

NATIONAL



AUTHORITY

Safe Drugs Save Lives

26th September 2025

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To: Marketing Authorization Holders (MAHs)
Local Technical Representatives (LTRs)

CIRCULAR NO. 006/DPAR/2025

REVISION OF NATIONAL DRUG AUTHORITY PROFESSIONAL GUIDELINES FOR VARIATIONS TO REGISTERED PRODUCTS

National Drug Authority (NDA) wishes to inform you of the revision of the professional guidelines for variations to registered products. The key change in the revised guidelines is recategorization of Local Technical Representative (LTR) and Marketing Authorization Holder (MAH) changes from Major Variation to Immediate Notification.

The following revised guidelines are now available on the NDA website (<http://www.nda.or.ug>).

- a) Guidelines on variation of registered biotherapeutic products (PAR/GDL/033, Rev 2).
- b) Guidelines on variation to registered pharmaceutical products (PAR/GDL/005, Rev 4).
- c) Guidelines on variation to registered human vaccines (PAR/GDL/018, Rev 2).


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OUR MISSION

To protect and promote human and animal health through the effective regulation of drugs and healthcare products.

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