Dr Paul Cornes
Disclosures March 2016

- Salary received:
  - United Kingdom National Health Service
- Honoraria received:
  - Accord Healthcare
  - Amgen
  - Bernstein
  - British Medical Journal
  - European Generics Association
  - Hospira
  - Janssen
  - Lilly
  - Merck Serono
  - Napp
  - Pharmaceutical Association of Malaysia
  - Pfizer
  - Roche
  - Sandoz
  - Teva

These slides and their content were created by Dr Paul Cornes.

Please let me know if there are errors or omissions

New targeted precision medicines are transforming cancer care

Cancer Disease	Old Model	Old Survival	Personalized Model	Personalized Survival
Acute promyelocytic leukemia	Chemotherapy	19 months	All-trans retinoic acid	>58 months
Chronic myeloid leukemia	Chemotherapy	6 years	Imatinib	>22 years
Melanoma	Dacarbazine	<10 months	Vemurafenib	16 months
Medullary thyroid cancer	Chemotherapy	36 months	Vandetanib	Not reached
Gastrointestinal stromal tumour	Chemotherapy	12-18 months	Imatinib	Close to 5 years
Rel lym			Brentuximab vedotin	22.4 months

Chemotherapy era vs. targeted medicines era

Examples where survival has more than tripled

We want these medicines for our patients

Ref: [1] European Patients' Rights Day: 10 benefits the EU brings to patients. EC Memo Brussels, 12 May 2014. http://europa.eu/rapid/press-release_MEMO-14-341_en.htm. Accessed June 19, 2015 .

EU Patients Rights

- We have rights under Article 168 of the Treaty on the Functioning of the EU & Article 35 of the Charter of Fundamental Rights of the EU

EUROPEAN COMMISSION

MEMO

Brussels, 12 May 2014

European Patients' Rights Day: 10 benefits the EU brings to patients

A high level of health protection; the right to benefit from medical treatment; access to healthcare - preventive, diagnostic and curative treatment regardless of financial means, gender or nationality. These principles

its Charter of Fundamental Rights

actions. On European Patients' Rights

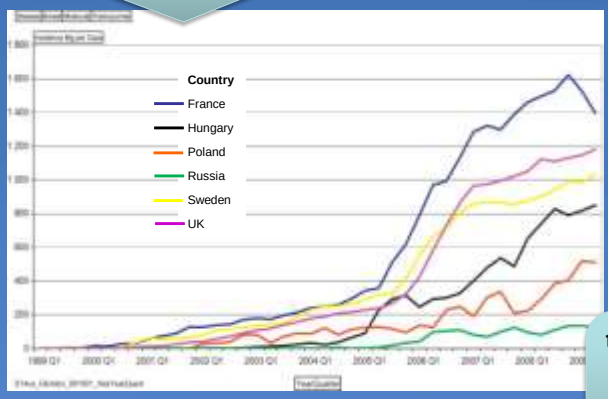
being a patient in the European Union

We want these medicines for our patients

the right to benefit from medical treatment…regardless of financial means, gender or nationality

Ref: [1] European Patients' Rights Day: 10 benefits the EU brings to patients. EC Memo Brussels, 12 May 2014. http://europa.eu/rapid/press-release_MEMO-14-341_en.htm. Accessed June 19, 2015 .

The value is real – without trastuzumab women lost an 6.4% absolute durable survival benefit [3]

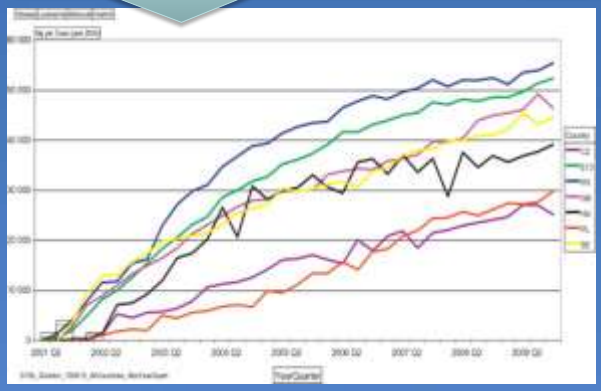


The use of trastuzumab - in France, Poland, Russia, UK, Sweden and Hungary 1999–2009 (expressed in mg/case of breast cancer) [2]

the right to benefit from medical treatment…regardless of financial means, gender or nationality

Ref: [1] European Patients' Rights Day: 10 benefits the EU brings to patients. EC Memo Brussels, 12 May 2014. http://europa.eu/rapid/press-release_MEMO-14-341_en.htm. Accessed June 19, 2015 .[2] Trastuzumab data Bengt Jönsson, Nils Wilking . New cancer drugs in Sweden: Assessment, implementation and access. Journal of Cancer Policy. Volume 2, Issue 2, Pages 45-62 (June 2014) .DOI: 10.1016/j.jcpo.2014.01.003 [3] Ades F et al. An exploratory analysis of the factors leading to delays in cancer drug reimbursement in the European Union: the trastuzumab case. Eur J Cancer. 2014 Dec;50(18):3089-97. URL: http://www.ecpc.org/Documents/Policy&Advocacy/Europe%20of%20Disparities/Europe%20of%20Disparities%2027th%20Sept%20015.pdf. Accessed Jan 20, 2016

The value is real – with imatinib treated patients return to a normal life expectancy [2]



The use of imatinib in France, Poland, UK, Sweden, Czech Republic and Hungary, and the average in the 13 Western European countries (E13) 2001-2008. (expressed as mg/case of leukaemia)

Use of Imatinib is determined by national wealth, not by medical need

Ref: [1] The use of imatinib (expressed as mg/case of leukaemia) in France, Poland, UK, Sweden, Czech Republic and Hungary, and the average in a section of the Western European countries (E13). from www.journalcancerpolicy.net/article/S2213-5383(14)00004-6/pyt. Journal of Cancer Policy 2014-2, 45-62DOI: (10.1016/j.jcpo.2014.01.003). Accessed Jan 27, 2016 [2] Gambacorti-Passerini C, et al. Multicenter independent assessment of outcomes in chronic myeloid leukemia patients treated with imatinib. J Natl Cancer Inst 2011;103(7). doi: 10.1093/jnci/djr060.

