Chapter 6

Building on the experience and success of biosimilar medicines

Biosimilar medicines are increasingly becoming an integral part of modern healthcare systems, so what does the future hold?

Biosimilar medicines are internationally recognized for expanding access to life-changing treatments[1]

"Biosimilars could be game-changers for access to medicines for certain complex conditions."[2]

Dr Suzanne Hill, Director Essential Medicines and Health Products, World Health Organisation (WHO)

"Biosimilars can provide more treatment options for patients, and possibly lower treatment costs, enabling greater access for more patients."[3]

Dr Janet Woodcock, Director, Centre for Drug Evaluation and Research, Food and Drug Administration (FDA)

"Whether it's in the public or the private sector, we need to provide sustainable healthcare and biosimilars are clearly a good way to improve affordability."[4]

Professor Josep Tabernero, President-elect, European Society of Medical Oncology (ESMO)

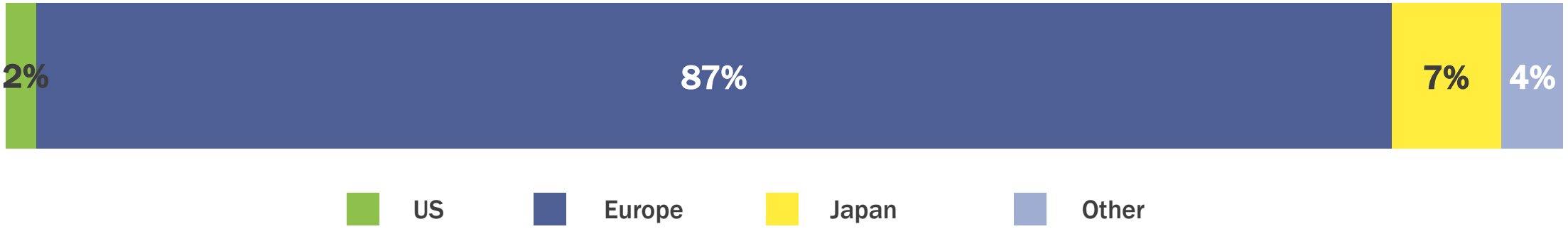
Biosimilar medicines are cost-effective therapeutic alternatives to reference biological products[1]

Reference: 1. QuintilesIMS. Delivering on the Potential of Biosimilar Medicines. 2016. Available at: http://bit.ly/2es03mY. Accessed July 2017; **2.** Hill S. WHO to begin pilot prequalification of biosimilars for cancer treatment. Available at: http://bit.ly/2q1WOtp. Accessed July 2017; **3.** Woodcock J. Biosimilars Implementation. Available at: http://bit.ly/2mkx1qP. Accessed July 2017; **4.** Tabernero J. Europe ready to embrace first copies of biotech cancer drugs. Available at: http://reut.rs/2rnAk35. Accessed July 2017.

Globally, there is a huge opportunity for biosimilar medicines to provide competition to existing biological medicines

Percentage of global biological medicine sales by region

Percentage of global biosimilar medicine sales by region



Experience of biosimilar medicines in Europe is expected to support faster uptake in other regions

Reference: QuintilesIMS. Market development in Europe and globally: MAT Dec 2016.

Uptake of biosimilar medicines is supported by an increasing number of biosimilar medicine approvals*

Active Substance	Europe[1]	Australia[2]	Japan[3]	Canada[4]	USA[5]	South Africa[6]
Adalimumab	✓				✓	
Enoxaparin sodium**	✓					
Epoetin (alfa/kappa/lamda/zeta)	✓	✓	✓			
Etanercept	✓	✓		✓	✓	
Filgrastim	✓	✓	✓	✓	✓	
Follitropin	✓	✓				
Infliximab	✓	✓	✓	✓	✓	
Insulin glargine§	✓	✓	✓	✓		✓
Rituximab	✓					
Somatropin¶	✓	✓	✓	✓		
Teriparatide	✓					

Often, for each active substance, more than one biosimilar medicine has been approved[1–6]

Footnotes: *Data compiled April 2017; **Approval of enoxaparin sodium in Japan and in the US was not under the biosimilar medicines pathway; §Approval of insulin glargine in the USA was not via the biosimilar medicines pathway; ¶Approval of somatropin in the USA and Australia was not via the biosimilar medicines pathway.

