CADTH Symposium 2019:

Enhancing Access to Oncology Biosimilars in Canada

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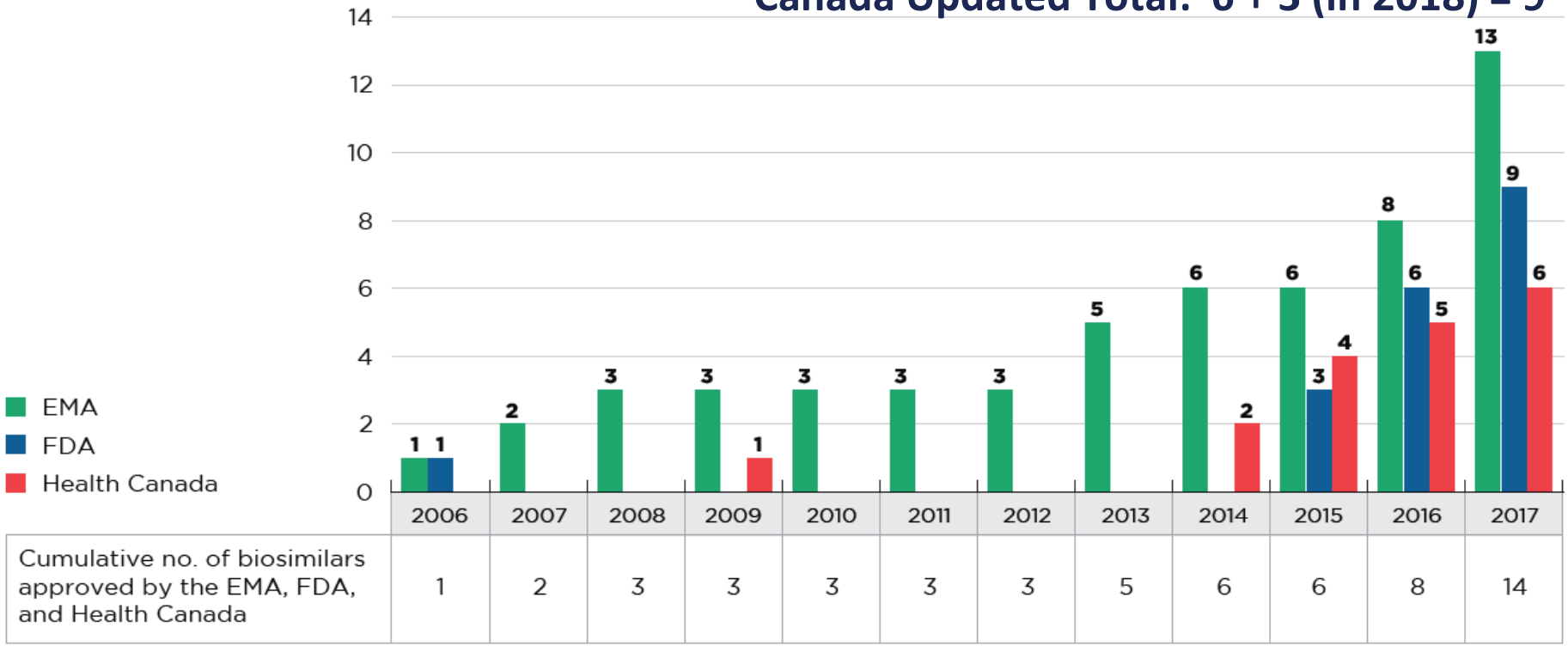
Disclosure:

I have no actual or potential conflict of interest in relation to this topic or presentation.

Biosimilars in Canada are Still Relatively 'Early'

14 biosimilars have been approved by Health Canada, the EMA and/or the FDA

Canada Updated Total: 6 + 3 (in 2018) = 9



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Cumulative no. of biosimilars approved by the EMA, FDA, and Health Canada	1	2	3	3	3	3	3	5	6	6	8	14

Source: http://www.pmprb-cepmb.gc.ca; Meds Entry Watch 2017 Report (Released Feb 20, 2019)

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Biosimilar Uptake in Canada Remains Low

