45 US states have passed biosimilar substitution laws

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Despite the fact that the US Food and Drug Administration (FDA) has yet to approve a biosimilar as interchangeable with its reference biological, many US states have been considering legislation on biosimilars substitution [1].

To date, 45 US states and Puerto Rico have passed laws that permit or require pharmacists to dispense an interchangeable biological product in certain situations. In fact, the only states that have not yet passed legislation on the topic are: Alabama, Arkansas, Maine, Mississippi, Oklahoma and the District of Columbia.

FDA gave marketing authorization to its first biosimilar in March 2015 [2]. To date, FDA has approved 16 biosimilars [3]. All the products approved so far have been approved as biosimilars, not as interchangeable products. According to the BPCI Act, only a biological that has been approved as interchangeable may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product.

Most of the bills authorize a pharmacist to substitute a biosimilar for a prescribed biological product if the biosimilar has been approved by FDA as 'interchangeable'. In addition, substitution will only be allowed if the prescriber has not designated on the prescription that substitution is prohibited. For example, where the prescriber writes 'brand necessary', 'no substitutions', 'NS' or words of similar meaning on the prescription.

In addition, in most states, the pharmacist must provide notice to the patient and the prescriber 'within a reasonable time' and allow the use of an interoperable electronic medical records system, thus reducing the burden on pharmacists. This is in line with compromise automatic substitution language supported by brand-name and biosimilars makers and unveiled by the Association for Accessible Medicines in 2014 [4]. However, some state laws require communication within a certain number of days of dispensing the biosimilar and also require that the pharmacy or pharmacist retains a record of the substitution.

Two states that with a unique approach, are South Carolina and West Virginia. In the former pharmacists may substitute a biosimilar if it is interchangeable or if the pharmacist determines in their 'professional judgement' that the biosimilar is therapeutically equivalent to the prescribed biological. West Virginia, on the other hand, requires pharmacists to substitute a less expensive, interchangeable biological unless the pharmacist believes that the biosimilar is not suitable for the patient.

Other states have focused on reducing costs for the government. For example, in Nevada patients may not refuse a substitution of a less expensive, interchangeable biosimilar if the product is being paid for by a governmental agency. In Michigan the pharmacist is required to pass on the cost savings, i.e. the difference in wholesale price to the pharmacist, to the purchaser or third-party payment source when substituting a less expensive, interchangeable biosimilar. While in New York the pharmacist is required to substitute an interchangeable biosimilar if it is less expensive than the prescribed biological and the prescriber does not instruct otherwise. If the biosimilar is not available, the pharmacist can dispense the prescribed biological only if he or she agrees to dispense it for a price that does not exceed the price that would have been charged for the biosimilar if it was available.

Editor's Comment

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References

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