Synergy Satellite Event - Biosimilars in colorectal cancer – what's your gut feeling?

25th Anniversary EAHP Congress - Hospital Pharmacy 5.0 - the future of patient care

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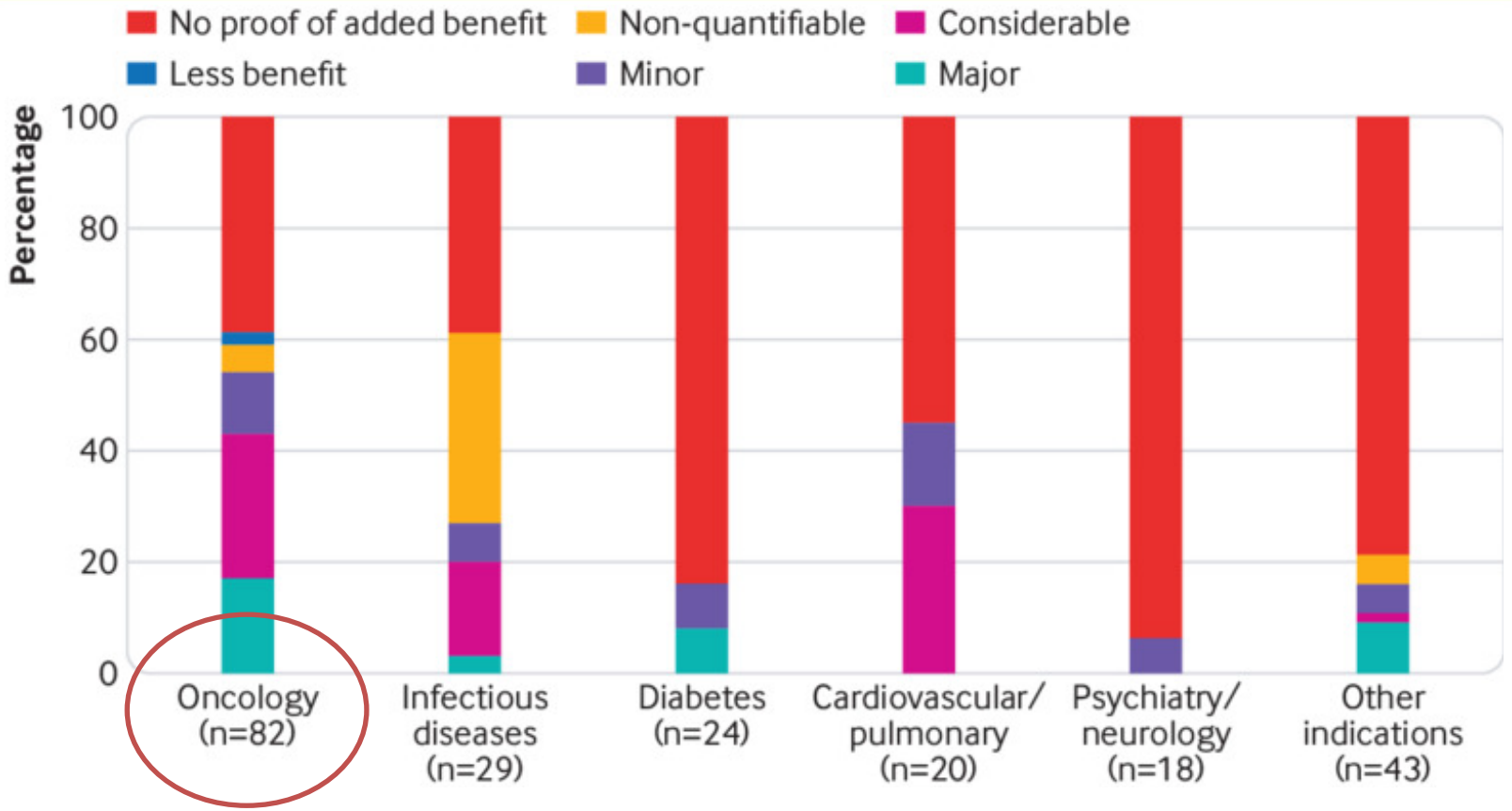
Disclosure: I declare that I have no conflict of interest.