Medicine (reference biologic)	Sales in Canada, 2017, $million	Share of pharmaceutical market (sales), 2017		First biosimilar approval*			First biosimilar sales*			Biosimilar uptake, share of units, Q4-2017 (no. of countries†)		
		Canada	PMPRB7 and Canada	EMA	FDA	Health Canada	EU	US	Canada	OECD median	PMPRB7 median	Canada
Infliximab (Remicade)	1,092.1	4.5%	1.3%	Sep-13	May-17	Jan-14	Q4-2013	Q4-2016	Q1-2015	40.5% (25)	45.4% (7)	4.0%
Adalimumab (Humira)	717.4	2.9%	3.4%	Mar-17	Sep-16	May-18	-	-	-	-	-	-
Etanercept (Enbrel)	316.3	1.3%	1.8%	Jan-16	Aug-16	Aug-16	Q1-2016	-	Q4-2016	9.9% (16)	37.4% (5)	3.1%
Trastuzumab (Herceptin)	277.4	1.1%	0.7%	Nov-17	Dec-17	-	Q2-2018	-	-	-	-	-
Insulin glargine (Lantus)	274.4	1.1%	1.7%	Sep-14	Dec-15	Sep-15	Q2-2015	Q4-2016	Q4-2016	8.1% (25)	8.5% (7)	2.6%
Rituximab (MabThera/ Rituxan)	255.7	1.1%	0.9%	Feb-17	-	-	Q2-2017	-	-	6.1% (10)	19.6% (4)	-
Filgrastim (Neupogen)	128.1	0.5%	0.2%	Sep-08	Mar-15	Dec-15	Q4-2008	Q2-2016	Q4-2016	88.6% (28)	91.1% (7)	43.5%
Bevacizumab (Avastin)	112.7	0.5%	0.7%	Jan-18	Sep-17	Apr-18	-	-	-	-	-	-

Source: http://www.pmprb-cepmb.gc.ca; Meds Entry Watch 2017 Report (Released Feb 20, 2019)

Biosimilar – pCPA Policy Principles / Directions

pCPA Pricing Principles (April 2016):

Commitment to a **pan-Canadian** pCPA negotiation process

Decisions informed by **evidence**

Foster **competitive biologics market**, supporting long term cost reductions & sustainability

Lower transparent pricing

Pursuit of **optimal value** from all industry stakeholders

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Biosimilar – pCPA Policy Principles / Directions

pCPA Biologics Policy Directions & pCPA Negotiations (Sept 2018):

1) The pCPA is committed to a unified, pan-Canadian process
2) Biologic drugs will be considered on an **individual basis, in their market context**
3) Negotiation for biosimilar drugs will **begin in parallel with the HTA** process
4) Offers for biologic drugs considered **after biosimilar**
5) Offers for biologics will **not be considered if seek to restrict / exclude biosimilars**
6) Offers for biologic/new biosimilar only considered with **transparent list price reductions**
7) **Tiered listings** for biologic drug products may be implemented
8) **Switching of patients** from a reference to a biosimilar may be implemented

Top 5 Best Sellers in 2017

1. **Adalimumab (Humira by Abbvie) - $18B**
2. Lenalidomide (**Revlimid** by Celgene) - $8B and growing
3. **Etanercept (Enbrel by Amgen/Pfizer) - $7.5B**
4. **Rituximab (Rituxan by Roche) - $7.5B**
5. **Trastuzumab (Herceptin by Roche) - $7B**

Source: Keith Speight from the Motley Fool 18/12/2017

Pan-Canadian Oncology Biosimilars Initiative

- **pCPA is implementing a pan-Canadian biosimilar strategy with the goal of ensuring appropriate and cost-effective use of biologics**
- **Cancer Care Ontario (CCO) and the pCPA** have partnered to develop and implement a pan-Canadian oncology-specific biosimilars strategy.

WHY?

- Implementation of oncology biosimilars across cancer agencies and hospitals will be different compared to our experience with implementing non-oncology biosimilars. Unlike the biosimilars negotiated thus far by the pCPA, oncology biosimilars will be used exclusively in the hospital environment and must be integrated into specific regimens and protocols.

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Ontario Cancer Care Ontario

Pan-Canadian Oncology Biosimilars Summit

(November 16, 2018, Toronto)

- **Aim:** Consultation and engagement event to discuss the challenges and opportunities of introducing therapeutic oncology biosimilars in Canada

- **Approach:** open, collaborative, consultative, and action-oriented

- **Stakeholders:** patients, patient advocacy organizations, clinicians, agencies, health system administrators and government officials

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Summit Key Learnings

Stakeholder Engagement

Ongoing stakeholder engagement is critical

Clinical Operations

Implementation issues at the hospital level and appropriate systems to maintain pharmacovigilance

Education & Information Sharing

Comprehensive education needed (e.g., to help clinicians discuss biosimilars with patients)

Reinvestment

Savings should be reinvested to help fund new and innovative cancer therapies

Monitoring

Real-world data should assess utilization, safety and effectiveness of oncology biosimilars

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