

**HIGHLIGHTS OF THE RECOMMENDATIONS OF THE BOE:**

<b>REVIEW OF HSRDIS GUIDELINE</b>	
<b>OLD</b>	<b>NEW (AMENDMENT)</b>
<p><b>1. Introduction</b></p> <p>The Central Bank of Nigeria (CBN), as part of its policy response to the COVID-19 pandemic, introduces the Healthcare Sector Research and Development Intervention Scheme (HSRDIS) to help strengthen the public healthcare system with innovative financing of research and development (R&amp;D) in new and improved drugs, vaccines and diagnostics of infectious diseases in Nigeria. Specifically, the HSRDIS is designed to trigger intense national R&amp;D activities to develop a Nigerian vaccine, drugs and herbal medicines against the spread of COVID-19 and any other communicable or non-communicable diseases through the provision of grants to biotechnological and pharmaceutical companies, institutions, researchers, and research institutes for the research and development of drugs, herbal medicines and vaccines for the control, prevention and treatment of infectious diseases. The Scheme is intended to boost domestic manufacturing of critical drugs and</p>	<p><b>1. Introduction</b></p> <p>The Central Bank of Nigeria (CBN), as part of its policy response to the COVID-19 pandemic, introduces the Healthcare Sector Research and Development Intervention Scheme (HSRDIS) to help strengthen the public healthcare system with innovative financing of research and development (R&amp;D) in new and improved drugs, vaccines and diagnostics of infectious diseases in Nigeria. Specifically, the HSRDIS is designed to trigger intense national R&amp;D activities to develop a Nigerian vaccine, drugs and herbal medicines/<b>medical devices</b> against the spread of COVID-19 and any other communicable or non-communicable diseases through the provision of grants to biotechnological and pharmaceutical companies, institutions, researchers, and research institutes for the research and development of drugs, herbal medicines/<b>medical devices</b> and vaccines for the control, prevention and treatment of infectious</p>

<p>vaccines to ensure their sustainable domestic supply and reduce the bulk manufacturing costs of the drugs, herbal medicines and vaccines in Nigeria.</p> <p>The Framework outlines the operational modalities for the Scheme.</p>	<p>diseases. The Scheme is intended to boost domestic manufacturing of critical drugs and vaccines to ensure their sustainable domestic supply and reduce the bulk manufacturing costs of the drugs, herbal medicines/<b>medical devices</b> and vaccines in Nigeria.</p> <p>The Framework outlines the operational modalities for the Scheme.</p>
<p><b>2. Objectives of the Scheme</b></p> <p>The broad objectives of Scheme include:</p> <p>2.1 Providing grants for R&amp;D in new or revalidation of drug molecule, phytomedicines and vaccines for the control, prevention and treatment of infectious diseases in Nigeria;</p> <p>2.2 Boosting domestic manufacturing of validated drugs (Active Pharmaceutical Ingredients or APIs), herbal medicines and vaccines for the control, prevention and treatment of infectious diseases in Nigeria and reduce the nation's dependence on other countries for these drugs and</p>	<p><b>2. Objectives of the Scheme</b></p> <p>The broad objectives of Scheme include:</p> <p>2.1 Providing grants for R&amp;D in new or revalidation of drug molecule, phytomedicines and vaccines for the control, prevention and treatment of infectious diseases in Nigeria;</p> <p>2.2 Boosting domestic manufacturing of validated drugs (Active Pharmaceutical Ingredients or APIs), herbal medicines/<b>medical devices</b> and vaccines for the control, prevention and treatment of infectious diseases in Nigeria and reduce the nation's dependence on other</p>

