



PMRC POLICY ANALYSIS OF THE NATIONAL HEALTH RESEARCH ACT No. 2 OF 2013

**GOVERNMENT ADVANCING NATIONAL HEALTH
RESEARCH IN POLICY AND PRACTICE**

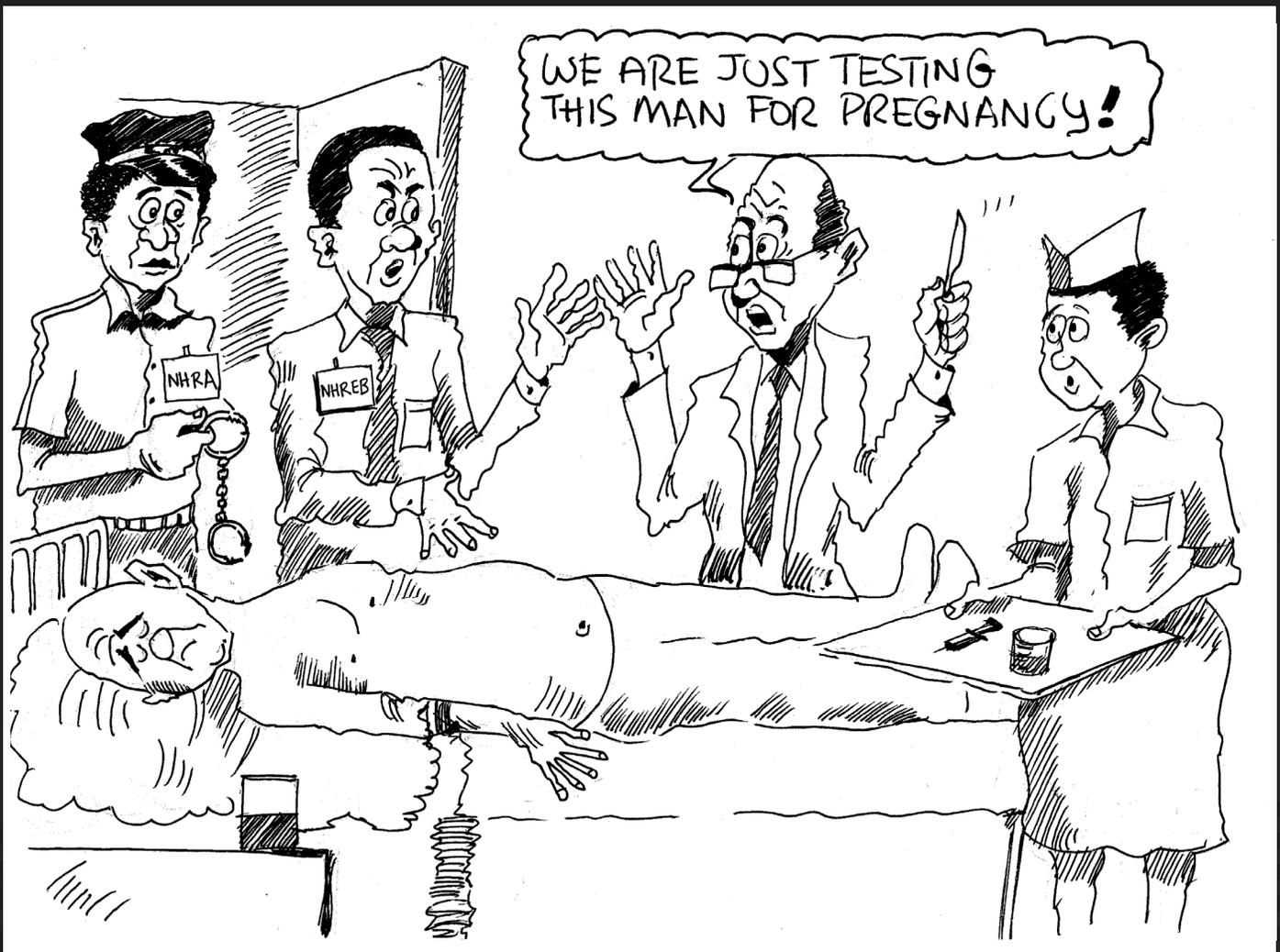
Unlocking Zambia's Potential

Message from PMRC

PMRC's vision is "Unlocking Zambia's Potential". We recognize that it is only discussion and debate on social and economic policy issues critical to poverty reduction that ultimately leads to policy reform to support a robust and thriving economy. PMRC's mission is Unlocking Zambia's Potential by:

- Producing high quality, relevant and timely policy analysis, policy monitoring, and reform proposals
- Promoting and encouraging an informed public debate on critical social and economic policy issues.