Self Assessment:

- Is EUnetHTA Joint Action 3 (2016-2021) developing the final phase of establishing a permanent HTA working structure for Europe?
- Should policy practices be implemented to maximize the social benefits of biosimilars in oncology?
- Can the objective of biosimilar policies be defined differently in countries with significant resource constraints?

More than half of new drugs entering the German healthcare system have not been shown to add benefit.



Source: Wieseler B, McGauran N, Kaiser T (2019) New drugs: where did we go wrong and what can we do better? *BMJ*, 366:l4340. DOI: 10.1136/bmj.l4340

Health Technology Assessment in oncology

HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle.

Note 1: A health technology is an intervention developed to prevent, diagnose or treat medical conditions; promote health; provide rehabilitation; or organize healthcare delivery. The intervention can be a test, device, medicine, vaccine, procedure, program, or system.

Note 2: The process is formal, systematic, and transparent, and uses state-of-the-art methods to consider the best available evidence.

Source: O'Rourke, B., Oortwijn, W., & Schuller, T. (2020). The new definition of health technology assessment: A milestone in international collaboration. *International Journal of Technology Assessment in Health Care, 36*(3), 187-190. doi:10.1017/S0266462320000215

Health Technology Assessment in oncology

Note 3: The dimensions of value for a health technology may be assessed by examining the intended and unintended consequences of using a health technology compared to existing alternatives. These dimensions often include clinical effectiveness, safety, costs and economic implications, ethical, social, cultural and legal issues, organizational and environmental aspects, as well as wider implications for the patient, relatives, caregivers, and the population. The overall value may vary depending on the perspective taken, the stakeholders involved, and the decision context.

Note 4: HTA can be applied at different points in the lifecycle of a health technology, that is, pre-market, during market approval, post-market, through to the disinvestment of a health technology.

Source: O'Rourke, B., Oortwijn, W., & Schuller, T. (2020). The new definition of health technology assessment: A milestone in international collaboration. *International Journal of Technology Assessment in Health Care, 36*(3), 187-190. doi:10.1017/S0266462320000215

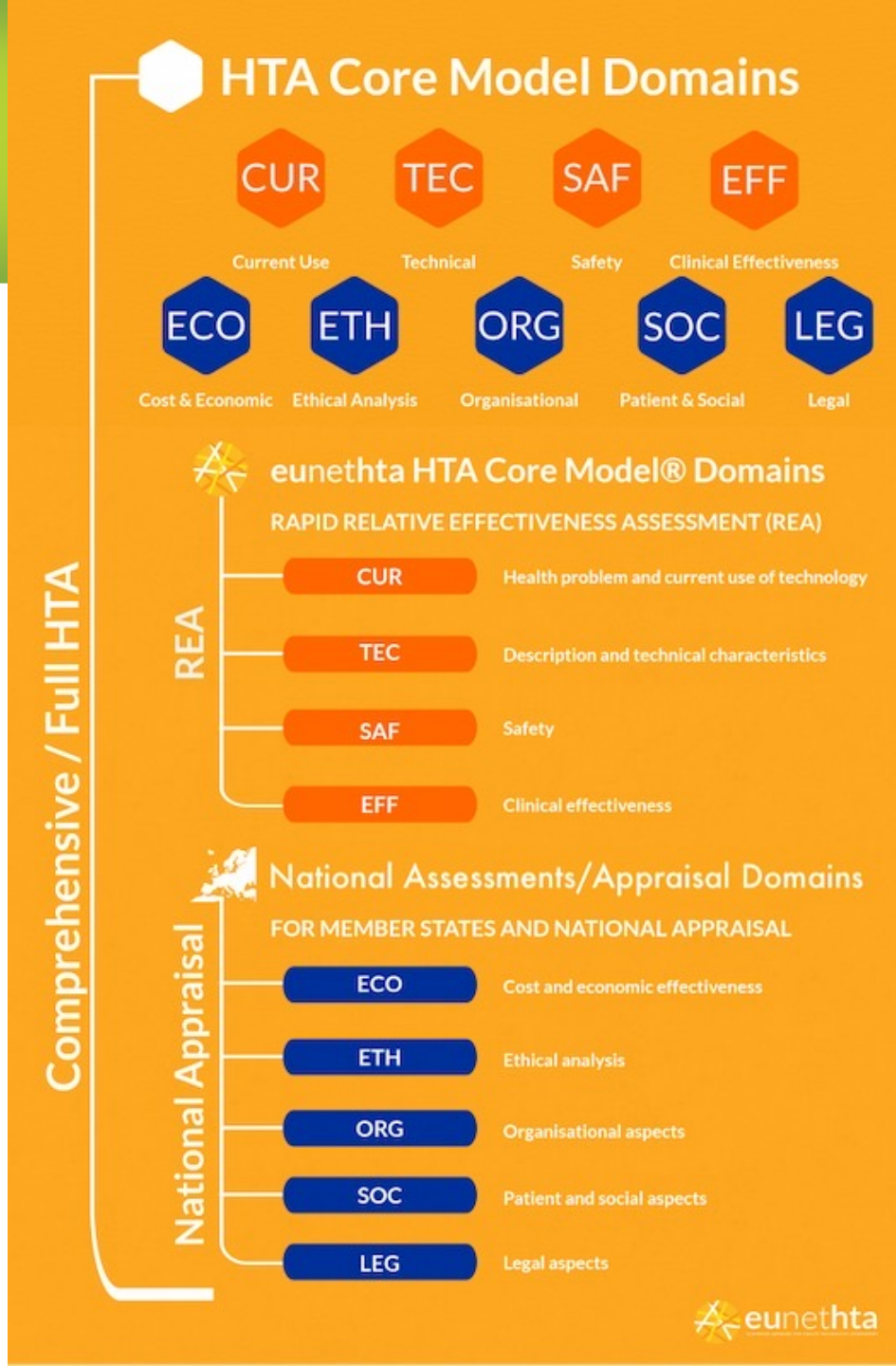
EUnetHTA Joint Action 3 (2016-2021) is now developing the final phase of establishing a permanent HTA working structure for Europe.