References: 1. European Medicines Agency. European public assessment reports. Available at: http://bit.ly/1DYP74U. Accessed July 2017; **2.** Australian Register of Therapeutic Goods (ARTG). ARTG search. Available at: http://bit.ly/2pTutk9. Accessed July 2017; **3.** Ministry of Health, Labour and Welfare (MHLW). Available at: http://bit.ly/2pRwSwH. Accessed July 2017; **4.** Health Canada. Data on file; **5.** Food and Drug Administration. Purple Book**.** Available at: http://bit.ly/2oEPDqH. Accessed April 2017; **6**. South African Journal of Diabetes 2017; 10: 12.

Switching biological medicines is considered safe[1,2]

- **Switching is a physician-led decision** to exchange one medicine for another medicine with the same therapeutic intent[1]
- **Europe is leading the way** in switching from the reference to a corresponding biosimilar medicine[3]
- EPARs, available on the EMA website, provide **substantial evidence** for the safety of a switch[3]
- In Japan, a switching study from reference product filgrastim to the biosimilar demonstrated the same clinical efficacy and safety, but at a **reduced cost**[4]
- **Large clinical experience** in Europe supports switching not only between new versions of the same product, but also between a reference and its biosimilar medicine[3]
- **EU data from thousands of patients** consistently shows that safety, efficacy, and immunogenicity is not affected when the switch is made[3]
- The lack of safety signals in Europe **provides further reassurance** of the safety of switching between the reference and the biosimilar medicine[3]

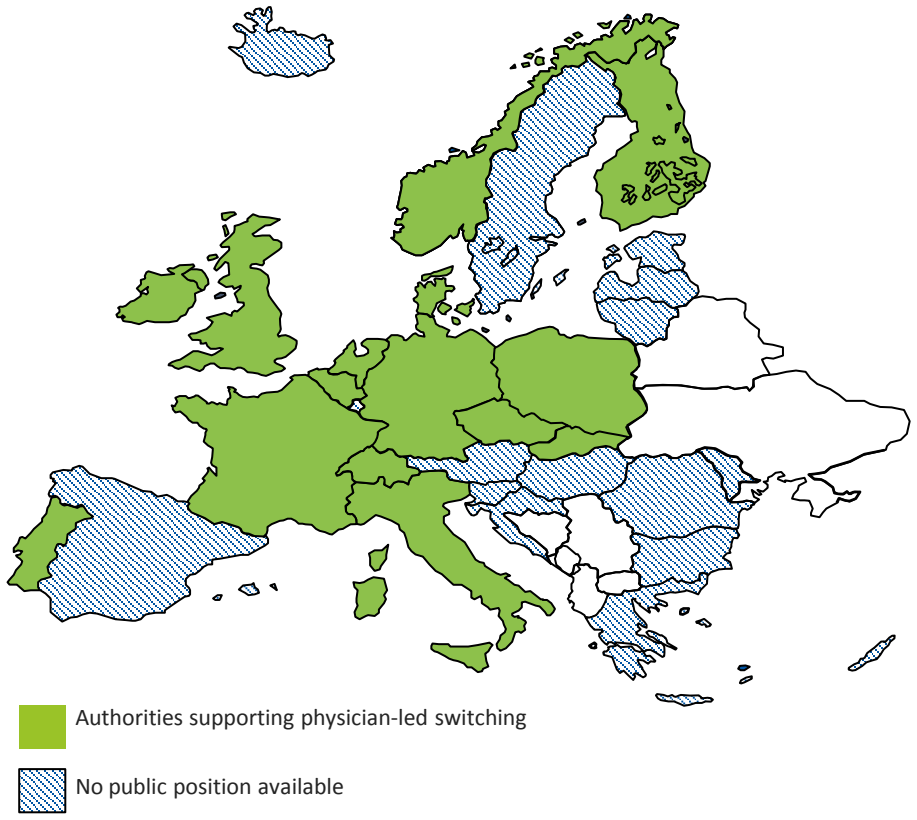
Under the supervision of the treating physician, patients can be safely switched from the reference product to the biosimilar medicine and vice versa[3]

Abbreviations: EMA, European Medicines Agency; EPAR, European Public Assessment Report.