We Have a Problem …

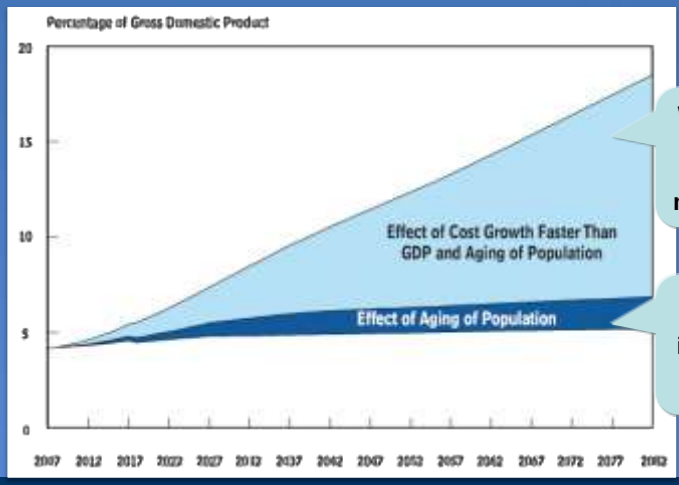
CAN WE AFFORD THE WAR ON CANCER?

Immunotherapy vaccines could extend survival in a handful of cancers. But personalizing treatment, payers argue, is not sustainable. Where should the line be drawn?

BY ED SILVERMAN

Ref: [1] Steven Brill. Bitter Pill: Why Medical Bills Are Killing Us. Time April 4, 2013 [2] Silverman E. *Biotechnol Healthc.* 2012;9(4):13-16.

What is the driver for increased spending: ageing populations or medical treatment?



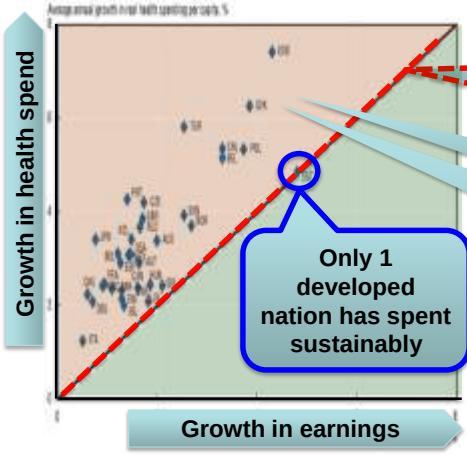
We cannot afford the increases in the cost of medical treatment

We can afford to plan for increased patient numbers from ageing

Ref: [1] US Congressional Budget Office. the Long Term Outlook for Health Care Spending. CBO publication/41646, November 2007, page 1. URL: http://www.cbo.gov/sites/default/files/11-13-lt-health.pdf. Accessed April 27, 2015

Healthcare – is funding sustainable?

- The growth in health expenditure has exceeded earnings in all but one developed nation (2000-2008)



Spending in proportion to wealth is probably sustainable

Spending more than we earn either means we create debt

Only 1 developed nation has spent sustainably

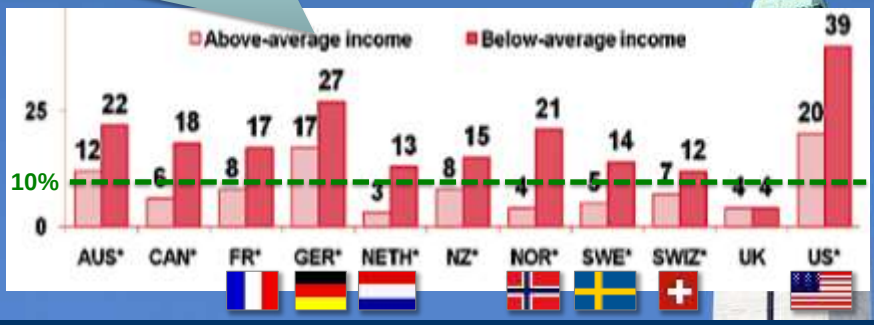
Or means that we have to cut opportunities for spending in other areas such as education, welfare, security, environment

Ref: [1] The Future of Healthcare in Europe: Summary report: Future of Healthcare in Europe conference UCL. https://www.ucl.ac.uk/european-institute/analysis-publications/publications/FHE_FINAL_online.pdf. Accessed March 7, 2016

Costs already limit access to healthcare in Europe

- Many patients did not fill or skipped a prescription, did not visit doctor with medical problem, or did not get recommended care.

Many Europeans may be surprised to see rich nations where >10% of those on below average income fail in 1 or more tests of access to healthcare



Ref: [1] The Future of Healthcare in Europe: Summary report: Future of Healthcare in Europe conference UCL. https://www.ucl.ac.uk/european-institute/analysis-publications/publications/FHE_FINAL_online.pdf. Accessed March 7, 2016

Access to innovation has one key rule

"The only drug that works is a drug that we can afford to give"

On our current spending patterns – healthcare is unsustainable

Especially for cancer

Ref: European Patients' Rights Day: 10 benefits the EU brings to patients. EC Memo Brussels, 12 May 2014. http://europa.eu/rapid/press-release_MEMO-14-341_en.htm. Accessed June 19, 2015 .

