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NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

Paediatric Medicinal Products Regulations, 2024

CLOSED FOR COMMENTS; UNDERGOING GAZETTING

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (CAP N1 LFN 2004)

Paediatric Medicinal Products Regulations, 2024

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NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (CAP N1 LFN 2004)

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[ ] **Commencement**

In exercise of the powers conferred on it by National Agency for Food and Drug Administration and Control by sections 5 and 30 of the National Agency for Food and Drug Administration and Control Act (Cap N1 LFN.) 2004 and section 12 of the Food, Drug and Related Products (Registration, Etc.) Act (Cap F33 LFN.,) 2004 and all other powers enabling it in that behalf, the Governing Council of the National Agency for Food and Drug Administration and Control with the approval of the Minister of Health makes the following Regulations -

1. **Application**
   These Regulations shall apply to paediatric medicinal products manufactured, imported, exported, advertised, sold, distributed, or used in Nigeria.

2. **Registration of Paediatric medicinal products**
   The registration of Paediatric medicinal products shall be in accordance with the provisions of the Agency's extant Drug and Related Products Registration Regulations and as may be prescribed by the Agency.

3. **Application for registration**
   (1) Further to regulation 2, application for a paediatric medicinal product Certificate of Registration shall include the submission of data concerning use of the product in paediatric population.
   (2) Application for a paediatric Certificate of Registration shall be accompanied by the particulars and documents necessary to establish quality, safety, and efficacy in the paediatric population, including any specific data needed to support an appropriate strength, pharmaceutical form or route of administration for the product, in accordance with an agreed paediatric investigation plan.
   (3) The application shall include the Paediatric Investigation Plan (PIP) as approved by the Agency for products developed in Nigeria and for products not developed in Nigeria, the Agency may deploy Reliance.
   (4) The data
      (a) shall be submitted in a manner as may be prescribed by the Agency.
      (b) may be derived from published literature or from new studies.

4. **Brand name or Trademark**
   The paediatric product in respect of which a Certificate of Registration is granted may retain the name of the medicinal product which contains the same active substance and in respect of which the same Holder of Use Certificate of Registration has been approved for use in adults.

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5. **Labelling of paediatric medicinal products**
   (1) The labelling of paediatric medicinal products shall be in accordance with the provisions of the Agency's extant Drug and Related Products Labelling Regulations and as may be prescribed by the Agency.
   (2) The statement 'For paediatric use only' shall be clearly indicated on Paediatric medicinal products.

6. **Product Information leaflet**
   (1) Further to Regulation 5, paediatric medicinal products shall
      (a) include relevant information on use in paediatric populations in the product information leaflet.
      (b) provide clear user information for correct and appropriate administration of paediatric medicinal product.

7. **Measuring device for Paediatric medicinal products**
   Packages for oral paediatric liquid drug products, shall contain an appropriate measuring device graduated as applicable.

8. **Advertisement of Paediatric medicinal products**
   The advertisement of paediatric medicinal products shall be in accordance with the provisions of the Agency's extant Drug and Related Products Advertisement Regulations and as may be prescribed by the Agency.

9. **Pharmacovigilance of Paediatric medicinal products**
   (1) The pharmacovigilance of paediatric medicinal products shall be in accordance with the provisions of the Agency's extant Good Pharmacovigilance Practice Regulations and as may be prescribed by the Agency.
   (2) Holder of Certificate of Registrations shall put in place pharmacovigilance mechanisms adapted to meet the specific challenges of collecting safety data in the paediatric population, including data on possible long-term effects.

10. **Clinical trials for paediatric medicinal products**
   (1) Medicinal products intended for paediatric population shall undergo clinical trials as specified in the PIP.
   (2) The clinical trials of paediatric medicinal products as specified in regulation 10 (1) shall be in accordance with the provisions of the Agency's extant Clinical Trials Regulations and as may be prescribed by the Agency.
   (3) Notwithstanding regulation 10 (1), Holder of Certificate of Registrations shall
      (a) conduct clinical efficacy and safety in the paediatric population.
      (b) submit results of studies conducted in compliance with an agreed paediatric investigation plan
      (c) shall submit proposal to ensure the long-term follow-up of possible adverse reactions to the use of the medicinal product in the paediatric population.

