Update on US state legislation on biosimilars substitution

Since the biosimilars pathway was introduced, many US states have been considering, or have introduced, legislation to allow for substitution of biosimilars deemed interchangeable. This paper gives an update of the current situation.

Keywords: Biologicals, biosimilars, legislation, notification, substitution

The Biologics Price Competition and Innovation (BPCI) Act of 2009 was signed into law on 23 March 2010 by President Barack Obama. The BPCI Act establishes an abbreviated approval pathway for biological products that are demonstrated to be 'highly similar' (biosimilar) to, or 'interchangeable' with a US Food and Drug Administration (FDA) approved biological product.

In the US, FDA, under the BPCI Act, has the authority to designate a biosimilar as interchangeable. The term 'interchangeable' is used in the US as a scientific designation to indicate that FDA has made a scientific determination that the product 'can be expected to produce the same clinical result as the reference product in any given patient', and for products administered more than once to an individual, 'the risk in terms of safety or diminished efficacy of alternating or switching between the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch'. The European Medicines Agency (EMA) does not have the authority to evaluate a product for its safety in terms of repeated switching[i].

On 28 April 2015, FDA released three final biosimilars guidances [1] and US states are now contemplating substitution of interchangeables biosimilars [2]. This follows the agency giving marketing authorization to its first biosimilar on 6 March 2015 [3]. Sandoz's Zarxio (filgrastim-sndz) injection became the first biosimilar ever to be approved in the US, for five of the indications for which the US-licensed originator biological, Neupogen, is approved. In anticipation of such an approval, many US states have been considering, or have introduced, laws related to the substitution of biosimilars at the pharmacy level [4].

Zarxio was approved as a biosimilar, not as an interchangeable product. Guidance on how to establish interchangeability is still lacking from FDA. Industry groups have called on the agency to promptly finalize guidance on establishing interchangeability, as well as to issue guidance on the issue of naming, given the fact that FDA has designated a placeholder non-proprietary name for Zarxio [3].

Most of the proposed legislation requires the retail pharmacist to communicate to the prescribing physician the identity of the product dispensed if an interchangeable product is available, regardless of which product (brand-name or interchangeable) was dispensed.

Compromise language developed by both biosimilar and originator manufacturers is supported by more than 20 companies and organizations, including the Biotechnology Industry Organization (BIO) and the Generic Pharmaceutical Association (GPhA). The compromise proposal requires the dispensing pharmacist to 'communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer' 'within a reasonable time'. It does not require the pharmacist to wait for approval from the physician and thereby reduces any delays for patients. An option to provide the information via an interoperable electronic system, such as a prescribing system, also reduces the burden on pharmacists [5].

Biosimilar substitution bills, including those with physician notification after the product had been dispensed, began appearing in US states in 2013. Opposition came from manufacturers of generics and from organizations representing pharmacists, who objected to the extra workload communication requirements might entail. However, now a new batch of bills is appearing, many using the newly proposed 'compromise wording'.

Communication periods vary from within 24 hours after dispensing in North Dakota to within 10 days in New Jersey. Record keeping is also a part of many of the proposed bills, with the length of time that records of biosimilars substitution have to be kept varying from two to 10 years as is consistent with each state's policy for generics.

Thirteen states: California, Idaho, Illinois, Louisiana, Maryland, Michigan, Mississippi, New Jersey, Oklahoma, Oregon, Pennsylvania, Texas, Vermont are currently considering legislation on the substitution of biosimilars for brand-name biologicals.

Twelve states, including Colorado, Delaware, Florida, Georgia, Indiana, Massachusetts, North Carolina, North Dakota, Tennessee, Utah, Virginia and Washington; have passed legislation requiring prescriber communication and record keeping for biosimilars.

Virginia has also passed a biosimilar substitution law, but with a sunset clause on the prescriber communication provision, which expires on 1 July 2015. The state is currently considering an extension to the clause, see Table 1.

The wording in the different state legislation varies, but, where a time limit for prescriber communication is specified, it is similar to that of Utah:

> *'Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry into an interoperable electronic medical records system, through an electronic prescribing technology, a pharmacy benefit management system, or a pharmacy record that is electronically accessible by the prescriber. Entry into an electronic records system as described in this Subsection (8) is presumed to provide notice to the prescriber.'*

For the 'compromise wording' the text in the bills is similar to that of Colorado:

> *'Within a reasonable time after dispensing a biological product, the*

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Table 1: US state legislation on biosimilars substitution