Economics and Ethics are inextricably linked in this topic

What is good for an individual ?	What is good for society ?
The best health for a patient	The most health for the population from the limited resources available

- Switching drugs may be a price worth paying
  - If the cost savings truly benefit patients
  - And the drugs truly have comparable risks and benefits

Ref: [1] argument aadapted from Duerden MG, Hughes DA. Generic and therapeutic substitutions in the UK: are they a good thing? British Journal of Clinical Pharmacology. 2010;70(3):335-341. doi:10.1111/j.1365-2125.2010.03718.x. [2]

We have to find a balance

Are cost savings beneficial to patients?

Does biologic drug switching carry a disproportionate risk ?

If a biosimilar has comparable safety and efficacy to an original reference drug

Then the only ethical reason to prescribe it is to save on cost

Ref: [1] balance Image, Creative Commons Lisence, https://upload.wikimedia.org/wikipedia/commons/b/b0/Balance_roberval.png. Accessed Feb 4, 2016

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The Promise of biosimilar medicines

High cost biologics create a problem

Cost Savings from Biosimilars

That cheaper biologics could resolve

Challenge		Result
Effective targeted therapy held back for later stage of disease	→	Effective targeted therapy used earlier in the disease
Treatment reserved for only the most severe cases	→	More patients have access to treatment
Innovative therapies unaffordable	→	Biosimilars free up budget to buy innovative medicines
Budgets for certain therapy areas are inadequate	→	Additional budget can be directed to areas of unmet need

Ref: Adapted from Henry D, Taylor C. Pharmacoeconomics of Cancer Therapies: Considerations With the Introduction of Biosimilars. Seminars in Oncology. 2014;41, Supplement 3:S13–20

Reality

The ~~Promise~~ of biosimilar medicines

Cost Savings from Biosimilars

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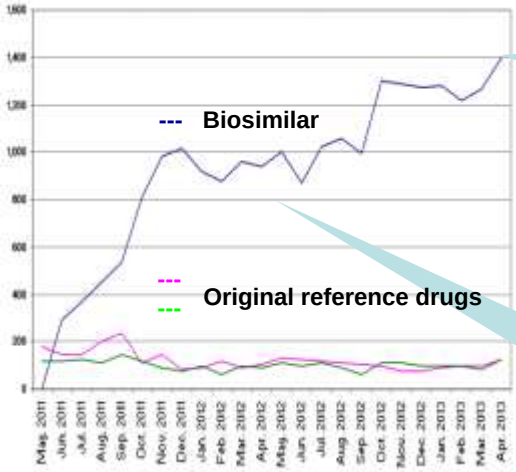
The impact of biosimilar filgrastim in London

- NHS London – daily volumes of G-CSF prescribed



5 times more patients treated within 2 years

While still saving almost 3 million euros each year

Would potentially save the EU 85 million euros annually

Biosimilars enabled treatment to be given to patients with lower risk or earlier stage disease

1. Antony Grosso, London Procurement Programme, 2012, quoted in Gascón P, et al. *Support Care Cancer*. 2013;21:2925-2932; 2. Kashyap Thakrar. Biosimilar G-CSF: Implementation & lessons learnt. Centre for Medicines Optimisation UK. http://centreformedicinesoptimisation.co.uk/files/Kash%20Thakrar%20Biosimiar%20-%20GCSF.pdf. Accessed 10 June 2015.

The impact of biosimilar filgrastim in Sweden

- **Savings from Biosimilar G-CSF switch in Southern Health Care region in Sweden (population 1.7 million)**

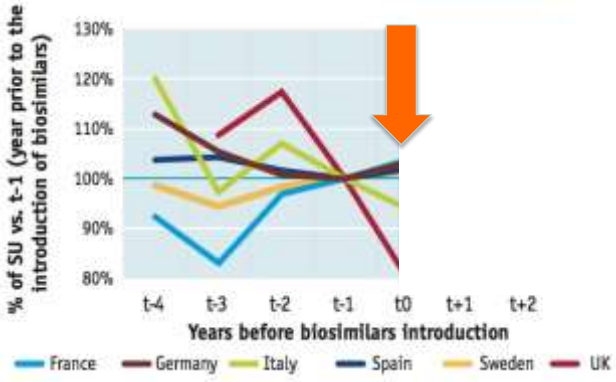
Five-fold increase in daily G-CSF usage

But still net savings of €2 million

This represents a saving of 4%–5% of the total drug budget

Gascón P, et al. Clinical experience with Zarzio® in Europe: what have we learned? *Support Care Cancer*. 2013;21:2925-2932.

Biosimilars Bring Treatments into Reimbursement That Might Otherwise Be Unaffordable



- **Trends in use of white cell growth factors – G-CSF before and after biosimilar introduction in the EU**

IMS Health. Shaping the biosimilars opportunity: A global perspective on the evolving biosimilars landscape. December 2011. http://www.imshealth.com/ims/Global/Content/Home%20Page%20Content/IMS%20News/Biosimilars_Whitepaper.pdf.