PMRC POLICY ANALYSIS OF THE NATIONAL HEALTH RESEARCH
ACT No. 2 OF 2013



On the 22nd of March 2013, The National Health Research Act No.2, 2013 was enacted by the parliament of Zambia. The major aims of Government as outlined in the Act are;

- To establish the National Health Research Authority and the National Health Research Ethics Board and to define their functions and powers
- To provide a regulatory framework for the development, regulation, financing and coordination of health research
- To provide for standardised ethical codes of behavior and standards in undertaking research

The Act is sub-divided into ten parts;

- Part I provides the interpretations of key concepts used within the Act
- Part II establishes the National Health Research

Authority (NHRA) and defines its functions, which include accreditation, monitoring and regulation of health research; and facilitation of research and development (R&D). The powers of the NHRA are also defined, including the power to ban research institutions that violate the Act. Part II of the Act further establishes the Council of Authority and supporting committees and states their responsibilities and powers

Part III provides for the establishment of the National Health Research Ethics Board and defines its functions and powers in ensuring ethical conduct in health research. Furthermore it defines professional misconduct in health research and its accompanying penalties

- Part IV provides a regulatory framework for prioritisation of areas for health research, dissemination of research information as well as monitoring and evaluation of health research and establishes a Trust for funding research

- Part V provides a regulatory framework for health research or experimentation with humans or animals. It prohibits cloning of human beings and removal of human tissue, organs or blood for research purposes unless with written consent of the concerned party
- Part VI addresses the use of biological materials in research
- Part VII regulates the conduct of clinical trials
- Part VIII endorses research in traditional, complementary and alternative medicine
- Part XIX addresses intellectual property rights
- Finally, Part X states the general provisions relating to enforcement of the Act including the powers of inspectors.

We, as PMRC believe that the National Health Research Act, 2013 will play a critical role in advancing health research, which is fundamental to public health and national development. This very timely Act addresses issues of (1) leadership, coordination and clear definition of roles and responsibilities for stakeholders in health research (2) prioritization of areas for research (3) capacity building (4) formation of partnerships for product development and commercialisation (5) ethical control in the conduct of research and clinical trials and (6) funding in health research.

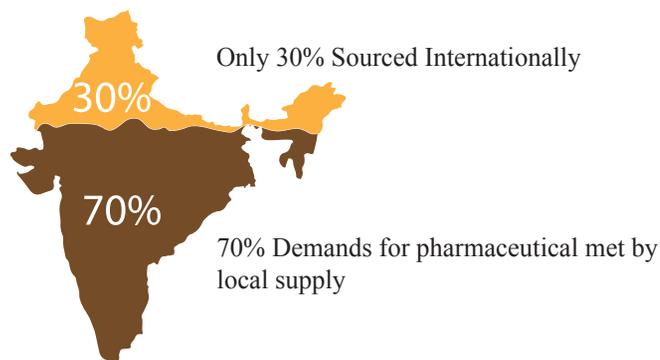
Clear leadership and delineation of roles and responsibilities are critical in promotion of coordination, avoidance of duplicated effort and role conflict and assurance of accountability in research. The formation of the National Health Research Authority is therefore vital in ensuring that all stakeholders are in agreement over the goals of research and are directed in strategies to be used in goal attainment.

The National Health Research Authority will also be responsible for identification and prioritisation of areas for research in Zambia, which is crucial for planning, decision-making and resource allocation. In the past, heavy reliance on external funding in research has resulted in donors deciding which areas of research to focus on while research areas of national concern for which there is no funding

have been sidelined¹. Donor priorities are therefore not always aligned to country needs hence the importance of having local bodies prioritise areas of research based on identified country needs. Furthermore, the establishment of the Health Research Trust Account, by the Act, for purposes of financing research will further reduce reliance on donors. The Trust Account will also address bottlenecks such reliance on archaic research equipment and failure to secure necessary laboratory substances due to lack of funding.

To effectively carry out research in prioritised areas, it is also important that a pool of human resource skills and technical expertise in health research be available. The National Health Research Act is therefore important in that it promotes capacity building in health research for individuals, institutions and systems so as to equip them to be more responsive to health research demands in Zambia. Health research is a highly knowledge intensive and specialist field. Limitations in technical expertise and institutional capacity have thus tended to constrain progress in health research. This legislation provides a basis for policy action to deliberately build-up quality human resource capacity, equip policy makers with analytical skills for appropriate use of research findings and support of physical infrastructure.

