REPÚBLICA PORTUGUESA
SAÚDE

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ONCOLOGY BIOSIMILARS – HOSPITAL

PHARMACISTS MAKING THE DIFFERENCE

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CONFLICT OF INTEREST

1. NO CONFLICT OF INTEREST
2. I work in the hospital pharmacy of a public hospital
3. I'm a member of the Health Technology Assessment Committee (CATS) in the medicines regulator in Portugal (INFARMED)

Questions

There is ample proof that all biosimilars are equivalent to each other, so switching between biosimilars of different manufacturers during the course of the treatment is not an issue. (True/False)

The main reason to use subcutaneous trastuzumab should be: (True/False)

- Cost
- Propaganda
- Patient Needs
- Resources for preparation and administration

New drugs with the same therapeutic indications as bevacizumab should be used: (True/False)

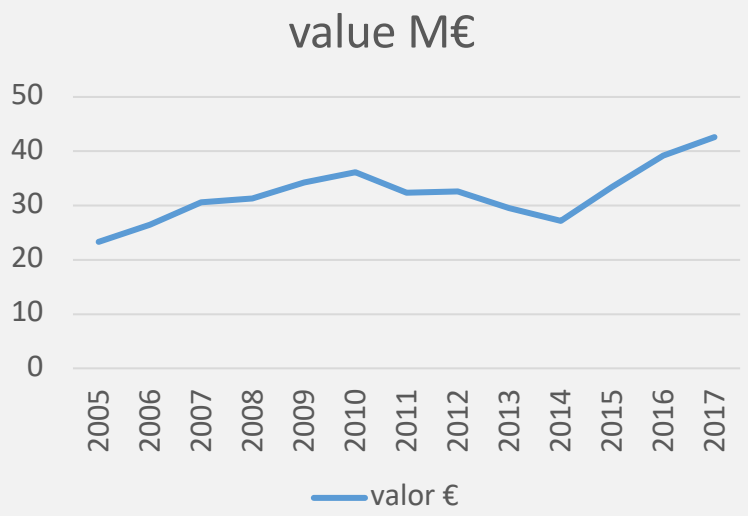
- Always, because they are originator products and thus better.
- Only when bevacizumab is not an adequate option in terms of efficacy and/or safety
- Never, because they are more expensive
- Whenever an increase response rate has been shown in clinical trials

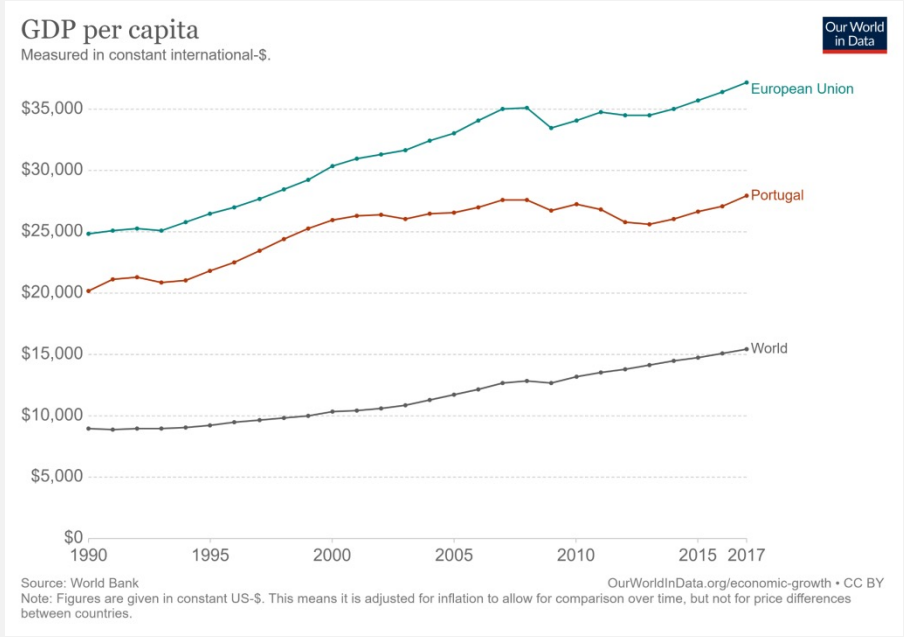
AGENDA

1. When all has been said and done…
2. Where is hospital pharmacy?
3. The switching dilema (is there one?)
4. The lure of inovation. Reality or myth?
5. So what's next?

1 When all has been said and done…

- You already know everything about biosimilars.
- You already know everything about the cost of drugs and the impact of biossimilars.
  - So what can this hospital pharmacist bring that is useful? My budget (83%) vs Our Money (5%PT; 12,8% EU)





1 When all has been said and done…

- So there is a problem: more than double budget for drugs in my hospital and GDP not growing so much. And most of it is oncology drugs.
- Must save somewhere but…
  - Already have all the generics.
  - Already done aggressive tenders
  - A big chunk of expense is in biologicals
- Urgently need to make the most out of biossimilars.

2 Where is hospital pharmacy?

- We are:
  - Somewhere in the hospital (the basement…)
  - In the purchasing committees
  - In the pharmacy and therapeutics committee
  - In the preparation of injectable drugs (including biologicals)
  - In the wards and day hospital, talking to doctors and nurses
  - Sometimes in the outpatient pharmacy, talking to patients.
- Each of these areas has specific challenges, such as …

1 Where is hospital pharmacy?

- The Challenges … we'll look at them in a minute.
- But first let's talk about us.
  - We are hospital pharmacists, which in the EU today means a master degree
  - Our studies are mostly science based, so this makes us unique in the healthcare setting, where most professions are more practice oriented.
  - This is sometimes our weakness, but it may also be our strength.
  - We are the best people in the hospital to look scientifically at the biosimilar issue, and have a science based approach, less biased by perceptions or "fake news" which may arise in this field.