Examples from oncology:

Alectinib (Alecensa) as monotherapy for first line treatment of adult patients with ALK-positive advanced non-small cell lung cancer (NSCLC).

Midostaurin with standard chemotherapy in FLT3 positive Acute Myeloid Leukaemia.

Source: www.eunethta.eu



Central and Eastern European countries compared to Western European countries:

- ❑ worse health status,
- ❑ even more limited health care resources,
- ❑ strategic pricing of new health care technologies is adjusted to large markets.

Lower income countries compared to higher income countries:

- ❑ pay even more penalties for inappropriate reimbursement decisions related to new technologies in oncology,
- ❑ the concept of applying HTA prior to the reimbursement of new medicines may be even more important for lower income countries than for higher income countries.

Source: Finn Børlum Kristensen, University of Southern Denmark and Director EUnetHTA Secretariat, Danish Health and Medicines Authority, Copenhagen, Denmark. ISPOR 18th Annual European Congress 7-11 November 2015, MiCo - Milano Congressi, Milan, Italy

The launch price of innovative pharmaceuticals, including high-cost biologic medicines, is determined according to highest acceptable price paid in large size and high-income countries with the greatest market potential.

<u>These prices are not usually justifiable in lower income countries for two reasons:</u>

- ❑ the savings from avoided medical events (e.g. surgical procedures, hospitalisation etc.) due to improved drug therapies are lower in countries with a lower price level of medical services and lower salaries of health care professionals,

- ❑ less affluent countries cannot afford to pay as much as higher income countries for one unit of health gain.

Source: András Inotai & Zoltán Kaló (2019) How to solve financing gap to ensure patient access to patented pharmaceuticals in CEE countries? – the good, the bad, and the ugly ways, Expert Review of Pharmacoeconomics & Outcomes Research, 19:6, 627-632, DOI: 10.1080/14737167.2019.1702524

Value proposition of biosimilars in different access-restriction settings for oncology:

	Originator is reimbursed without access limits to patients	Originator is reimbursed with access limits to patients	Originator is not reimbursed
Value proposition	• savings in drug budget	• no increase in drug budget • improved patient access → health gain	• potential increase in drug budget • health gain
Decision	Disinvestment	Re-investment of savings	Investment

Source: Inotai A, Csanádi M, Vitezic D, Francetic I, Tesar T, et al. (2017) Policy Practices to Maximise Social Benefit from Biosimilars. J Bioequiv Availab 9: 467-472. doi: 10.4172/jbb.1000346

There were 58 biosimilars approved by the European Medicines Agency in August 2020:

Availability:

- ☐ Slovakia 31 **biosimilars** (53 %),
- ☐ Poland 31 **biosimilars** (53 %),
- ☐ Hungary 33 **biosimilars** (57 %),
- ☐ Czech Republic 35 **biosimilars** (60 %).