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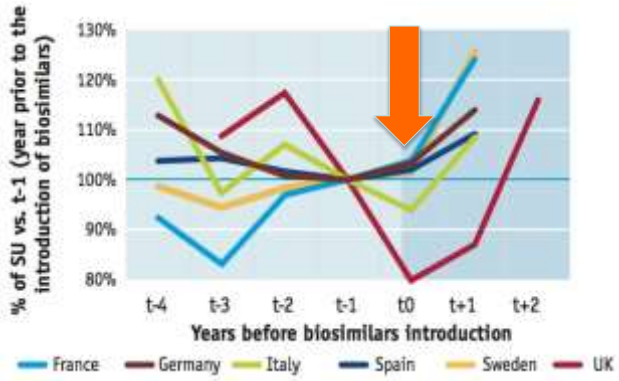

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Biosimilars reverse negative funding decisions

- **2008 – NICE Technology Appraisal Guidance No. 142**
  - **Epoetin alfa, epoetin beta and darbepoetin alfa are clinically effective for cancer treatment-induced anaemia**
  - **But not cost-effective**
- **2014 – NICE Technology Appraisal Guidance No. 323**
  - **Erythropoiesis-stimulating agents (epoetin and darbepoetin) for treating anaemia in people with cancer having chemotherapy are clinically effective**
  - **And are now cost-effective at real contract prices**

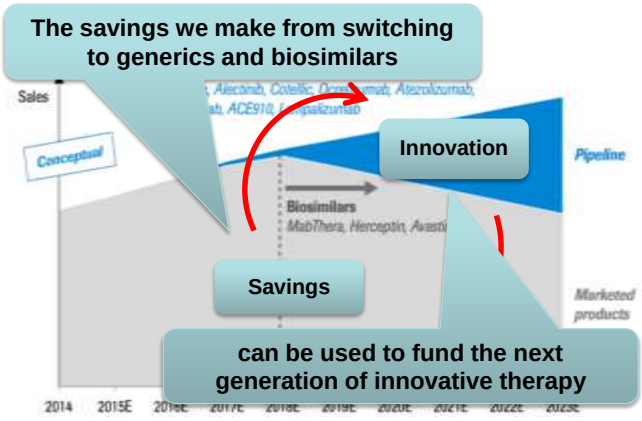
NICE accepted that biosimilar price competition had dramatically reduced the actual contract prices for epoetin

1. NICE technology appraisal guidance [TA142] May 2008. Epoetin alfa, epoetin beta and darbepoetin alfa for cancer treatment-induced anaemia. http://www.nice.org.uk/guidance/ta142. Accessed 10 June 2015;
2. NICE technology appraisal guidance [TA323] November 2014. Erythropoiesis-stimulating agents (epoetin and darbepoetin) for treating anaemia in people with cancer having chemotherapy (including review of TA142). http://www.nice.org.uk/guidance/ta323. Accessed 10 June 2015.

Biosimilar savings fund access to innovative therapy

- **Roche has outlined its plan to adapt to biosimilars - using the savings to allow payers to reinvest in their next generation of innovation**

The chart from Roche's presentation at the J.P. Morgan Healthcare Conference demonstrates how biosimilars are expected to affect sales in coming years [1]



Ref: [1] Lorenzetti L. Biosimilars Are Coming After Big Pharma's Bottom Line. Fortune. Jan 12, 2016, 2:02 PM EST. URL: http://fortune.com/2016/01/12/biosimilars-big-pharma/. Accessed Jan 25, 2016

The ~~Promise~~ Reality of biosimilar medicines

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Cost Savings from Biosimilars

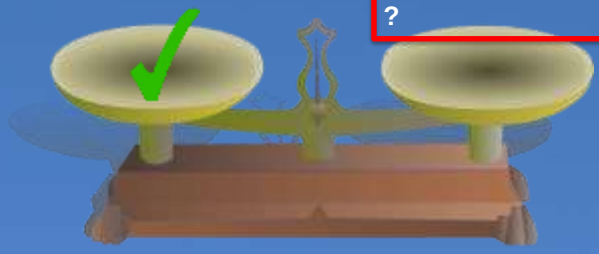
Payers need biosimilars to sustain healthcare

Ref: Adapted from Henry D, Taylor C. Pharmacoeconomics of Cancer Therapies: Considerations With the Introduction of Biosimilars. Seminars in Oncology. 2014;41, Supplement 3:S13–20

We have to find a balance

Are cost savings beneficial to patients?

Does biologic drug switching carry a disproportionate risk ?



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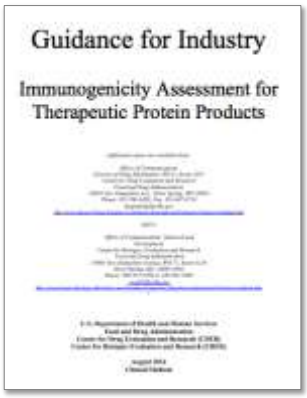
Then the only ethical reason to prescribe it is to save on cost

Ref: [1] balance Image, Creative Commons Lisence, https://upload.wikimedia.org/wikipedia/commons/b/b0/Balance_roberval.png. Accessed Feb 4, 2016

Can switching be harmful? Theory

- For switching to be a problem – there would have to be a "carry over" effect from one drug to another
  - The only mechanism that we can imagine causing this would be immunogenicity leading to anti-drug antibody formation
- For switching to be a problem, the two drugs would need to have a different immune profile
  - For this reason, regulators set strict guidance on immunogenicity before a biologic can be approved [2]

