomes
 - This would imply a delay in the appraisal process and a duplication of the efforts
- In two countries, it is necessary to have a formal change in the appraisal process and methodology [France, England]



Changes required in national laws and regulations

What changes would be required?

Changes in the legislation would be required to:

- In three countries, changes to the legislation are necessary to make EU REAs replacing national HTA (otherwise EU REAs would be considered as an additional input)



Mild barrier: Updates to the formal appraisal process within the HTA body would be necessary in order to adopt EU REA



Possible actions

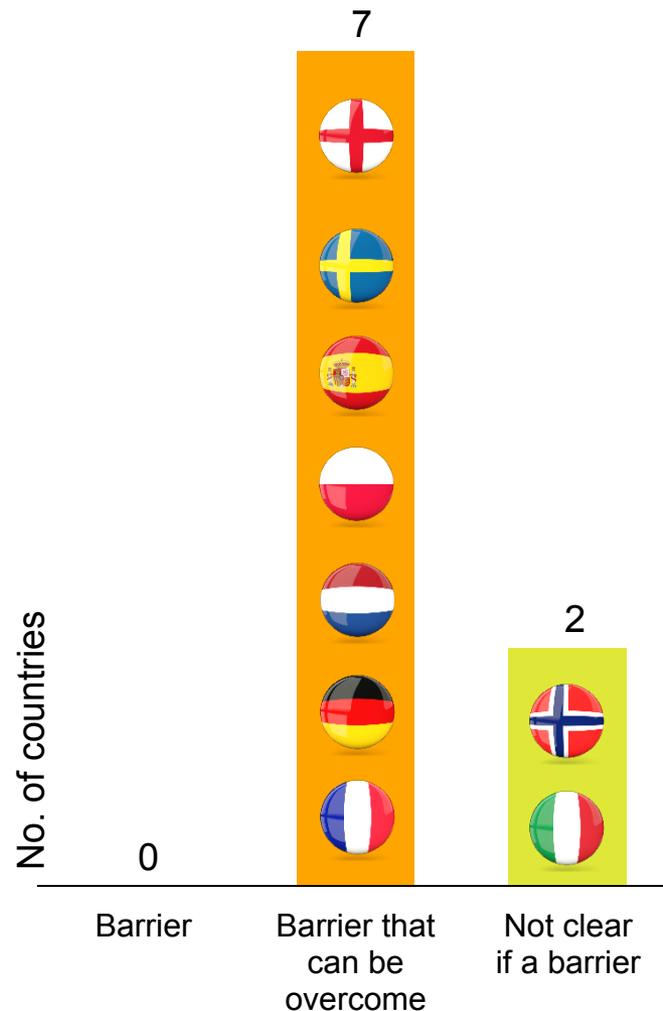
- More discussions amongst relevant stakeholders
- Clarify the difference between the assessment phases (European) and the appraisal that would still be undertaken by the national HTA
- Focus on the role of national HTA agencies in undertaking the EU REA and their ability to participate in the process
- Consider EU legislation to require Member States to change their national legislation to make adoption of EU REAs possible

Ensure that the formal appraisal process is updated to accept EU REAs

Differences between EU REA and national HTA methodology

Is national HTA methodology different with EUnetHTA's with respect to: outcomes (type of endpoints), choice of comparators, comparison methods, subgroup analysis?

- This is a potential barrier in eight countries [France, Germany, NL, Norway, Poland, Spain, Sweden, England]
- In other countries there are concerns about the possible implications of differences in the methodology [Italy, Norway]
- If EU REA is not mandatory and the national HTA agency does not accept EUnetHTA methodology (or does not trust the quality of EU REAs), national assessments may duplicate some of the EU REA



Differences between EU REA and national HTA methodology

What is the barrier?

Local acceptance of EUnetHTA:

- Choice of comparators*
 - At country level comparators could be different from EUnetHTA's 
 - At country level comparators could be selected to be the cheapest 
- Comparison methods
 - Local comparison methods may differ from EUnetHTA's 
 - Reluctance to use results from indirect comparisons 
- Choice of endpoints 
- Subgroup analysis
 - Subgroup identification at country level could be different 
 - Post-hoc subgroup analysis is not accepted 
- Willingness to follow a supra-national HTA decision 
- Willingness to recognise the quality of a supra-national HTA decision** 

Possible actions

- Discussion with the national HTA agency to establish what changes would be required to accept EUnetHTA methodology
- Clarification of the EU REA process and the potential for national HTA bodies to input into the scope of the REA and provide comments on the draft report