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(d) where there is a particular cause for concern, the applicant should submit and implement a risk management system and perform specific post-marketing studies as a condition for the granting of the Certificate of Registration.

11. **Data on medicinal products for paediatric populations**
    (1) The Agency shall maintain a database of clinical studies and information on medicinal products for the paediatric population.
    (2) Further to regulation 11 (1), the Agency shall maintain the following additional information
        (a) register of clinical trials of medicinal products for paediatric use including all ongoing, prematurely terminated, and completed paediatric studies conducted in Nigeria.
        (b) details of the study results of the paediatric clinical trials submitted to the Agency.
    (3) As may be required by the Agency, applicant or Holder of Certificate of Registration with relevant clinical data on safety or efficacy in the paediatric population for products shall submit such data to the Agency to improve the information available on the use of medicinal products in the paediatric populations and make such data accessible.
    (4) Further to regulation 11 (3) applicant or Holder of Certificate of Registration shall include such information in the product information aimed at healthcare professionals and patients as approved by the Agency.

12. **Regulatory Reliance**
    The Agency shall adopt regulatory reliance mechanisms in making regulatory decisions where the quality, safety and efficacy of paediatric medicinal products have been confirmed or where the NRA is a WHO listed Authority or where the paediatric medicinal product has been assessed by experts within a competent body.

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13. **Reference to National or International bodies**
    The label of paediatric medicinal product shall not refer, directly or indirectly, to a national or international body, except as prescribed by the Agency.

14. **Withdrawal of paediatric medicinal product**
    (1) Holders of Certificate of Registration may withdraw a paediatric medicinal product from the market.
    (2) In the interests of public health to ensure the continuing availability of safe and effective medicinal products for paediatric indications, Holder of Certificate of Registration shall ensure that products as specified in regulation 13 (1) are available for the paediatric population.
    (3) The compliance of regulations 13 (1) and (2) by Holders of Certificate of Registration shall be with the Approval of the Agency.

15. **Power to seal**
    The Agency shall have power to seal up any premises used or being used in connection with any offence under these Regulations until such time as the paediatric medicinal product is removed or such time as the paediatric medicinal product is removed or such reasonable time as the Minster may determine.

16. **Prohibition**

Paediatric medicinal product shall not be manufactured, imported, exported, advertised, sold, distributed, or used in Nigeria unless the paediatric medicinal product complies with the provisions of these Regulations.

17. **Offences and Penalties**

(1) Any person who contravenes any of the provisions of these Regulations commits an offence and liable on conviction. In the case of: -

(a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N800,000:00 or both,

(b) a body corporate, to a fine not exceeding N5,000, 000:00.

(2) Where an offence under these Regulations is committed by a body corporate, firm or any other association of individuals, every: -

(a) director, manager, secretary or other similar officer of the body corporate;

(b) partner or officer of the firm;

(c) trustee of the body concerned;

(d) person concerned in the management of the affairs of the association; or

(e) person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this regulation,

commits an offence and liable to be proceeded against and punished in the same manner as if he

had himself committed the offence, unless he proves that the act or omission constituting the

offence took place without his knowledge, consent, or connivance.

18. **Forfeiture after conviction**

(1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government::

(a) any asset or property constituting proceeds derived from or obtained, directly or indirectly, from the offence; and

(b) any of the person's property or instruments used in any manner to commit or to facilitate the commission of the offence.

(2) In this section, "proceeds" means any property derived or obtained, directly or indirectly, through the commission of the offence.

19. **Enforcement of the Regulations**

The Agency is exclusively responsible for the enforcement of these Regulations.

20. **Interpretation**

In these Regulations, unless the context otherwise requires -

Agency means the National Agency for Food and Drug Administration and Control (NAFDAC);

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"Competent Authority" means a government agency or body statutorily responsible for carrying out the function.

Paediatric population means that part of the population aged between birth and 18 years and includes the subpopulation age groups of neonates, infants, children and adolescents;

Paediatric Investigation Plan means a research and development programme aimed at ensuring that the necessary data are generated determining the conditions in which a medicinal product may be approved to treat the paediatric population;

21. **Citation**

These Regulations may be cited as the Paediatrics Medicinal Products Regulations, 2024

MADE at Abuja this …….day of …….. 2024

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Chairman of the Governing Council
National Agency for Food and Drug Administration and Control (NAFDAC)

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