



By Electronic Mail

Federal Trade Commission
Office of the Secretary
Room H-113 (Annex X)
600 Pennsylvania Avenue NW
Washington DC 20580

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RE: Workshop on Follow-On Biologics: Project No. P131208

To whom it may concern:

The FTC is considering naming conventions for follow-on biologics and biologics in the context of pharmacovigilance and the need to differentiate the adverse events caused by different products. To the extent they may have impact on those considerations, The Pew Charitable Trusts would like to provide a summary of the new requirements for product identification and serialization established by the Drug Quality and Security Act of 2013 (DQSA).

Beginning November 27, 2017, four years after enactment of DQSA, drug manufacturers are required to place a “product identifier” on the smallest saleable package of each prescription drug product¹ they distribute in the United States. By November 27, 2018, five years after enactment, drug repackagers must also place product identifiers on the medicines they repackage, and must maintain records to link these identifiers to those originally applied by manufacturers.

The product identifier is defined as a standardized graphic that includes the product lot number, expiration date, and a “standard numerical identifier” (see below). This information must be encoded into a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization. For individual drug packages, the law requires this data carrier to be a two-dimensional bar code. For cases of drug packages, the data carrier may be either a two-dimensional or linear barcode. Information in the product identifier must also be presented in human-readable form.

¹ Exceptions to the definition of “product”: blood or blood components intended for transfusion, radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Federal Regulations) that are regulated by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021), imaging drugs, an intravenous product described in clause (xiv), (xv), or (xvi) of paragraph (24)(B), any medical gas (as defined in section 575), homeopathic drugs marketed in accordance with applicable guidance under [The Federal Food, Drug and Cosmetic Act], or a drug compounded in compliance with section 503A or 503B.



A component of the product identifier, the standard numerical identifier (SNI) is the unique code that can differentiate one package of drug from another otherwise identical package. According to the law, the SNI is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

It is important to note that the DQSA serialization requirement applies only to the packaging done by the manufacturer or repackager, and not the pharmacy. For many drugs, manufacturer packaging is removed once the drug reaches the pharmacy, and drugs are dispensed to patients in alternate containers. In these cases, it would be more difficult to use the serial number, or SNI, for pharmacovigilance. In the case of biologics, however, there may be a greater likelihood that manufacturers are packaging drugs at the patient-dose level, so that serial numbers could be read at the point of dispense.

Unlike INN names or NDC codes, SNIs and product lot numbers can be associated with a particular point in time and could, in principle, be used to detect adverse events associated with product drift or specific storage or handling conditions. However, use of SNIs numbers in pharmacovigilance would also introduce technical challenges that might offset any potential advantages.

We would be pleased to provide further technical assistance if useful.

Sincerely,


Allan Coukell
The Pew Charitable Trusts