Satellite symposium EAHP 2017

Scenario 2: Leading a switching protocol

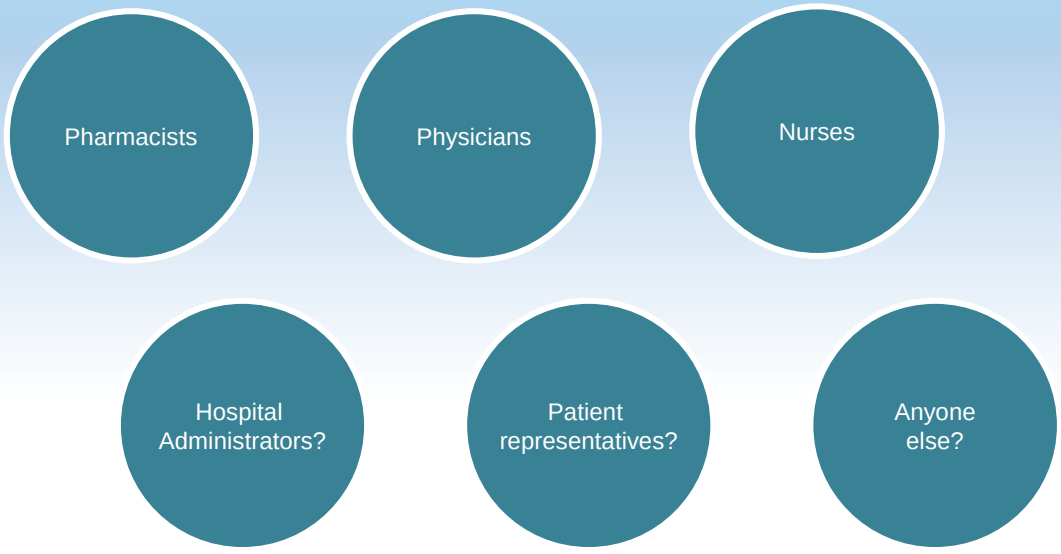
Professor João Gonçalves

Date of preparation: March 2017
PP-IFA-GLB-0555

Managing a switching programme

- Formulate plan with all stakeholders
- Educate staff
- Educate patients
- Follow-up/pharmacovigilance
- Publish outcomes

Identifying key stakeholders

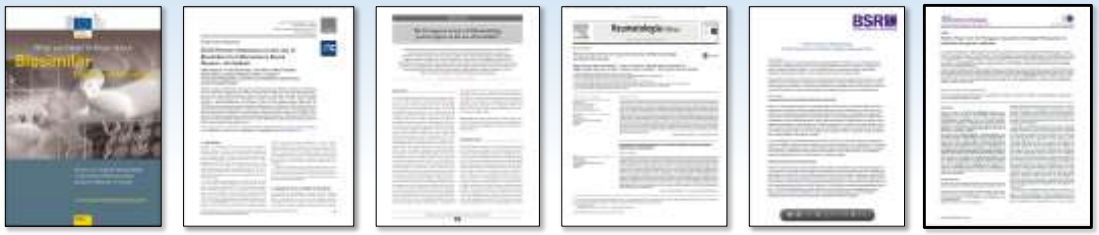


Key items for discussion

- How to inform the hospital staff?
  - Education on the topic of biosimilars?
- Who tells the patient about the switch?
  - Treating physician? Nurse? Pharmacist?
  - What supporting information is required?
- What level of patient review/follow-up is needed?
  - Which assessments to administer?
  - How to record outcomes?

Educating staff

- It is vital to explain to physicians and nurses what a biosimilar is, the regulatory process underpinning them, and the evidence supporting a switch to CT-P13 in particular
- The European Consensus Document “What you Need to Know about Biosimilar Medicinal Products” provides information on biosimilars for healthcare providers and is available in 7 European languages[1]
- Many national bodies and learned societies have published position papers on biosimilars, e.g.:
  - European Crohn’s and Colitis Organisation (ECCO) 2016 position paper[2]
  - Portuguese, Spanish and British Societies of Rheumatology position papers[3-5]
  - Position paper from the Portuguese Association of Hospital Pharmacists[6]



1. European Commission. *What you need to know about biosimilar medicinal products*. 2013; 2. Danese S, et al. *J Crohns Colitis* 2017;11:26-34; 3. Fonseca JE, et al. *Acta Reumatol Port* 2013;39:60–71; 4. British Society of Rheumatology. Position statement on biosimilar medicines (February 2015). http://www.rheumatology.org.uk/includes/documents/cm_docs/2015/b/bsr_biosimilars_position_statement_feb_2015.pdf [Accessed March 2017]; 5. Abad Hernandez M, et al. *Reumatol Clin* 2015;11:269-78. 6. Portuguese Association of Hospital Pharmacists. *J Clin Pharm Ther* 2016 doi: 10.1111/jcpt.12477.

Educating patients

- Patient education and buy-in is important in preventing the ‘nocebo effect’[1]
  - Introducing biosimilars in the context of payer requirements or cost savings is unlikely to produce positive outcomes
  - Instead, focus on the data supporting biosimilars and the potential to treat more patients
  - Discuss patient concerns and counsel patients in such a way to avoid the nocebo effect
- The International Alliance of Patients’ Organizations provides a Biosimilars Toolkit in English, Spanish and Portuguese[2]
- Physicians and nurses could be provided training on how to introduce biosimilars to their patients
- General information on biosimilars is available from the European Commission[3]
- Additional patient information materials can be obtained from the manufacturers

1. Planes S, et al. *Pharma Res Per* 2016;4:e00208. doi: 10.1002/prp2.208
2. Biosimilars Toolkit. An information and advocacy toolkit for patients’ organisations. https://www.iapo.org.uk/biosimilars-toolkit. Accessed March 2017.
3. European Commission. *What you need to know about biosimilar medicinal products*. 2013

What to do before the switch?

Decide which patients should be switched

- Any patient stable on originator therapy could be switched?
- Avoid switch in patients with contraindications?
- Avoid switch in patients that have Anti-Drug Antibodies or accept the risk of secondary failure?

Follow-up/pharmacovigilance

- Decide a follow-up protocol as part of the managed switching plan
  - Frequency of follow-up
  - Which member of the team will administer which tests
- Establish the endpoints that will be measured, for example:
  - Drug trough levels and immunogenicity testing?
  - Adverse events (inclusion in a biologic registry?)
  - Patient-reported side effects
  - Patient-reported outcome measures (PROMS) – which measures?
  - Disease activity assessment(s)
  - Laboratory tests of inflammation (CRP, ESR)
  - Other blood tests?
  - Economic endpoints – dispensing records, billing records, procurement records

Wherever possible, publish your results!

- Additional data are always welcome on biosimilar use and outcomes

But remember…

We should get better data, not just bigger data.

With bigger numbers, you can get a precise, but still wrong, answer.

- Understanding the factors impacting drug performance should help in obtaining reliable evidence
- A number of factors can influence a patient's outcome, including age, exposure to other medicines, and inconsistencies in reporting outcomes. There are also issues with adherence
- It's very important to identify those who stay on the medicine and those who discontinue. Is there a factor driving adherence that may be related to the patient's underlying clinical status?

Satellite symposium EAHP 2017

Panel discussion

Panel discussion

- Are there potential problems with winner-takes-all tenders, both for individual stakeholders and in terms of sustainability of the biosimilar market?
- What potential practical difficulties could scenario 2 entail?
  - How can these be overcome?
- What is the role of the hospital pharmacist in leading a managed switching programme?
- Questions from the audience?