<p>vaccines;</p> <p>2.3 Improving the capacity of the biotechnological and pharmaceutical companies, institutions, researchers, and research institutes in the development of approved Nigerian drugs, herbal medicines and vaccines for infectious diseases;</p> <p>2.4 Supporting capacity of relevant health agencies towards attaining WHO Maturity Level 3, a prerequisite for manufacturing of vaccines in Nigeria;</p> <p>2.5 Facilitating partnership between academia (researchers, research institutes and universities) and industry into the research and development of drugs, phytomedicines and vaccines for the control, prevention and treatment of infectious diseases in Nigeria; and</p> <p>2.6 Reduce dependence on imported drug products</p>	<p>countries for these drugs and vaccines;</p> <p>2.3 Improving the capacity of the biotechnological and pharmaceutical companies, institutions, researchers, and research institutes in the development of approved Nigerian drugs, herbal medicines/<b>medical devices</b> and vaccines for infectious diseases;</p> <p>2.4 Supporting capacity of relevant health agencies towards attaining WHO Maturity Level 3, a prerequisite for manufacturing of vaccines in Nigeria;</p> <p>2.5 Facilitating partnership between academia (researchers, research institutes and universities) and industry into the research and development of drugs, phytomedicines and vaccines for the control, prevention and treatment of infectious diseases in Nigeria; and</p>
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<p>(synthetic and herbal) and vaccines for the control, prevention and treatment of infectious diseases in Nigeria.</p>	<p>2.6 Reduce dependence on imported drug products (synthetic and herbal) and vaccines for the control, prevention and treatment of infectious diseases in Nigeria.</p>
<p><b>3. Eligible Research and Development Activities</b></p> <p>Activities eligible for consideration under the Scheme shall include:</p> <ul style="list-style-type: none"> <li>i. Research and development of candidate drugs, herbal medicines and vaccines validated by relevant health authorities for the control, prevention and treatment of infectious diseases;</li> <li>ii. Manufacturing of drugs, herbal medicines and vaccines validated by relevant health authorities for the control, prevention and treatment of infectious diseases;</li> <li>iii. Red biotechnological R&amp;D in new health technology for the control, prevention and treatment of infectious diseases;</li> <li>iv. Research partnership between</li> </ul>	<p><b>2. Eligible Research and Development Activities</b></p> <p>Activities eligible for consideration under the Scheme shall include:</p> <ul style="list-style-type: none"> <li>i. Research and development of candidate drugs, herbal medicines/<b>medical devices</b> and vaccines validated by relevant health authorities for the control, prevention and treatment of infectious diseases;</li> <li>ii. Manufacturing of drugs, herbal medicines/<b>medical devices</b> and vaccines validated by relevant health authorities for the control, prevention and treatment of infectious diseases;</li> <li>iii. Red biotechnological R&amp;D in new health technology for the control, prevention and treatment of infectious diseases;</li> <li>iv. Research partnership between</li> </ul>

academia and industry into the development drugs and vaccines for the control, prevention and treatment of infectious diseases;

- v. Research and development into validated phytomedicines for the control, prevention and treatment of infectious diseases; and

**NOTE:** Candidate vaccines undergoing pre-clinical testing or trials shall not be eligible for consideration under this Scheme. However, candidate vaccines undergoing clinical testing or trials shall be eligible for consideration under the Scheme if considered to have high potentials to cross the clinical trial stage and prospects of scale by the BoE.

In applying for the grant, the applicant shall be required to have conducted pre-clinical testing of the candidate drugs, herbal medicines and vaccines, and obtained certification from relevant health authorities for further research and development.

Special consideration shall be given to candidate drugs, herbal medicines and vaccines with high scientific merit against emerging infections and contribute to the development of the

academia and industry into the development drugs and vaccines for the control, prevention and treatment of infectious diseases;

- v. Research and development into validated phytomedicines for the control, prevention and treatment of infectious diseases; and

**NOTE:** Candidate vaccines undergoing pre-clinical testing or trials shall not be eligible for consideration under this Scheme. However, candidate vaccines undergoing **late preclinical and early** clinical testing or trials shall be eligible for consideration under the Scheme if considered to have high potentials to cross the clinical trial stage and prospects of scale by the BoE.

In applying for the grant, the applicant shall be required to have conducted pre-clinical testing of the candidate drugs, herbal medicines/**medical devices** and vaccines, and obtained certification from relevant health authorities for further research and development.

Special consideration shall be given to

<p>Nigerian vaccine.</p> <p>For this purpose, a Body of Experts (BoE) shall be constituted from the academia and industry to review validated research proposal submitted and recommend for financing, as appropriate. The BoE shall meet regularly to appraise the research and development project and submit progress reports to the CBN.</p>	<p>candidate drugs, herbal medicines/<b>medical devices</b> and vaccines with high scientific merit against emerging infections and contribute to the development of the Nigerian vaccine.</p> <p>For this purpose, a Body of Experts (BoE) shall be constituted from the academia and industry to review validated research proposal submitted and recommend for financing, as appropriate. The BoE shall meet regularly to appraise the research and development project and submit progress reports to the CBN.</p>
<p><b>4. Funding</b></p> <p>The Scheme shall be funded from the Developmental Component of the Micro, Small and Medium Enterprise Development Fund (MSMEDF).</p>	<p><b>4. Funding</b></p> <p>No Amendment</p>
<p><b>5. Grant Limit</b></p> <p>i. <b>Research activities:</b> Maximum of ₦50.0 million.</p> <p>ii. <b>Development/Manufacturing activities:</b> Maximum of ₦500.0 million.</p> <p><b>NOTE:</b> Disbursement under the Scheme</p>	<p><b>5. Grant Limit</b></p> <p>No Amendment</p>