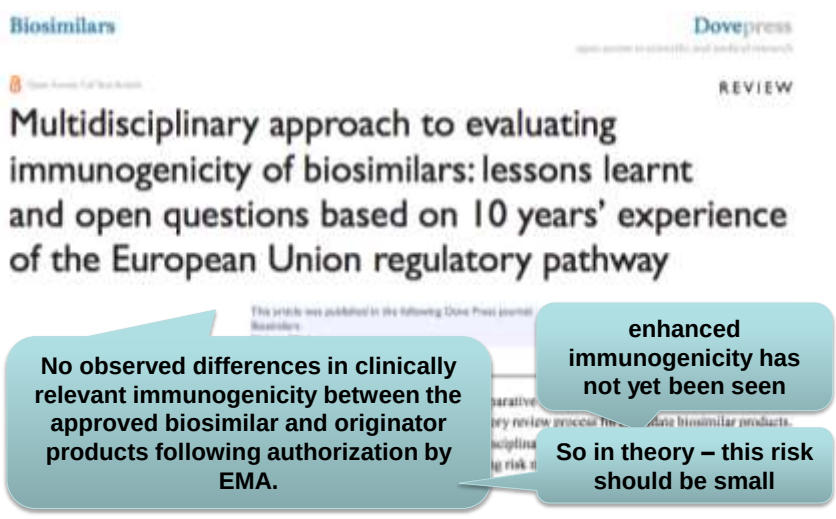

Guidance for Industry

Immunogenicity Assessment for Therapeutic Protein Products

So in theory – this risk should be small

Ref: [1] Yanai H et al. Levels of drug and antidrug antibodies are associated with outcome of interventions after loss of response to infliximab or adalimumab. Clin Gastroenterol Hepatol. 2015 Mar;13(3):522-530.e2. doi: 10.1016/j.cgh.2014.07.029. Epub 2014 Jul 25. [2]Guidance for Industry Immunogenicity Assessment for Therapeutic Protein Products. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER),

Can switching be harmful? Theory
Anti-drug immunity



Ref: [1] European Medicines Agency. Similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues, CHMP/BMWP/42832/2005 rev1, Draft Revision, June 3, 2013. Available from: http://www.ema.europa.eu/ema/index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500144124&mid=WC0b01ac058009a3dc.2.

Can switching be harmful? Practice

- In practice, with 10 years of experience of biosimilars in Europe, no problems have been identified.
  - Over that time, patient exposure to biosimilars has been measured in millions

And in practice – this risk has not been seen

enhanced immunogenicity has not yet been seen

So in theory – this risk should be small

Ref: [1] Ebbers HC et al. The safety of switching between therapeutic proteins. Expert Opin Biol Ther 2012;12(11):1473-85

Review of all published data on switching between originator and biosimilar

12,039 patients in 58 clinical trials

193 Post Authorisation Adverse event reports from EU DRA Vigilance

Review

The safety of switching between therapeutic proteins

Hans C Ebbers, Michael Muenzberg & Huub Schellekens†

†*Utrecht University, Utrecht Institute for Pharmaceutical Sciences (UIPS), Department of Pharmaceutics, TB Utrecht, The Netherlands*

Ebbers HC et al. The safety of switching between therapeutic proteins. Expert Opin Biol Ther 2012;12(11):1473-85

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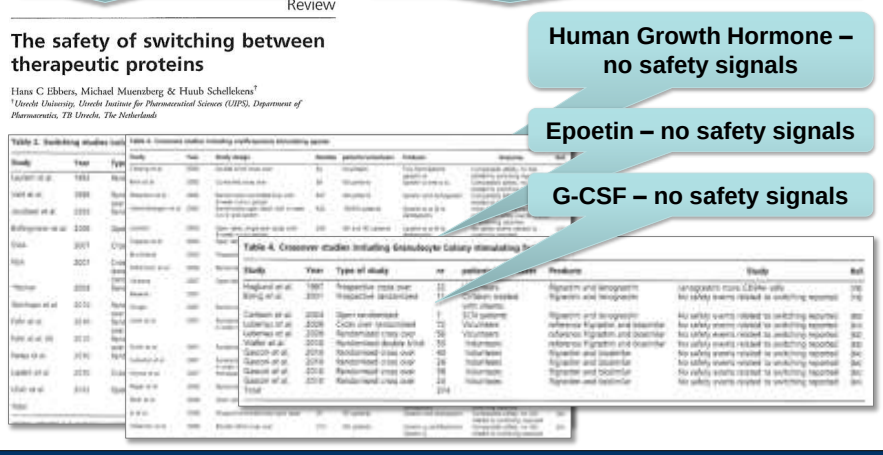


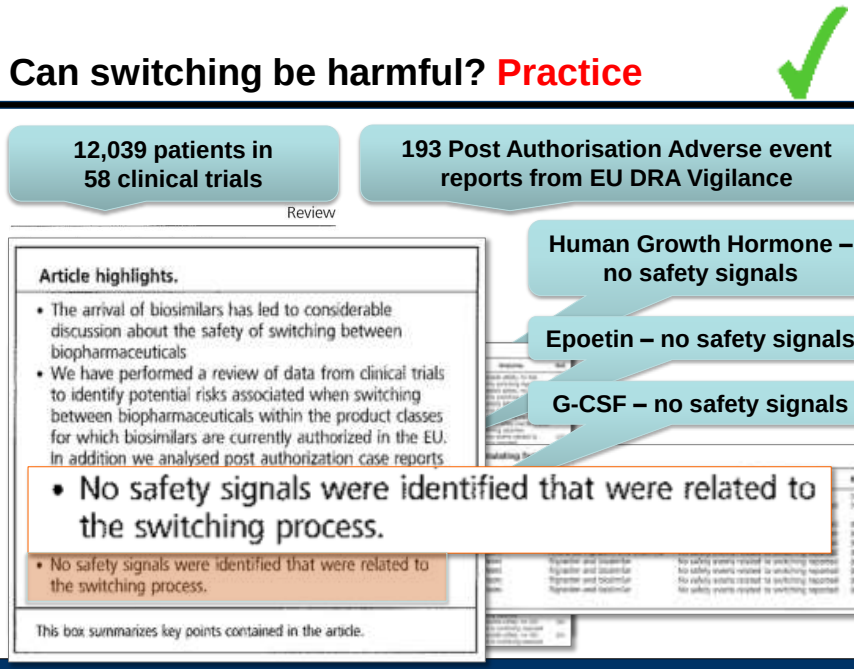
Human Growth Hormone – no safety signals