References: 1. Ebbers HC, *et al. Expert Opin Biol Ther.* 2012;12(11):1473–85; **2.** Glintborg B, et al. *Ann Rheum Dis* 2017; [Epub ahead of print]; **3.** Kurki P, *et al. BioDrugs.* 2017;3(2):83–91; **4.** Kamada I, et al. *RSMP* 2017;7(1):3–15.

Widespread support for switching biosimilar medicines under supervision of a healthcare person

National guidance



Regulatory guidance

BioDrugs
DOI 10.1007/s40259-017-0210-0

CURRENT OPINION

Interchangeability of Biosimilars: A European Perspective

Pekka Kurki[1] · Leon van Aerts[2] · Elena Wolff-Holz[3] · Thij
Venke Skibeli[5] · Martina Weise[6]

> "In our opinion, switching patients from the original to a biosimilar medicine or vice versa can be considered safe."

Clinical guidance

ESMO Open
Cancer Horizons
CrossMark

Biosimilars: a position paper of the European Society for Medical Oncology, with particular reference to oncology prescribers

Josep Tabernero,[1] Malvika Vyas,[2] R
Paolo G Casali,[6] Andres Cervantes,
Jacek Jassem,[10] George Pentherou
Christoph C Zielinski,[14] Rolf A Stahe
Keith McGregor,[2] Fortunato Ciardiel

ECCO Position Statement

ECCO Position Statement on the Use of Biosimilars for Inflammatory Bowel Disease—An Update

Silvio Danese,[a,b] Gionata Fiorino,[c] Tim Raine,[d] Marc Ferrante,[e]
lian Panes,[k]

JCC

Consensus-based recommendations for the use of biosimilars to treat rheumatological diseases

Jonathan Kay,[1] Monika M Schoels,[2] Thomas Dörner,[3] Paul Emery,[4] Tore K Kvien,[5] Josef S Smolen,[2,6] Ferdinand C Breedveld,[7] on behalf of the Task Force on the Use of Biosimilars to Treat Rheumatological Diseases

Source: Medicines for Europe Internal Biosimilar Mapping

Switching studies confirm no differences in safety, efficacy or immunogenicity

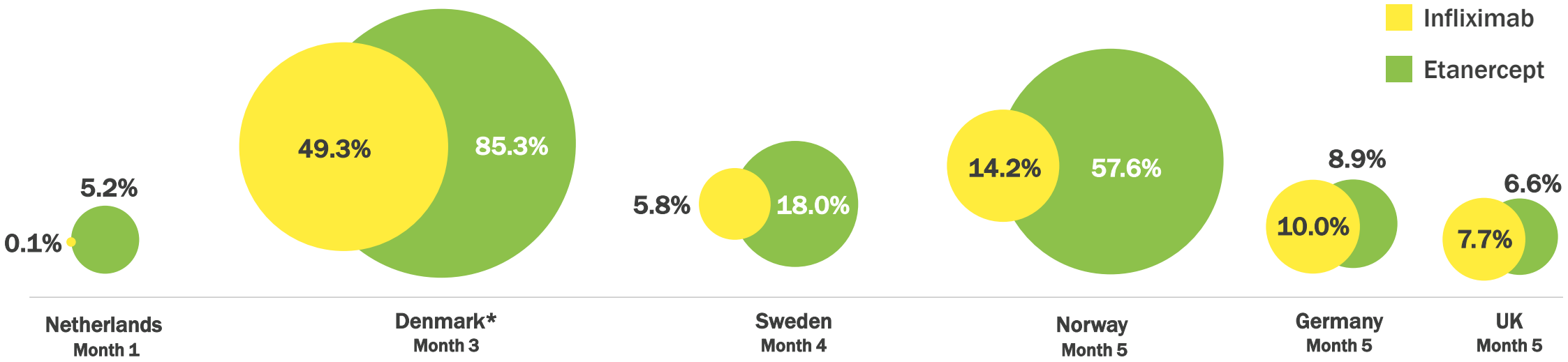
- Scientific literature (1993 up to 30 June 2017) on **single or multiple switching** from reference biological medicines to biosimilars.
- **90 studies** identified involving **7 molecular entities for 14 disease indications**, and enrolled a total of 14,225 individuals.
- Huge majority of single switch studies **did not report differences in safety, efficacy or immunogenicity** compared to patients not switched.
- Small number (three) of multiple switch studies published, but likewise **no differences detected**.
- Overall results suggest a low risk of either a safety concern or a loss of efficacy after switching to a biosimilar.