<p>shall be made to beneficiaries in tranches subject to approved milestones achieved.</p>	
<p><b>6. Research and Development Timeframe</b></p> <ul style="list-style-type: none"> <li>i. <b>Research activities:</b> Not more than two (2) years from the date of release of fund.</li> <li>ii. <b>Development/Manufacturing activities:</b> Not more than one (1) year from the date of release of fund.</li> </ul>	<p><b>6. Research and Development Timeframe</b></p> <p>No Amendment</p>
<p><b>7. Body of Experts</b></p> <p>The Body of Experts (BoE) shall be responsible for the review and evaluation of submitted research proposals, as well as recommend for financing R&amp;D projects with high potentials to contribute to the development of the Nigerian vaccines for infectious diseases. The composition of the BoE shall be as detailed below:</p> <ul style="list-style-type: none"> <li>i. Two (2) independent research specialists appointed by the CBN;</li> <li>ii. One (1) nominee from National Agency for Food and Drug</li> </ul>	<p><b>7. Body of Experts</b></p> <p>The Body of Experts (BoE) shall be responsible for the review and evaluation of submitted research proposals, as well as recommend for financing R&amp;D projects with high potentials to contribute to the development of the Nigerian vaccines for infectious diseases. The composition of the BoE shall be as detailed below:</p> <ul style="list-style-type: none"> <li>i. Two (2) independent research specialists appointed by the CBN;</li> <li>ii. One (1) nominee from National Agency for Food and Drug</li> </ul>

<p>Administration and Control (NAFDAC);</p> <p>iii. One (1) nominee from Nigeria Institute for Pharmaceutical Research and Development (NIPRD);</p> <p>iv. One (1) nominee from Nigeria Centre for Disease Control (NCDC); and</p> <p>v. One (1) nominee from Nigeria Institute of Medical Research (NIMR)</p> <p><b>NOTE:</b> The Chair of the BoE shall be appointed by the CBN.</p>	<p>Administration and Control (NAFDAC);</p> <p>iii. One (1) nominee from Nigeria Institute for Pharmaceutical Research and Development (NIPRD);</p> <p>iv. One (1) nominee from Nigeria Centre for Disease Control (NCDC); and</p> <p>v. One (1) nominee from Nigeria Institute of Medical Research (NIMR)</p> <p>vi. One (1) nominee from National Biotechnological Development Agency (NABDA)</p> <p><b>NOTE:</b> The Chair of the BoE shall be appointed by the CBN.</p>
<p><b>8. Modalities</b></p> <p>i. The applicant(s) shall submit its application, with relevant documentation of validation from relevant health authorities, trial results, patent registration details (if any) and development timetable to the Body of Experts (BoE).</p> <p>ii. The BoE shall evaluate applications</p>	<p><b>8. Modalities</b></p> <p>i. The applicant(s) shall submit its application, with relevant documentation of validation from relevant health authorities, trial results, patent registration details (if any) and development timetable to the Body of Experts (BoE).</p> <p>ii. The BoE shall evaluate applications</p>



<p>and recommend to the CBN</p> <p>iii. The CBN shall review for documentation adequacy and completeness;</p> <p>iv. Upon approval, the approved grant sum shall be released to the applicant's account with any PFI of his/her choice.</p> <p>v. The beneficiary shall submit periodic report on the project to the CBN.</p> <p><b>NOTE:</b> The CBN shall have proprietary right over all financed R&amp;D outcomes or products. Equally, licensing protocol for the mass manufacturing of developed drugs, phytomedicines and vaccines shall be defined by the BoE in accordance with the World Health Organisation's current Good Manufacturing Practices (cGMP).</p>	<p>and recommend to the CBN</p> <p>iii. The CBN shall review for documentation adequacy and completeness;</p> <p>iv. Upon approval, the approved grant sum shall be released to the applicant's account with any PFI of his/her choice.</p> <p>v. The beneficiary shall submit periodic report on the project to the CBN.</p> <p><b>NOTE:</b> Inventions arising from HSRDIS financed research and development projects must be reported to CBN that funded the grants. Individual researchers and pharmaceutical manufacturers are to retain substantial (80%) ownership of the drugs, medical devices, herbal medicines and vaccines made under HSRDIS funded research. Inventors are expected to file for patent protection and to ensure commercialization upon licensing for the benefit of public health.</p>
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<p><b>9. Monitoring</b></p> <p>Periodic joint monitoring of research and development activities shall be conducted by the BoE and periodic progress reports submitted to the CBN.</p>	<p><b>9. Monitoring</b></p> <p>No Amendment</p>
<p><b>10. Amendments</b></p> <p>The Framework shall be subject to review from time to time as may be deemed necessary by the CBN.</p>	<p><b>10. Amendments</b></p> <p>No Amendment</p>
<p><b>11. Enquiries and Returns</b></p> <p>All enquiries and returns should be addressed to:</p> <p><b>Director, Development Finance Department, Central Bank of Nigeria, Abuja.</b></p> <p><u>May 2020</u></p>	<p><b>11. Enquiries and Returns</b></p> <p>All enquiries and returns should be addressed to:</p> <p><b>Director, Development Finance Department, Central Bank of Nigeria, Abuja.</b></p> <p><u>September, 2020</u></p>