Epoetin – no safety signals

G-CSF – no safety signals

Ref: [1] Ebbers HC et al. The safety of switching between therapeutic proteins. Expert Opin Biol Ther 2012;12(11):1473-85

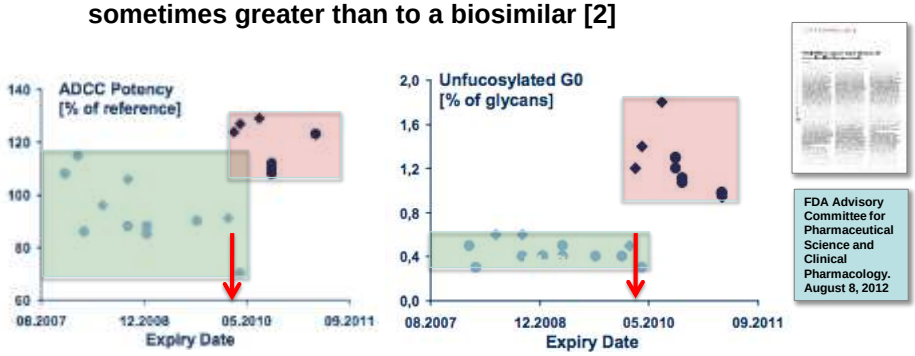
Can switching be harmful? Practice



Ref: [1] Ebbers HC et al. The safety of switching between therapeutic proteins. Expert Opin Biol Ther 2012;12(11):1473-85

Can switching be harmful? Proportionality

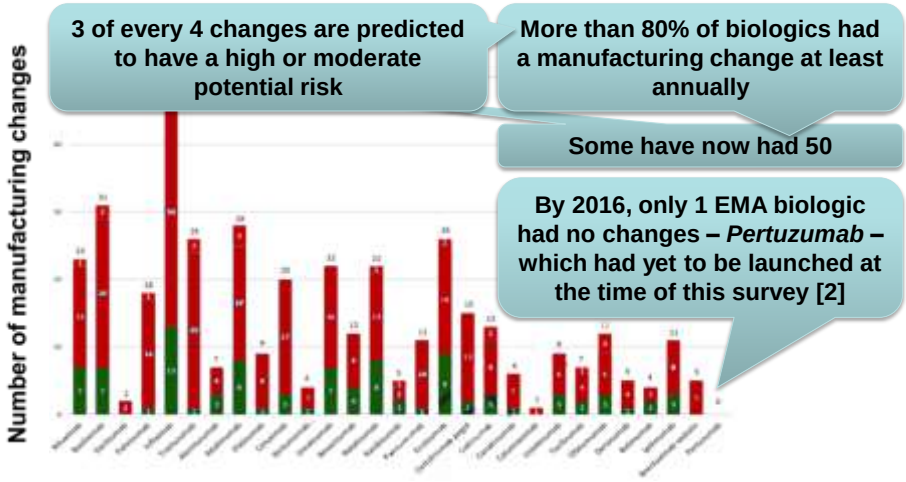
- **Manufacturing changes in reference drugs [1]**
  - **Introduce differences between 2 versions of that drug that are sometimes greater than to a biosimilar [2]**



Ref: [1] Schiestl, M. et al., Nature Biotechnology 2011;29:310-312 [2] McCamish M. FDA ACPS-CP update on biosimilars. FDA. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AdvisoryCommitteeforPharmaceuticalScienceandClinicalPharmacology/UCM315764.pdf. Accessed Jan 27, 2016

Can switching be harmful? Proportionality

- Is any potential risk in proportion to risks we accept already ?



Ref: [1] Vezér B, Buzás Z, Sebeszta S, Zrubka Z. Authorized manufacturing changes of therapeutic monoclonal antibodies (mAbs) in European Public Assess- ment Report (EPAR) documents. Current Medical Research and Opinion. Doi: 10.1185/03007995.2016.1145579. [2]

Can switching be harmful? Proportionality ✓

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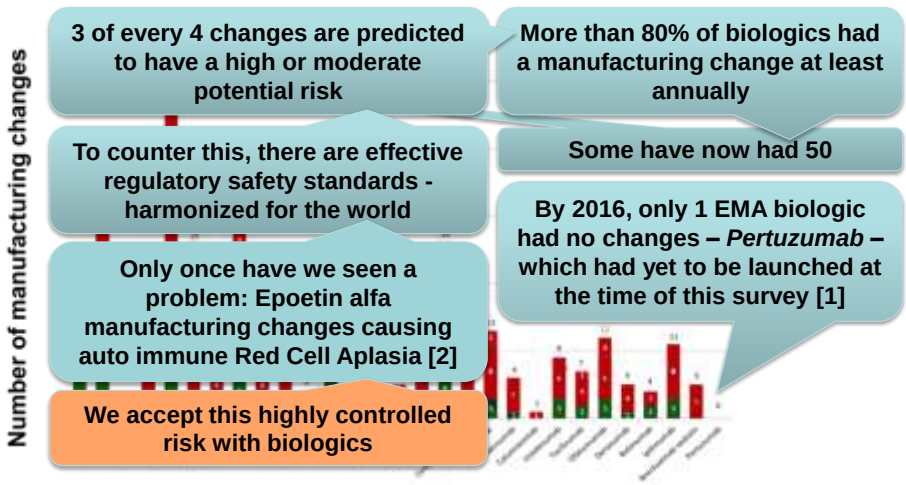