Source: H. P. Cohen – °Switching Reference Medicines to Biosimilars: A Systematic Literature Review of Clinical Outcomes

Increasing experience with biosimilar medicines is supporting faster uptake of new biosimilar medicines

- Infliximab was the first biosimilar monoclonal antibody (mAb) to be launched in Europe
- Uptake of a subsequent complex biosimilar, etanercept, was generally similar or improved compared with that of infliximab

Comparison of post-launch market share of biosimilar infliximab with that of etanercept for the same time period



The launch and uptake of multiple biosimilar medicines provides a competitive biologics marketplace

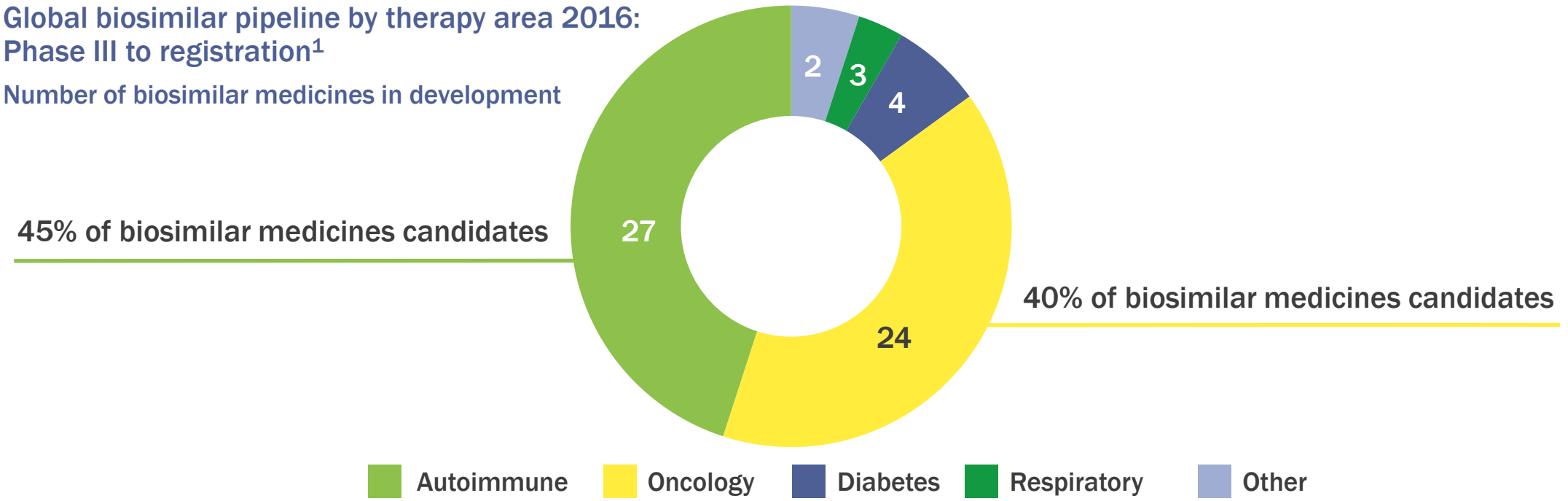
*Denmark data from MIDAS monthly restricted database

Reference: QuintilesIMS. MIDAS July 2016.

