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Licensing of Niprisan: Lessons Learnt.

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Outline

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- Business options for use of IP
- Criteria for effective license (WIPO)
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- MoU for collaboration between THP and NIPRD
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- Patents and Royalties
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Role of WIPO

- Workshops
- Elements of Licensing Agreements
- Negotiations
- Patent Attorney-training

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Business options for use of IP

- In-house to create the needed IP in a stand alone mode;
- Create a spin-off or a start-up business to nurture its IP
- Merge with or acquire another business which has complementary IP;
- share or team up with others to share IP assets for mutually beneficial results.

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Criteria for effective license (WIPO)

- The licensor must have ownership of relevant IP or authority from the owner to grant a license;
- The IP must be protected by law or at least eligible for protection;
- The license must specify what rights with respect to IP it grants to the licensee;
- The payment or other economic or IP assets to be given in exchange for the license must be clearly stated.

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Stakeholders

- Federal Government of Nigeria : Minister of Health
- National Institute for Pharmaceutical Research and Development (NIPRD)
- Traditional Health Practitioner (THP)
- Researchers
- Sickle cell patients (accessibility, affordability)

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MoU for collaboration with THPs

- MoU 1992 : 10 years before CBD and 18 years before Nagoya Protocol (2010).
- Served as prior informed consent
- Responsibilities of parties
- Benefit sharing
- Patents
- Scientific publications.

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Robust preclinical data

- WHO Handbook on Nonclinical Studies
- Grants for research equipment
- Skilled researchers
- Publications in top journals in Europe, Britain and USA
- Accorded high regards by Pharmaceutical company.

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Beyond the Gold Standard RCT

- RCT plus health journal
- Miracle medicine : Sickle Cell Comprehensive Center, CHOP, USA.
- Publications.
- Most crucial document for the licensee

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Patents and Royalties

- Patents in Nigeria, USA and other countries added immense value to the IP.
- Royalties : difficult negotiations
- Goodwill one time pay off
- Time frame for negotiations

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Local production

- Licensee USA based pharmaceutical company
- Local production crucial to economic boost., employment, skills acquisition.
- Initially GMP, then USP.

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Marketing

- Exclusive license
- Commercial manufacturing .
- Global marketing.
- Affordability

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Second Licensing Agreement

- License of Niprisan withdrawn from the USA company
- British company lobbied for the license for over a year.
- Negotiations took another one year to complete-due to Minister of Health heavy schedule
- Smoother than previous negotiations.
- More acceptable terms.
- Close involvement in the local production.
- Better royalties.
- Commercial production to commence this year

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Take Home Lessons

- Good knowledge of IP License an asset.
- Value additions: robust preclinical data, gold standard RCT.
- Patent enhanced the value of the good will package.
- Outcomes of the clinical trials boosted the value of the royalties based on sales not profit.
- Uniqueness of Niprisan regarding management of SCD gave us strong advantage in negotiations.
- Publications in peer reviewed international journals enabled USA FDA and European Medicine Evaluation Agency to accord Niprisan orphan drug status.
- Local production at Abuja critical for Government to approve the process.
- MoU with THP signaled to the Licensee the importance we accorded fair and equitable benefit sharing.

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