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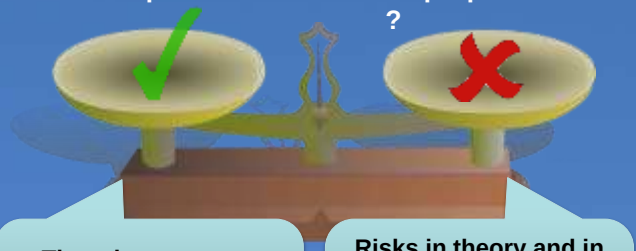


There is no proven mechanistic or empirical argument to suggest increased risk

Risks in theory and in practice have been proportional to the risks of biologics in general

Ref: [1] balance Image, Creative Commons Lisence, https://upload.wikimedia.org/wikipedia/commons/b/b0/Balance_roberval.png. Accessed Feb 4, 2016

In assessing the balance between the risks and benefits of biosimilars

Payers want the savings from biosimilars and will push physicians and pharmacists to switch patients

Physician and originator manufacturer pushback has been based on a suggested risk of biosimilars

For payers – the theoretical risk of biosimilars are proportionate to those of manufacturing change

Which has never been seen in a decade of European Biosimilar use 2006-16

while the risk from lack of access is real and significant costing lives and health

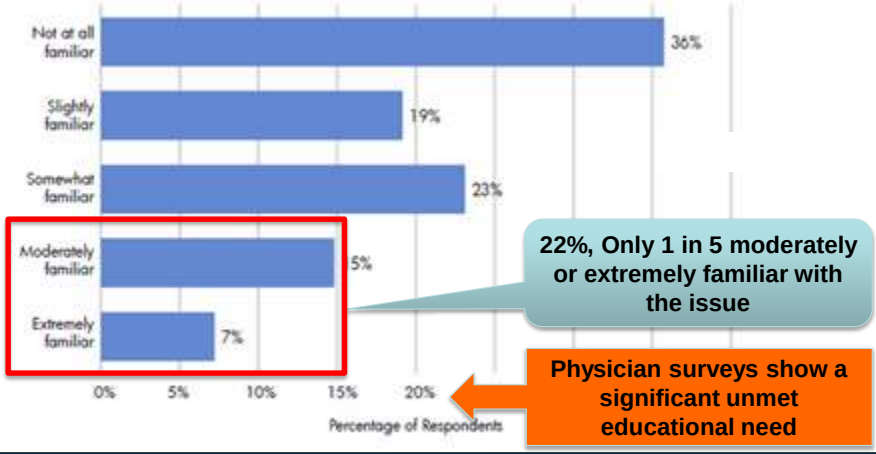
Payers see biosimilars as the clear "dominant" economic choice

Physician surveys show a significant unmet educational need

Photo: woodleywonderworks - finding balance. URL = https://creativecommons.org/licenses/by/2.0/. Accessed July 5, 2015

Physicians' knowledge of biosimilars remains insufficient:

- **USA NCCN conference Respondents were asked to rate their overall familiarity with developments for biosimilars (n = 277)**



22%, Only 1 in 5 moderately or extremely familiar with the issue

Physician surveys show a significant unmet educational need

Ref: [1] Edward C. Li. Biosimilars: More Education Is Needed. URL: http://www.nccn.org/about/news/ebulletin/2011-04-18/biosimilars.asp

Physicians' knowledge of biosimilars remains insufficient:

- **In a survey of 470 European prescribers**
  - **France, Germany, Italy, Spain and UK**

- **a quarter of participants cannot define or have not heard about biosimilars before.**
- **Only 22% consider themselves as very familiar with them**

Bloomberg News http://www.bloomberg.com/news/2014-03-18/a-quarter-of-doctors-in-europe-can-t-define-biosimilars.html

A Quarter of Doctors in Europe Can't Define Biosimilars

Physician surveys show a significant unmet educational need

Ref: [1] ASBM European physicians survey on biosimilars: key findings on knowledge, naming, traceability and physicians' choice. http://www.europabio.org/sites/default/files/report/asbm_european_physicians_survey_on_biosimilars-_ex_summary.pdf. Accessed May 12th, 2014