State*	Bill	Status**	Key votes	Physician veto	Physician notification period (after substitution)	Preferred method of notification	Record-keeping period
Arizona	SB 1438	Not enacted	Passed Senate committee	'DAW'/'do not substitute'	3 days	Electronic	7 years
Arkansas	SB 149	Not enacted	None	Yes	3 days	Written/electronic	2 years
California	SB 671	Under consideration	Passed by Senate 22 May 2015	'do not substitute'	'within a reasonable time'	Electronic	None specified
Colorado	SB 71	Enacted	Governor signed 3 April 2015	'DAW'/'do not substitute'	'within a reasonable time'	Electronic	2 years
Delaware	SB 118	Enacted	Passed by Senate 14 May 2014	Yes	2 days	Electronic/fax/written/telephone	3 years
Florida	H 365	Enacted	Signed 3 June 2013	Yes	None specified	–	2 years
Georgia	SB 51 HB 195	Enacted	Governor signed 6 May 2015	Not specified	2 days	Electronic	None specified
Idaho	H 175	Under consideration	Referred to Health and Welfare Committee 23 February 2015	Not specified	5 days	Electronic	None specified
Illinois	SB 1611	Under consideration	Senate committee deadline 31 May 2015	Yes	'within a reasonable time'	Electronic	5 years
Indiana	SB 262	Enacted	Governor signed 25 March 2014	Yes	10 days	Electronic/written	2 years
Louisiana	HB 319	Under consideration	Referred to Committee on Health and Welfare 25 May 2015	DAW	5 days	Electronic	None specified
Maryland	SB 537 HB 733	Under consideration	Passed by Senate 18 March 2015. House hearing 2 April 2015	Yes	'within a reasonable time' – not exceeding 10 days	Electronic	None specified
Massachusetts	SB 2176 HB 3734	Enacted	–	Yes	'within a reasonable time'	Fax/electronic	1 year
Michigan	HB 4437	Under consideration	Filed in House 15 April 2015	DAW	Before dispensing	Not specified	None specified
Mississippi	HB 32	Under consideration	Died In Committee 3 February 2015	Yes	'within a reasonable time' – not exceeding 10 days	Electronic	10 years
New Jersey	A 2477	Under consideration	Referred to Senate Health, Human Services and Senior Citizens Committee 18 May 2015	'do not substitute'	10 days	Electronic/written/telephonic	5 years
North Carolina	S 197 H 195	Enacted	Governor signed 21 May 2015	DAW	'within a reasonable time'	Electronic	None specified
North Dakota	S 2190	Enacted	–	Yes	1 day	–	5 years

(*Continued*)

Table 1: *Continued*

State*	Bill	Status**	Key votes	Physician veto	Physician notification period (after substitution)	Preferred method of notification	Record-keeping period
Oklahoma	HB 1503	Under consideration	Referred to House Rules Committee 11 February 2015	Yes	5 days	Written/electronic	2 years
Oregon	SB 147 HB 2026	Under consideration	Public hearing held 16 March 2015	Yes	'within a reasonable time'	Electronic	3 years
Pennsylvania	SB 514	Under consideration	Referred to Senate Health Committee 14 May 2015	Yes	'within a reasonable time'	Electronic	None specified
Tennessee	SB 984 HB 572	Enacted	Governor signed 4 May 2015	Yes	'within a reasonable time'	Electronic	2 years
Texas	SB 542 HB 751	Under consideration	House adopts Conference Committee Report 22 May 2015	Yes	'within a reasonable time'	Electronic	None specified
Utah	HB 279	Enacted	Governor signed 27 March 2015	DAW	5 days	Electronic	None specified
Vermont	H 289	Under consideration	Referred to Healthcare Committee 27 February 2015	Yes	Consent required – no period indicated	Not specified	None specified
Virginia	H 1422	Enacted	Governor signed 16 March 2013 Sunset clause 1 July 2015	'brand medically necessary'	5 days	Electronic/written/telephonic	2 years
	HB 1436	Under consideration	Extension of sunset to 1 July 2016. Stricken 19 February 2015	–	–	–	2 years
Washington	SB 5935 HB 1675 HB 1679	Enacted	Governor signed 11 May 2015. Effective date: 24 July 2015.	DAW	5 days	Electronic	2 years

*Data updated as of 21 April 2015; **Details on legislation reflect the most recent versions of bills as amended in legislatures.
DAW: dispense as written.

dispensing pharmacist or his or her designee shall communicate to the prescribing practitioner the specific biological product dispensed to the patient, including the name and manufacturer of the biological product. The pharmacist or his or her designee shall communicate the information to the prescribing practitioner by making entry into an interoperable electronic medical records system, through electronic prescribing technology, or through a pharmacy record that the prescribing practitioner can access electronically. Otherwise, the pharmacist or his or her designee shall communicate to the prescribing practitioner the name and manufacturer of the biological product dispensed to the patient using facsimile, telephone, electronic transmission, or other prevailing means.'

'The pharmacy from which the biological product was dispensed must retain a written or electronic record of the dispensed biological product for at least two years after the substitution.'

[1]The term 'interchangeable' is used to mean different things in the US and Europe. In the US, it is the result of a scientific evaluation by FDA. In Europe, no entity makes a scientific evaluation of the safety of repeated switching, but EU Member States have the authority to determine that pharmacists may distribute a different product.

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References 3–5 can be found on page 94.

Update on US state legislation on biosimilars substitution

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