Biosimilar medicine development focuses on autoimmune diseases and oncology

Global biosimilar pipeline by therapy area 2016: Phase III to registration[1]

Number of biosimilar medicines in development



In a competitive market, physicians, payers and patients are able to benefit from the improved choice on offer[2]

Data not exhaustive, contains only publically announced biosimilar medicines

References: 1. QuintilesIMS. R&D focus. Oct 2016; **2.** QuintilesIMS. Delivering on the Potential of Biosimilar Medicines. 2016. Available at: http://bit.ly/2es03mY. Accessed July 2017.

A rich pipeline supports the long-term availability of biosimilar medicines

- Introduction of biosimilar medicines has increased **competition**[1]
- At the end of 2015, **41 biosimilar medicines candidates** were in the pipeline for four key reference biological products[2]

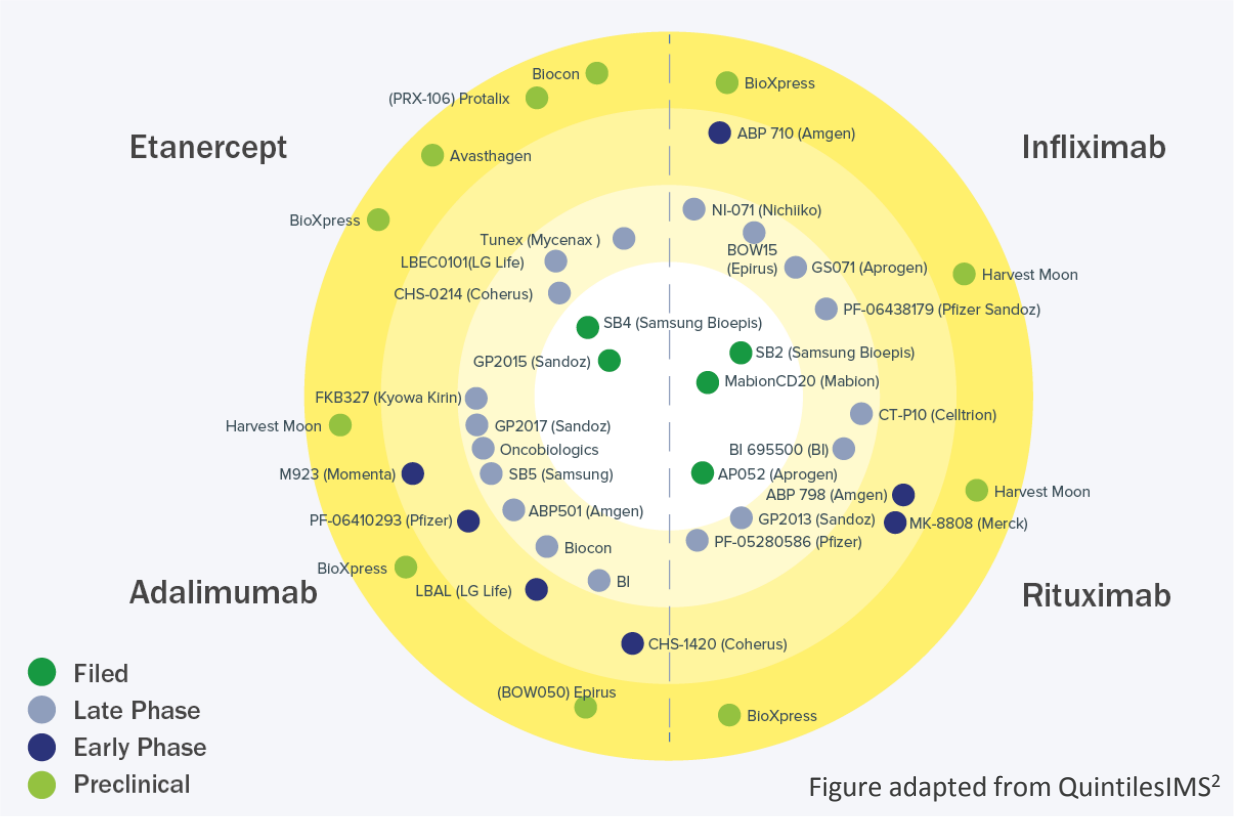


Figure adapted from QuintilesIMS[2]

A stable supply chain helps to ensure patients have access to these important treatments

References: 1. QuintilesIMS MIDAS MAT Q2. 2016; **2.** QuintilesIMS. Delivering on the Potential of Biosimilar Medicines. 2016. Available at: http://bit.ly/2es03mY. Accessed July 2017.