Source: Goliaš P. Analýza stavu a možností širšieho využívania generických a biosimilárnych liekov na Slovensku. INEKO, October 2020. Available: http://www.ineko.sk/clanky/publikacie

Utilisation pattern of treatment naive patients:

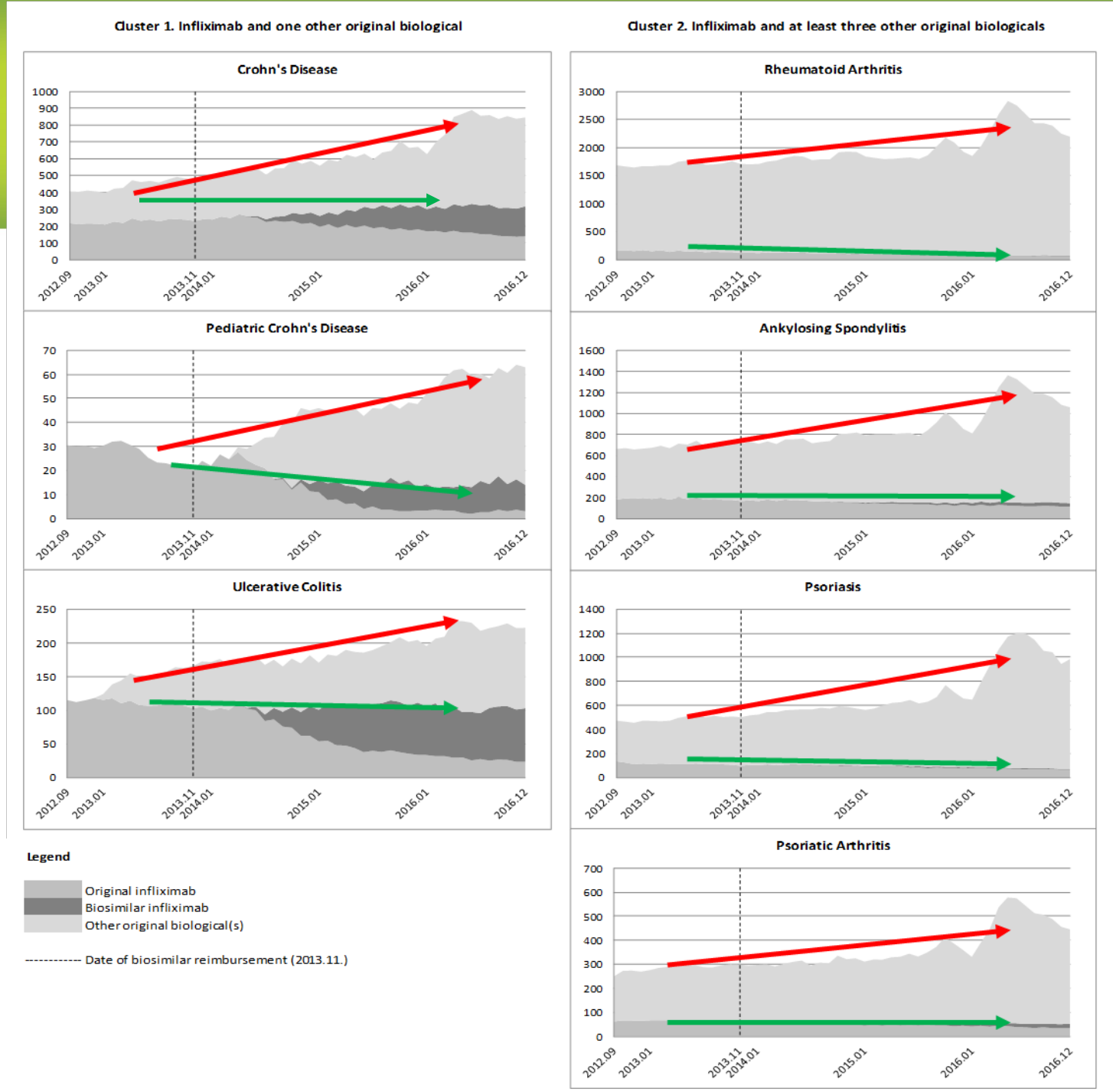
(Majority of new patients started on other original biologicals)

