Regulation/HTA

How to define common grounds

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Disclaimer

- *the views presented are personal and may not be understood or quoted as being made on behalf of or reflecting the position of AEMPS*

Two different objectives

Regulators

-Absolute Benefit/Risk

-No economic considerations involved

-Possibility of being on the market if similar on clinical grounds

Is the efficacy observed due to the MP? Does the efficacy compensate the safety profile?

HTAs

-Relative Benefit/Risk

-Economic considerations involved

-Not so clear that a MP should be on the market

What are we really paying for? Is it worth it? Do we have the budget to afford it?

How is it mainly done?

Regulators

-RCT
-Vs. placebo or one comparator (rarely ≥2)
- Primary endpoints may not be the most robust ones
-Option of CMA, exceptional circumstances

HTAs

-Indirect comparisons
-Preferrably all potential competitors
-Final endpoints

Is this understood?

Suerly we all have heard:

-Why is another molecule of the same type authorised?

-Why is this promising drug not reimbursed when it has been approved by accelerated/CMA/excepcional circumstances?

-There are so many barriers that a drug hardly reaches the market

Principal common goals

-Avoid uncertanties as much as possible

-Still allowing scientific developments

-Access to MP needed

Different approaches

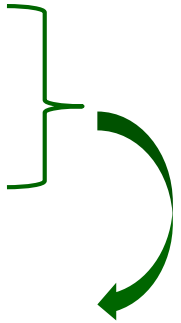
-Relaxing CT criteria (characteristics more in line with real world patients)

-Post-authorisation studies more focused on HTA /economic considerations

-Considering further information (beyond CT) by the time of the authorisation

-CT considering (EMA and HTA) approaches

-Trying to reach a common European HTA position



Parallel consultation with regulators and health technology assessment bodies and Rapid Relative Effective Assessments EUnetHTA

Parallel consultation

-Prospective feedback from EMA and HTAs

-Information usefull to future MAH

-Divergencies may be minimized (e.g three arm trial)

-No need for consensus

-Not mandatory. Is it followed by MAHs?

-Does it really increase market access?

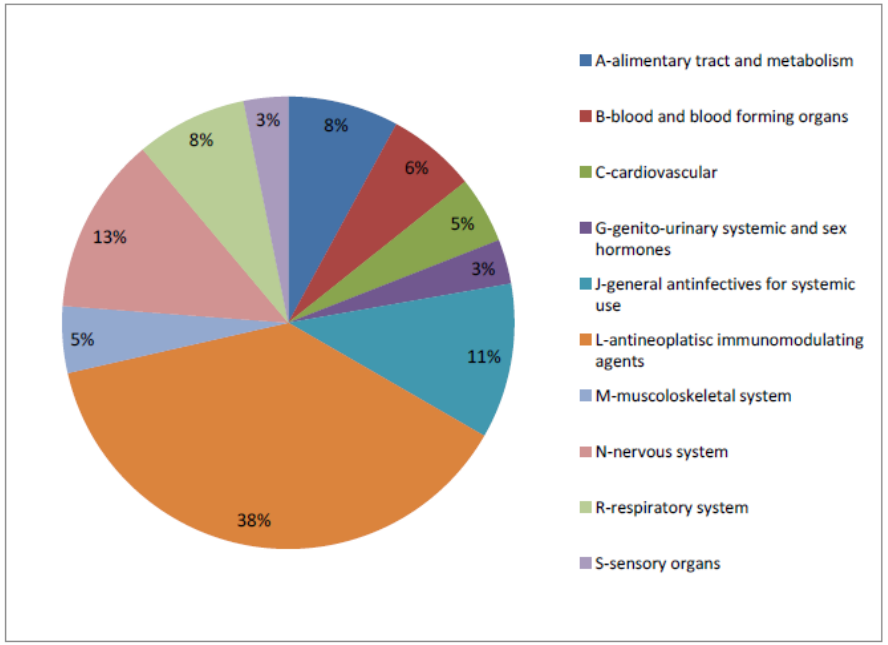


Figure 3: Procedures per ATC (n=63)

Rapid Relative Effective Assessments EUnetHTA

-Gathering all possible information

-Analysing it to be of help in next steps (P&R)

-Conclusions? Possible implications

-Timelines. Recent authorisation

So will the European market be the same?

-Scientific agreements more easily achieved, but the more uncertainty, the more possible outcomes (HTAs)

-Besides, possible econcomic barriers managed differently in different countries

Heterogeneity in the outcome (access and conditions) is not to be avoided

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National level

- Eventually a national phase is needed (even if a common European HTA view is reached)

In our experience (I)

Need of participation of different stakeholders (different levels)

Group taking decisions

-Regulator (AEMPS)

-Responsible of P&R (DGCBSSNSF)

-Payer (Regional Health Authorities)

Commenting the report

-MAH

-Scientific Societies

-Patient Associations

Respecting competences

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In our experience (II)

-Decisions taken by consensus

-Common national position on the potential added value to be shared with decisors (P&R)

-Common national position after receving the outcome on P&R

-Gainging confidence and mutual understanding

-Reports publicly available

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What have we seen?

-Share information

-To reach consensus the final wording may not be completely understood

-Enthusiasm from authorisation reworded when checking payers needs

-Describing subgroups or potential restrictions of the indication

-Differentiate: clinical from economical aspects

-Not the perfect solution but a better one

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Thank you