Availability of biosimilar medicines improves the security of the supply chain

- The FDA and EMA have identified manufacturing problems, delays in supply, and lack of available active ingredients as the **most frequent causes of drug shortages**[1]
- Drug shortages can **compromise patient safety and clinical outcomes**, and increased healthcare costs, due to delays or changes in treatment regimens[1]
- Biosimilar medicines **help prevent future biologic shortages** and ensure access to effective and safe treatment options[1]

"[…] the biosimilar market will see a more diverse range of companies, greater competition, and improved supply chain security."[2]

Alex Kudrin, Biopharmaceutical Consultant, United Kingdom

Biosimilar medicines offer improved access to more cost-effective healthcare, today and in the future

EMA, European Medicines Agency; FDA, Food and Drug Administration.

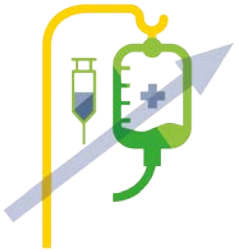
References: 1. Li E, *et al. Drug Des Devel Ther* 2015;9:3247–55; **2.** Kudrin A. Why 2017 Is The Year To Watch Biosimilars. Available at: http://bit.ly/2qNWej1. Accessed July 2017.

Summary: Building on the experience and success of biosimilar medicines

The benefits offered by biosimilar medicines are **internationally recognized**[1]

Around the world, **multiple biosimilar medicines** have been approved[2–6]

Switching from a reference product to a biosimilar medicine is considered safe[7]



Experience with biosimilar medicines **improves uptake**[8]

A **strong pipeline** supports the continuous introduction of new biosimilar medicines[1]

Availability of biosimilar medicines **safeguards the supply chain**, ensuring patient access to key therapeutics

References: 1. QuintilesIMS Institute for Healthcare Informatics. Delivering on the Potential of Biosimilar Medicines. 2016. Available at: http://bit.ly/2es03mY. Accessed July 2017; **2.** European Medicines Agency. Available at: www.ema.Europa.eu Accessed July 2017; **3.** Ministry of Health, Labour and Welfare (MHLW). Available at: http://bit.ly/2pRwSwH. Accessed July 2017; **4.** Health Canada. Data on file; **5.** Food and Drug Administration. Purple Book**.** Available at: http://bit.ly/2oEPDqH. Accessed July 2017; **6.** Australian Register of Therapeutic Goods (ARTG). Available at: http://bit.ly/2pTutk9. Accessed July 2017; **7.** Ebbers HC, *et al. Expert Opin Biol Ther.* 2012;12(11):1473–85; **8.** QuintilesIMS MIDAS MTH July 2016.

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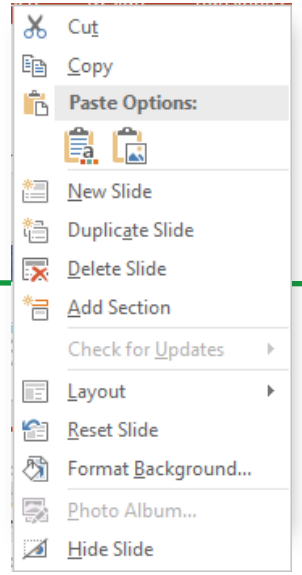

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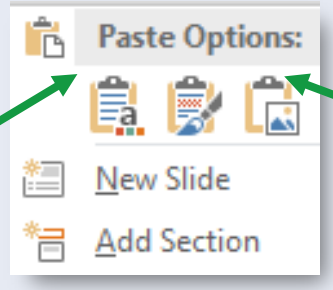

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