Requirements for a sustainable biosimilar market in the EU

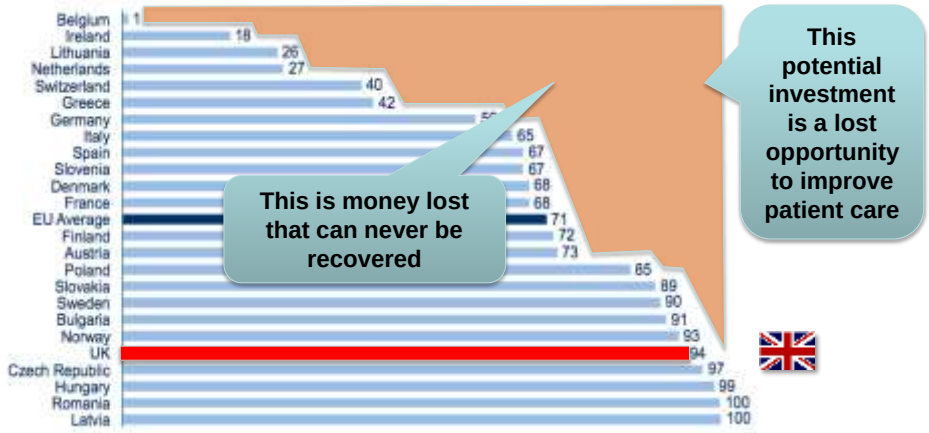
Education and Understanding

- There is a need for **clear** information from **unbiased** sources, that is non-promotional, targeting doctors, other healthcare professionals, payers and patients
- Stakeholders require an appreciation that **biosimilar medicines are not generic medicines**. The development and manufacturing processes of biosimilar medicines are more complex and much more expensive than of chemical small molecule medicines
- Education is required on the **scientific concept of biosimilar medicines**, their approval process, and their safety and efficacy
- The concept of "Indication Extrapolation", an essential aspect of the biosimilar medicines regulatory pathway, should be clearly **communicated and explained to all stakeholders in a context and language that provides complete understanding and support.**

Ref: A study undertaken by GfK Market Access on behalf of the European Biosimilars Group (EBG), a sector group of the EGA, about the future sustainability of the biosimilar medicines market. Sept 2014. http://www.egagenerics.com/images/Website/GfK%20Final%20Report-%20Factors%20Supporting%20a%20Sustainable%20European%20Biosimilar%20Medicine%20Market.pdf. Accessed Oct 14, 2014.

Requirements for a sustainable biosimilar market in the EU = *Education*

- **% of G-CSF as biosimilars vs Neupogen in Europe, 5 years after biosimilars were approved**



IMS MIDAS, Feb 2013, quoted in - Walsh K. Biosimilars' utilization and the role payers do play in driving uptake in Europe: an industry perspective. Biosimilar Medicines 11th EGA International Symposium, April 2013. Accessed 5 March 2014.

We are given clear leadership on Rational Medicine Use

World Health Organization

- **"Medicine use is rational (appropriate, proper, correct) when**
  - **patients receive the appropriate medicines,**
  - **in doses that meet their own individual requirements,**
  - **for an adequate period of time, and**
  - **at the lowest cost both to them and the community.**
- **Irrational (inappropriate, improper, incorrect) use of medicines**
  - **is when one or more of these conditions are not met."**
    - (WHO World Medicines Report, 2011).

Ref: WHO World Medicines Report, 2011 .

Leadership on Rational Medicine Use

eahp

If we stand for anything in EAHP – it must be for the rational, appropriate, proper, correct use of medicines

Ref: [1] WHO World Medicines Report, 2011 [2] Word pictogram created at http://www.wordle.net, March 14, 2016.

- **CME Questions**

3 key questions - Is our present system economically sustainable?: Q1

1. **Which is correct - The rising cost of medical care is caused…**

A. **mainly by the ageing of the population**
B. **mainly by the increasing costs of new treatments**
C. **equally shared between the ageing of the population and by the increasing costs of new treatments**

Ref: [1]

3 key questions - Is our present system economically sustainable?: Q1

1. **Which is correct - The rising cost of medical care is caused**

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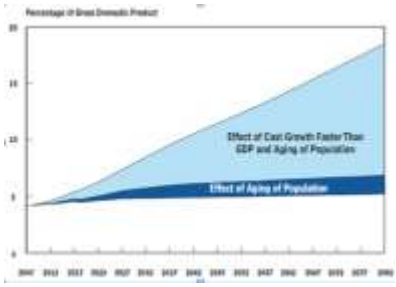
- **Correct Answer is B**



Ref: [1]

3 key questions - Is our present system economically sustainable?: Q2

2. **Biosimiar drugs have …**

A. **proven to increase access to treatment**
B. **enabled treatment to be given to patients with lower risk or earlier stage disease**
C. **both a and b**
D. **neither of a or b**

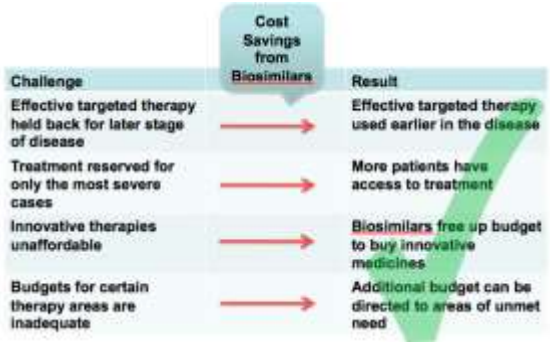
Ref: [1]

3 key questions - Is our present system economically sustainable?: Q2

2. Biosimiar drugs have …

A. proven to increase access to treatment
B. enabled treatment to be given to patients with lower risk or earlier stage disease
C. both a and b
D. neither of a or b

- Correct Answer is C



Ref: [1]

3 key questions - Is our present system economically sustainable?: Q3

3. The risks of switching to Biosimilar Medicines are greater than the risks from lack of access to targeted biologic drugs

A. Strongly agree
B. Agree
C. Neither agree nor disagree
D. Disagree
E. Strongly disagree

Ref: [1]

3 key questions - Is our present system economically sustainable?: Q3

3. The risks of switching to Biosimilar Medicines are greater than the risks from lack of access to targeted biologic drugs

A. **Strongly agree**
B. **Agree**
C. **Neither agree nor disagree**
D. **Disagree**
E. **Strongly disagree**

E. To date this is the correct answer – no significant risks have been seen with our current established EMA approved biosimilar drugs and European switching practice

Ref: [1]

QUESTIONS & COMMENTS