

THE LANDSCAPE OF THE BIOSIMILAR MARKET

A changing world for follow-on biologics

An infographic from
Industry Standard Research | ISRReports.com

WHAT ARE BIOSIMILARS?

biosimilars (bīō'simələrs) *noun* – a term used to describe officially approved subsequent (or “generic”) versions of innovative biopharmaceutical products made by a different sponsor following patent and exclusivity expiry on the innovator product.

Low hanging fruit

2009



Between 2009 and 2019 **21 blockbuster biopharmaceuticals**, mainly in the areas of **oncology** and **inflammatory diseases**, will have lost patent protection.

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These 21 blockbuster drugs have a combined annual market value of over **\$50 Billion** (US).

2019

Safety concerns

Because the manufacturing process is more complex, biosimilars often come with safety concerns that are not common to generic pharmaceutical products. Physicians, Pharmacists and Payers have different opinions regarding the safety of biosimilars. ISR asked each group if biosimilars should require full-fledged clinical trials.



Physicians
55% Yes



Pharmacists
26% Yes



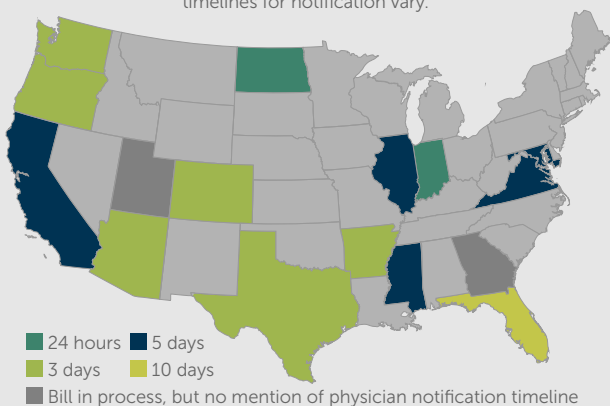
Payers
10% Yes

Legislation

In its "Draft Guidance" the FDA has stated that biosimilars must be "interchangeable"; however final guidance has not yet been provided. State legislatures have seen an influx of bills on biosimilars in the past two months, but the details vary.

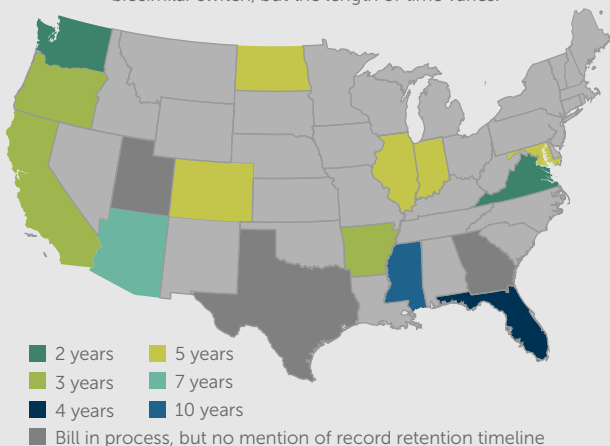
PHYSICIAN NOTIFICATION

Most bills require the pharmacist to notify the prescribing physician of a biosimilar switch, but the timelines for notification vary.



RECORD RETENTION

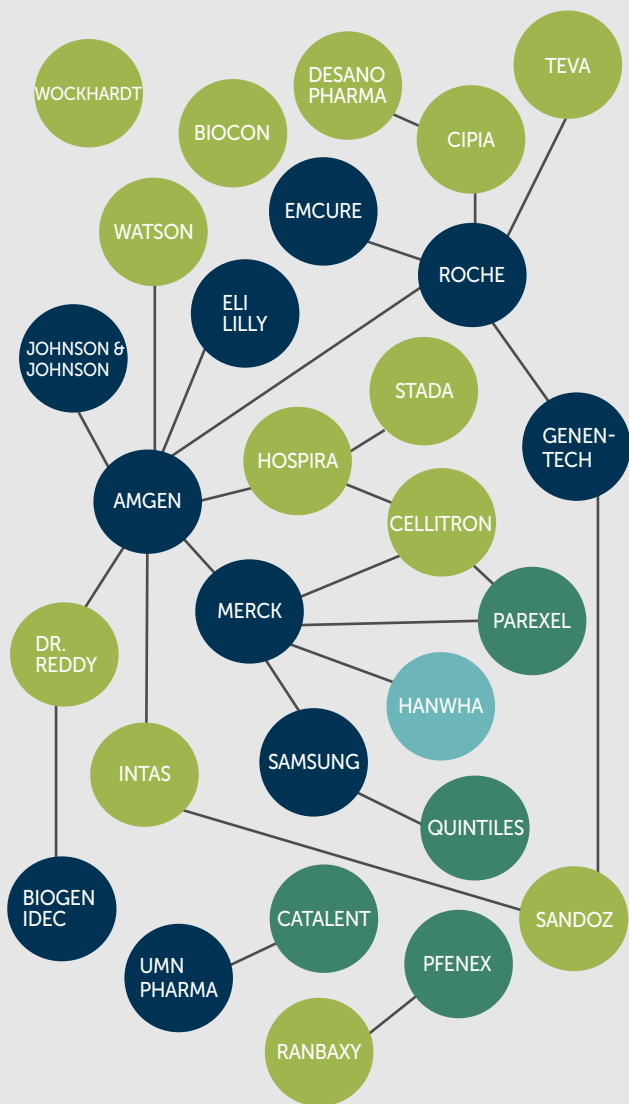
Most bills require the pharmacy to retain a record of the biosimilar switch, but the length of time varies.



Key Players and Partnerships

The pharmaceutical and biotech industry is forming alliances and partnerships for the development of biosimilar drugs. Here is just a portion of the web of alliances.

● CRO/CMO ● GENERIC ● BIOPHARMA ● OTHER



SOURCES:

Industry Standard Research (Biosimilar Primer Series)
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