1 Where is hospital pharmacy?

- The Challenges
  - In the purchasing committees:
    - designing the best technical specifications for the tenders and checking for their compliance. Beware of formulation issues (dosage form, etc.)
    - Advising on strategies to make the most of biosimilars in the long run – do not let the market run dry! Crushing prices may be costly in the long term!
    - Advising on future opportunities from biosimilars and helping make sensible decisions. Avoid long term traps with "wonder options" like the subcutaneous formulation.
    - Supporting negotiations: a good deal with the innovator product may be good but beware of long term impact!

1 Where is hospital pharmacy?

- The Challenges
  - In the pharmacy and therapeutics committee
    - Looking at the market and looking ahead, influencing therapeutic decisions when the usual "me too" options come to us (more of this in a minute).
    - Supporting strategies of implementation and information of professionals (doctors and nurses) so they support the use of biosimilars as an opportunity to get more options in real innovation and not as a threat. EU biosimilars are SAFE and EFFECTIVE!
    - Handling "switching issues" sensibly – depends on the drug, disease, duration.

1 Where is hospital pharmacy?

- The Challenges
  - In the preparation of injectable drugs (including biologicals)
    - Looking at eventual preparation specificities, adapting, and enforcing hospital policy.
    - Making adequate records to support any challenge (such as … my patient is very bad because of biosimilar…).
    - Advising management on resources needed and cost-benefit (e.g., IV vs SC trastuzumab)

1 Where is hospital pharmacy?

- The Challenges
  - In the wards and day hospital, talking to doctors and nurses
    - And making sure the facts get trough, not the biased perceptions.
  - Sometimes in the outpatient pharmacy, talking to patients.
    - And making sure the facts get trough, not the biased perceptions, although with extra care to avoid conflict or doubts about the patient-doctor relationship.

3 The switching dilema (is there one?)

To switch or not to switch, that is the question:

Whether it is nobler in the mind to suffer
The slings and arrows of outrageous fortune,
Or to take arms against a sea of troubles.
(adapted from William Shakespeare's "Hamlet" …)

- You have seen the science.
- It's easy to start with new patients but …
  - trastuzumab treatments can go for as long as 2 years
  - Maybe you can switch from reference to the first BS but …
  - … can you switch from BS to BS, and if so, how many times?

3 The switching dilema (is there one?)

On the other hand…

- Can we have, at the same time, up to 6 diferente BS of trastuzumab in the hospital?
- Juggling the stocks … but sometimes things can get out of hand.

The key is perception:

- Doctors and nurses must be on our side
- Strong information about the best option
- Flexibility in action. to switch or not to switch must have a risk/benefit balance in terms of perceptions. Common sense is the key!

4 The lure of inovation. Reality or myth?

Innovation (?) regarding trastuzumab, bevacizumab, cetuximab…

- New route of the administration (subcutaneous versus IV)
- New drugs: the new and improved antibodies or small molecules or or combinations.
  - Look at clinical trials: is benefit Overal Survival, or …
    - Progression Free Survival, Response rate, biomarker eveolution…
    - How is safety? How many Serious Adverse Events? How serious?

4 The lure of inovation. Reality or myth?

New route of the administration (subcutaneous versus IV)

- It is supposed to save time and resources.
- Is it this true when you are making trastuzumab in combination with chemotherapy or pertuzumab?
- The patient is really in the day care hospital!
- How much is the cost human resources and facilities vs the difference in the cost of Drug?
  - In my hospital at current prices, BS means less 1,5M€/year
  - With this I could build a new facility and hire extra staff (pharmacists, technicians, nurses) and still save quite a lot of money.

5 So what's next?

- **Conclusions**
  - Altough all has been said and done, there is a need to make the most out of the market of biossimilars
  - The hospital pharmacy as a key role in managing and implementing the use of biossimilars
  - Switching may have a scientifically sound base, but we have to take care of perceptions and have a good cost/benefit ratio
  - Innovations may not be what they seem, SC trastuzumab may be an expensive option and the new drugs may not be the best for the patients in all situations.

Questions

There is ample proof that all biosimilars are equivalent to each other, so switching between biosimilars of different manufacturers during the course of the treatment is not an issue. (True/False)
False, because we also have to take care of people's perceptions and look at cost/benefit

The main reason to use subcutaneous trastuzumab should be: (True/False)

- Cost: *False, it is usually more expensive, even considering staff and facilities*
- Propaganda: *False, people in hospitals are smart and just propaganda is not enough.*
- Patient Needs: *False, if it's in combination with other IV therapy the patient always needs to do infusion therapy. Anyway, even if used withouth other IV therapy, subcutaneous administration is usually done in the same hospital facilities.*
- Resources for preparation and administration: *True. If you absolutely don't have the resources, then SC maybe a good option*

New drugs with the same therapeutic indications as bevacizumab should be used: (True/False)

- Always, because they are innovative and thus better: *False, the proof that they are better is not always conclusive.*
- Only when bevacizumab is not an adequate option in terms of efficacy and/or safety: *True*
- Never, because they are more expensive: *False, see above*
- Whenever an increase in response rate has been shown in clinical trials: *False. Response rate is a surrogate marker and should be viewed with caution depending on the pathology.*

Thank You!

Obrigado!