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51	The Federal Competition and Consumer Protection Act, 2018--- Merger Review (Amended) Regulations, 2021	B2651-2652

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SCHEDULE
CLASSIFICATION OF IVDs

IVDs are categorised by risk as follows—

- (a) those that constitute a direct risk to patients ; and
- (b) those that could constitute a serious risk to health and are essential to control *e.g.* AIDS and hepatitis, etc.

These categories are further subdivided into four classes, dependent on risk and the level of conformity assessment required, which provides a summary of the class, perceived risk and conformity assessment requirement.

IVDs categories are as follows—

Based on intended use; expectation of users, importation information, health impact of the regulation—

A—LOW RISK AND D—HIGH RISK

- Rule 1 : Class D—Tests for blood, tissue, organ screening prior to transfusion or transplantation.
- Rule 2 : Class C/D—Tests of immunological compatibility classified by their criticality.
- Rule 3 : Class C—Moderate public health risk or high individual risk providing the critical or sole determinant for correct diagnosis.
- Rule 4 : Class B/C—Self-testing devices classified by their criticality.
- Rule 5 : Class B—IVD reagents, instruments and test receptacles.
- Rule 6 : Class A/B—Applies to all other devices.
- Rule 7 : Class A: IVD controls without an assigned value.

S. I. No. 51 of 2021

**THE FEDERAL COMPETITION AND CONSUMER
PROTECTION ACT, 2018**

MERGER REVIEW (AMENDED) REGULATIONS, 2021

[2nd Day of August, 2021]

Commence-
ment.

In exercise of the powers conferred upon it by Sections 17, 18 and 163 of the Federal Competition and Consumer Protection Act, 2018 ("the Act"), and all other powers enabling it in that behalf, the Federal Competition and Consumer Protection Commission hereby makes the following amendments to its Merger Review Regulations, 2020—

1. Schedule 1 of the Regulations is amended as follows—

Applicable Fees for Merger Notifications

Amendment
of
Schedule 1.

2. As approved by the Federal Competition and Consumer Protection Commission ("the Commission") pursuant to Section 18 (1) (h) of the Act and the Merger Review Regulations, the following fees shall apply to all mergers to be notified to the Commission—

Fees.

S/N	Threshold	Fees (consideration of transaction)	Fees (last combined annual turnover)
1.	First ₦500 Million	0.45%	0.45%
2.	Next ₦500 Million	0.40%	0.40%
3.	Any sum thereafter	0.35%	0.35%

Fee Table

1. The applicable fees for the merger notifications, where applicable, shall be a sum of either—

(i) the percentages of the consideration sum payable for the transaction as specified in the Fee Table above ; or

(ii) the percentages of the last annual turnover as specified in the Fee Table above,

whichever is higher.

2. All merger applications shall be subject to the payment of an application fee in the sum of ₦50,000 per undertaking.

3. The applicable fee for the expedited procedure service is ₦10,000,000 (Ten Million Naira).

4. The applicable fee for the negative clearance procedure is ₦2,500,000 (Two Million Five Hundred Thousand Naira).

5. The relevant turnover for the purposes of calculating the applicable fees in respect of mergers involving foreign entities with a local component, is the turnover based on, or attributable to the business of or in the local component(s) in Nigeria.

6. The relevant turnover for the purposes of calculating the applicable fees for transactions involving Private Investment Entities is the combined turnover of the relevant Fund (subject to fulfilling applicable conditions set out by the Commission) and the target.

Citation.

3. These Regulations may be cited as the Merger Review (Amended) Regulations, 2021.

MADE at Abuja this 2nd day of August, 2021.

BABATUNDE IRUKERA
Executive Vice-Chairman
Federal Competition and Consumer
Protection Commission