Engagement of national HTA agency in EUnetHTA discussions

* Italy also noted that choice of comparators is a very important parameter

** Italy also noted that authorities also consider crucial the quality of EU REA

Regionalisation of final decisions

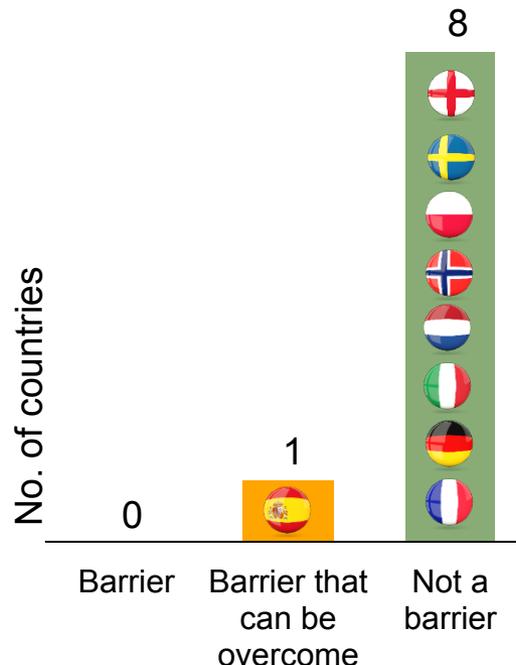
Are regional bodies taking final decisions based on local HTA that could neglect EU REAs?

- This is a potential barrier in one country [Spain]
 - If regions that undertake their own HTA appraisals do not recognise the value of EU REA, EUnetHTA assessments may not be influential in practice even if they are adopted at national level
- In other countries, the regional process has recently changed and it is not expected to represent a barrier [England]

What changes would be required?

Regional HTA agencies should recognise the value of EU REA and observe their conclusions in their respective territories 

In Italy, although regionalisation was historically important, nowadays it might not be perceived as a barrier. However, it remains a significant topic of debate strictly monitored at the local level.



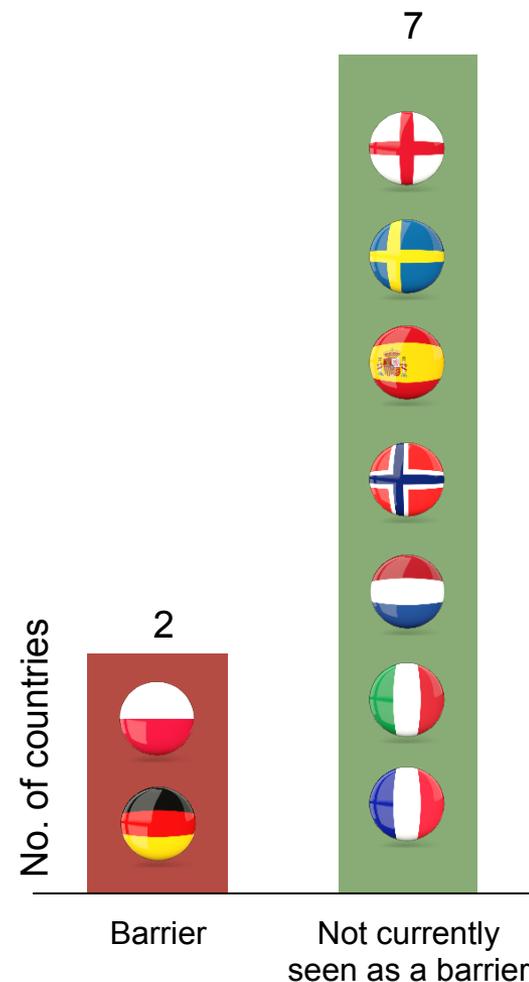
Possible actions

- Have greater co-ordination between the regional HTA and the central agency
 - This probably means that regional HTA agencies, provided they represent the central integrated system, could be directly involved in EUnetHTA assessments

Position of relevant stakeholders

Is there any lack of support to EU REA adoption from politicians, payers, patients, other stakeholders?

- This is a potential barrier in two countries [Germany, Poland]
- In other countries the position of key stakeholders is not currently seen as a barrier [France, Italy, Netherlands, Norway, Spain, Sweden, England]
- If key stakeholders do not support the national adoption of EU REAs, EUnetHTA assessments may not be adopted in practice at national level



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Conclusions

1. All of the countries identified some products where EU REA could be used in the national process but the type of product differs significantly – this is primarily determined by the timeline
 - In some countries, only products that do not follow the ‘standard’ process (typically orphan, more targeted therapies)
 - In others, all products could potentially use EU REA
2. This will require support from national government and HTA agencies in most markets and, although in most countries there is an understanding of the benefits, in some markets this is not the case. This support needs to be developed
3. There are issues associated with methodology which can be mitigated by greater understanding and contribution during the EU REA review process
4. In the majority of Wave 1 countries, although there are potential barriers, the use of REA is possible if stakeholders work together but these discussions at the national level are only now developing