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National Agency for Food & Drug Administration & Control (NAFDAC)

Director General's Office (DGO)

Guidance on Master Data Attributes required for Implementation of Traceability for Pharmaceutical Products in Nigeria

Background

The Federal Government of Nigeria through the Federal Ministry of Health, FMOH established the National Pharmaceutical Traceability Strategy to leverage global standards to establish and implement pharmaceutical traceability in Nigeria. Given the mandate of the National Agency for Food and Drug Administration and Control, NAFDAC, the burden of drug distribution, sale, use and security rests on the Agency. Hence, NAFDAC developed a 5-Year Traceability Implementation plan in line with the national strategy to achieve supply chain visibility and strengthen its pharmacovigilance activities against the scourge of Substandard and Falsified Medicines and Medical Devices. From this strategy document, it is expected that traceability becomes fully operational in the Nigerian Pharmaceutical Supply Chain by the end of the year 2024.

The foundation for all traceability implementation is adopting a common business language, that can be used by all trading partners from manufacturer to dispenser. Hence, Nigeria has adopted the global GS1 standards to identify, capture and share information about pharmaceuticals and their movement along the supply chain. Considering Nigeria's context and the goals of its traceability system, a full track and trace model with data aggregated in a centralized repository, has been adopted. Integral to this model is the availability of master, transaction and event data associated with the product at each point of the supply chain.

Requirement to share Master Data by Marketing Authorization Holders, MAHS

Master Data describes attributes or characteristics of an item, entity or location that is created by the owner of that item or entity. Access to consistent, quality master data is necessary to enable traceability. To meet the 2024 implementation date, as part of regulatory compliance all stakeholders, particularly product brand owners, will be required to share legal, functional and location master data with the NAFDAC.

Given the need for a common language, uniformity, consistency, accuracy and completeness of data, and compliance with global standards; this document is published as guidance for stakeholders on the uniform list of Master Data attributes that will be required with their respective descriptions.

List of Master Data Attributes

SN	Attribute	Description
1.	BRAND NAME	A brand name is a drug marketed under a proprietary, trademark-protected name. (Please provide if applicable).
2.	FUNCTIONAL NAME	This describes the use of the product or service by the consumer.
3.	GENERIC NAME	The official nonproprietary name of a drug, under which it is licensed and identified by manufacturer. Generic name of a pharmaceutical from the World Health Organization International Non-proprietary Names system is recommended.
4.	PRODUCT DESCRIPTION	This is the description of the product commonly used in trade. This generally contains information about the product name, strength, dosage form, and package size such as “atorvastatin 10 mg tab 500” for mono units.
5.	TRADE ITEM DESCRIPTION	Same as above but for aggregates (shippers/pallets identified with GTINs) e.g., "20 packs of atorvastatin 10mg tabs for shippers.
6.	STRENGTH	The strength of a drug product tells how much of the active ingredient is present in each dosage.
7.	ACTIVE INGREDIENT	An active ingredient is any component that provides a pharmacological activity or other direct effects in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans.
8.	PRODUCT FORM	The way a medicine is presented such as a tablet, a capsule, or an injectable, cream, solution for injection, etc.
9.	ROUTE OF ADMINISTRATION	The method(s) of administering the product. In pharmacology and toxicology, a route of administration is the path by

		which a drug, fluid, or other substance is brought into contact with the body.
10.	SHELF LIFE	The period of time, from the date of manufacture, that a product is expected to remain within its approved product specification while handled and stored under defined conditions.
11.	GLOBAL PRODUCT CATEGORY (GPC) CODE	It is a code specifying a product category according to the GS1 Global Product Classification (GPC) standard. The GPC brick code is a mandatory attribute in the Global Data Synchronization Network (GDSN).
12.	ATC CODE	Anatomical Therapeutic Chemical/Defined Daily Dose pharmaceutical classification structure number.
13.	PACK SIZE	The amount of product in a pack or container.
14.	QUANTITY	The total dosage units contained in one unit of the drug product. The quantity or weight of the drug given as a proportion of the PACK size.
15.	UNIT OF MEASUREMENT	A unit of measurement is a definite magnitude of a quantity, defined and adopted by convention or by law, that is used as a standard for measurement of the same kind of quantity, e.g., ml, mg etc.
16.	PRIMARY PACKAGING MATERIAL	Any material, including printed material, employed in the packaging of pharmaceutical products, excluding any outer packaging used for transportation or shipment. Primary packaging materials are those that are in direct contact with the product.
17.	PACKAGING LEVEL	The packaging level is described by the GTIN. Suggested values include Each and Case, but additional packing levels may be appropriate depending on the product.
18.	PACKAGING TYPE	Packaging may be defined as the collection of different components (e.g., bottle, vial,

		closure, cap, ampoule, blister) which surround the pharmaceutical product from the time of production until its use.
19.	LABEL DESCRIPTION	See the sections on the guidelines for the registration of both imported and local drugs in NAFDAC
20.	NET WEIGHT	Weight of item without packaging.
21.	GROSS WEIGHT	Weight of item with packaging.
22.	DIRECTIONS FOR USE	The directions under which a layman can use a drug safely for the purposes for which it is intended. They tell you exactly how and when to take a medication.
23.	NAFDAC REGISTRATION NUMBER (NRN)	The NRN is assigned to every approved drug product in Nigeria.
24.	STORAGE INFORMATION	The conditions specified for storing the drug e.g., at Room Temperature, Between 2-8 degrees Celsius etc.
25.	COMPANY	The applicant (also called BRAND OWNER in GS1 parlance) is the Marketing Authorization Holder.
26.	ADDRESS OF COMPANY	Address of the Brand Owner.
27.	MANUFACTURER	Name of the product manufacturer.
28.	ADDRESS OF MANUFACTURER	Address of the product manufacturer.
29.	GTIN FOR ALL TRADE ITEM PACKAGING LEVELS	GTIN for each unit or Case or any other packaging described as a trade item for sale.

Note:

THE BRAND OWNER IS USUALLY ONE ORGANIZATION. HE PROVIDES MARKETING AUTHORIZATION TO AS MANY ORGANIZATIONS AS HE WISHES BUT THEY OWN THE BRAND.

ONE SKU=1 GTIN

MONO PACK WILL HAVE DIFFERENT GTIN FROM CASE OR PALLET IF IDENTIFIED AS TRADE ITEMS (i.e., they are invoiced or sold as described)

CASE WILL HAVE DIFFERENT GTIN FROM PALLET FOR TRADE ITEMS (i.e., they are invoiced or sold as described)