	Number of reimbursed biologicals	Indication	Originator infliximab	Biosimilar infliximab	Other patent protected biological(s)
Before Patent Expiry 2013.01. - 2013.10.	Infliximab and one other original biological	Ulcerative Colitis	59.6%	N/A	40.4%
		Adult Crohn's Disease	49.7%		50.3%
		Paediatric Crohn's Disease	100.0%		0.0%
	Infliximab and at least three other original biologicals	Rheumatoid Arthritis	2.6%		97.4%
		Ankylosing Spondylitis	11.0%		89.0%
		Psoriasis	8.9%		91.1%
		Psoriatic Arthritis	6.3%		93.8%
After Patent Expiry 2013.11. - 2016.12.	Infliximab and one other original biological	Ulcerative Colitis	13.5%	50.3%	36.3%
		Adult Crohn's Disease	14.3%	37.0%	48.7%
		Paediatric Crohn's Disease	17.1%	18.4%	64.6%
	Infliximab and at least three other original biologicals	Rheumatoid Arthritis	**0.4%**	**1.2%**	**98.4%**
		Ankylosing Spondylitis	**1.1%**	**4.1%**	**94.8%**
		Psoriasis	**1.4%**	**1.6%**	**97.0%**
		Psoriatic Arthritis	**1.5%**	**5.4%**	**93.1%**

Source: Harsányi A, et al (2019) Influence of biosimilar infliximab launch on the utilization pattern of biological medicines: the case of Hungary, Expert Review of Pharmacoeconomics & Outcomes Research, DOI: 10.1080/14737167.2019.1667232

Overall utilisation pattern:

- **After patent expiry the market share of multisource infliximab showed a decreasing trend in each indication of infliximab.**
- **Market share of other patented biologics shows an increase.**



Source: Harsányi A, et al (2019) Influence of biosimilar infliximab launch on the utilization pattern of biological medicines: the case of Hungary, Expert Review of Pharmacoeconomics & Outcomes Research, DOI: 10.1080/14737167.2019.1667232

The following policy practices should be implemented to maximize the social benefits of biosimilars:

- ☐ Administrative tools and policy measures should be implemented to incentivize the use of more affordable biosimilars;
- ☐ The pricing and reimbursement processes for biosimilars should be expedited to facilitate their prompt market entry;
- ☐ Amendments to clinical guidelines recommending the extended use of biosimilars should be implemented if justified by health benefits, such as providing patients with improved or earlier access to biological therapy;
- ☐ Off-patent biologics (including biosimilars) should be set as the preferred first-line biological therapy for treatment-naive patients; other, still patent-protected biologic medicines with no or limited added benefit should be used only in subsequent treatment lines;

Source: Tesar T, Golias P, Kobliskova Z, Wawruch M, Kawalec P and Inotai A (2020) Potential Cost-Savings From the Use of the Biosimilars in Slovakia. *Front. Public Health* 8:431. doi: 10.3389/fpubh.2020.00431

The following policy practices should be implemented to maximize the social benefits of biosimilars:

- ☐ After the expiration of a patent, patients should be switched, under medical supervision, from the original biologic medicine to the more affordable biosimilar alternative;
- ☐ There should be no separate reimbursement categories for biosimilars and original biologics with the same active compound or slightly modified formulations (e.g., subcutaneous vs. intravenous forms), unless the modified formulation has significant and proven added benefits to patients or healthcare systems;
- ☐ In addition to being informed about scientific evidence on biosimilars, physicians should be guided on how to appropriately educate their patients regarding these medicines;
- ☐ Information exchange platforms on good practices related to biosimilars between EU Member States should be established.

Source: Tesar T, Golias P, Kobliskova Z, Wawruch M, Kawalec P and Inotai A (2020) Potential Cost-Savings From the Use of the Biosimilars in Slovakia. *Front. Public Health* 8:431. doi: 10.3389/fpubh.2020.0043

Conclusions:

- The objective of biosimilar policies can be defined differently in countries with significant resource constraints, where accessibility of patients to high-cost biologic medicines is limited.

- In lower income European countries with barriers towards the use of patented biologic treatments, the policy objective of biosimilar medicines is not only to save money, but to increase patient access to biological medicines.