

§ 90-85.27. Definitions.

As used in G.S. 90-85.28 through G.S. 90-85.31:

- (1) Biological product. – As defined in section 351(i) of the Public Health Service Act, 42 U.S.C. § 262(i).
- (1a) Equivalent drug product. – A drug product which has the same established name, active ingredient, strength, quantity, and dosage form, and which is therapeutically equivalent to the drug product identified in the prescription.
- (2) Established name. – As defined in section 502(e)(3) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 352(e)(3).
- (3) Good manufacturing practice. – As defined in Part 211 of Chapter 1 of Title 21 of the Code of Federal Regulations.
- (3a) Interchangeable biological product. – A biological product determined by the United States Food and Drug Administration to meet the standards set forth in 42 U.S.C. § 262(k)(4), or deemed therapeutically equivalent by the United States Food and Drug Administration.
- (4) Manufacturer. – The actual manufacturer of the finished dosage form of the drug.
- (4a) Narrow therapeutic index drugs. – Those pharmaceuticals having a narrowly defined range between risk and benefit. Such drugs have less than a twofold difference in the minimum toxic concentration and minimum effective concentration in the blood or are those drug product formulations that exhibit limited or erratic absorption, formulation-dependent bioavailability, and wide inpatient pharmacokinetic variability that requires blood-level monitoring. Drugs identified as having narrow therapeutic indices shall be designated by the North Carolina Secretary of Health and Human Services upon the advice of the State Health Director, North Carolina Board of Pharmacy, and North Carolina Medical Board, as narrow therapeutic index drugs and shall be subject to the provisions of G.S. 90-85.28(b1). The North Carolina Board of Pharmacy shall submit the list of narrow therapeutic index drugs to the Codifier of Rules, in a timely fashion for publication in January of each year in the North Carolina Register.
- (5) Prescriber. – Anyone authorized to prescribe drugs pursuant to the laws of this State. (1979, c. 1017, s. 1; 1981 (Reg. Sess., 1982), c. 1188, s. 3; 1983, c. 196, s. 9; 1997-76, s. 1; 1997-443, s. 11A.118(b); 2015-27, s. 1.)