Botulinum Toxins Get New Generic Names

By ALICIA AULT

The Food and Drug Administration’s recent decision to require Neuronetics, Botox’s former manufacturer, to use a new ‘generic’ name for botulinum toxin is not likely to have much of an impact on patient safety, say dermatologists.

Citing the introduction of Dysport in April as the agency’s trigger, the FDA said that it was seeking to reduce confusion and the potential for prescribing errors. Dysport is the botulinum toxin A, similar to Botox.

Now, Botox will be known generically as onabotulinumtoxinA; Myobloc will be known as rimabotulinumtoxinB, and Dysport will be known as abobotulinumtoxinA.

Each product will also carry the same boxed warning of the potential for distant spreading, which can lead to life-threatening respiratory difficulties.

FDA first required this warning in April, but Dysport was not then on the market.

All of the toxins also will have a Medication Guide for patients discussing the potential for adverse effects from distant spreading.

“The revised labels also emphasize that the different botulinum toxin products are not interchangeable, because the units used to measure the products are different,” said the FDA in a statement.

With each product having a distinct established name, we believe the chance of serious medication errors is minimized,” an agency spokesman said in an interview.

But several dermatologists said that since botulinum toxins are generally ordered, purchased, and dispensed by physicians, the new requirement won’t have much effect.

Dr. Christopher Zachary, who is chairman of the dermatology department at the University of California in Irvine, said that he supports the FDA’s efforts to increase safety.

“But, he added, ‘I’d suggest from a practical point of view that people keep using trade names,” noting that these are the names that stick in the minds of physicians, staff, and patients.

Dr. Michael Kaminer, assistant clinical professor in the dermatological surgery oncology service at Yale University, New Haven, Conn., said in an interview, “I can’t imagine this would have any impact on consumers or physicians.”

Distinct established names for the toxins could make a difference when and if a generic version becomes available, he said.

Dr. Kaminer disclosed no conflict of interest. Dr. Zachary disclosed that he receives grants and research support from Allergan.