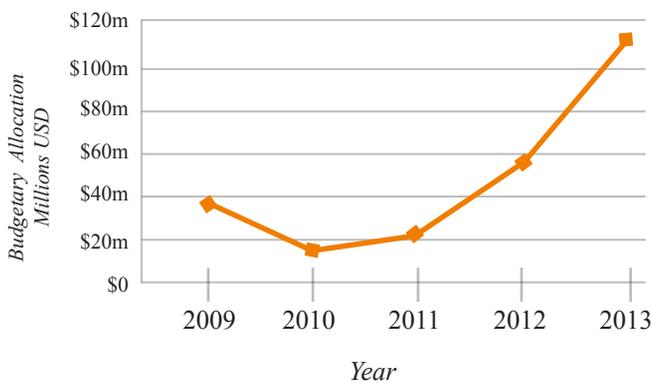
The Act further promotes the forging of partnerships in product development and commercialization of innovations in health research. Lessons for best practice in commercialisation can be drawn from the United States and Indian pharmaceutical industries, which have significantly contributed to these countries' economies. India's pharmaceutical industry is valued at US\$4.5 billion (2013) with 70% of the local demand for drugs catered for in India².



¹ (COHRED Statement, 2007) Are international health research programmes doing enough to develop research systems and skills in Low and Middle income countries? Council of Health Research and Development (COHRED)
² Corporate Catalyst India (2013)

In 2001 India's export of bulk drugs was valued at US\$1.35 billion, which represented a boost in the country's foreign exchange earnings and Balance of Payments position³. The National Health Research Act lays the foundation for formulation of policies, which could potentially spur development and trade in health products. This would increase government revenues and save foreign exchange used in the purchase of drugs and other health products. In 2013, Government's allocation to drugs and medical supplies increased from K301 billion (approximately US\$57 million) to K594 billion (approximately US\$ 111 million) representing an increase of approximately over 90% in drug and medical supply allocations (See Table 1). Part of such expenditure could be reduced through local production and export of drugs. Commercialisation of health products would also create employment and wealth for Zambians.

Table 1 Budgetary Allocation to Drugs and Medical Supplies



*2010 amount excludes allocation to HIV treatment and prevention

Apart from the commercial benefits, which are more secondary; advances in health research have led to a reduction and in some cases elimination, of disease prevalence, disability and mortality rates. The urgent need for evidence based disease control mechanisms and quality data to inform policy decisions is particularly recognized in Africa, which has a high incidence and prevalence of infectious diseases such as malaria, TB and HIV/AIDS⁵. A healthy population assures a more productive labour force, reduced expenditure on health treatments and better quality of life.

These benefits of medical research are undisputed, however the risks of abuse cannot be overlooked. Allegations abound

and in some cases proven records exist of illegal human experimentation. In 2011 president Obama apologized to the Guatemalan president for the unethical behavior of American researchers who, in the 1940's, deliberately exposed 1,300 people in Guatemala to sexually transmitted disease (STD's) to determine whether penicillin could prevent infection⁶. Of the number experimented on 83 died, although it was not proven that death was a direct result of the experiment⁷. In Africa, allegations were raised in 2011 against large pharmaceutical companies such as Pfizer, Columbia University and Population council carrying out human experiments including the testing of the contraceptive Depo-Provera and other unidentified contraceptives on poor, uneducated people in Ghana, Nigeria, South Africa and other African countries⁸.

It is in light of these risks of illegal, unethical behavior in health research that various countries such as the United States, The United Kingdom, Nigeria⁹, Ghana and many other countries world over¹⁰ have instituted regulations and ethical codes to guide the undertaking of health research and clinical trials. The Act is also to regulate the entry and exit into health research through accreditation and expulsion of non-conformist researchers and research institutions. It provides protocols for undertaking of research and prevents and controls unethical conduct by researchers.

In 2007, the Ministry of Health realized that health research involving extraction of bodily tissues was being undertaken in Zambia without ethical approval, exposing the public to health risks¹¹. The establishment of the National Health Research Ethics Board and a supporting regulatory framework thus holds positive implications for protection of the public from bodily harm arising from activities of unqualified researchers and unethical conduct. Regulatory control and monitoring also extends to the conduct of clinical trials.

While clinical trials are highly important for medical breakthroughs; deaths sometimes occur while they are being undertaken. In a study carried out in the United States by

³ Joshi (2003) Analysis of India's Pharmaceutical Industry with Emphasis on Opportunities for 2005. Pharmaceutical Technology.

⁴ Chikwanda, A. (2012). 2013 Full Budget address speech by Finance Minister Alexander Chikwanda, www.zra.org.zm/2012_Budget_Address.pdf

⁵ Health research for disease control and development High Level Meeting: Accra Ghana 15th – 17th June, 2006

⁶ The Guardian; guardian.co.uk, Tuesday 30 August 2011 08.12 BST

⁷ The Guardian; guardian.co.uk, Tuesday 30 August 2011 08.12 BST

⁸ Non-Consensual Research in Africa: The Outsourcing of Tuskegee"

⁹ (National Health Research Ethics Committee of Nigeria (NHREC) Federal Ministry Of Health Department Of Health Planning And Research, 2006)

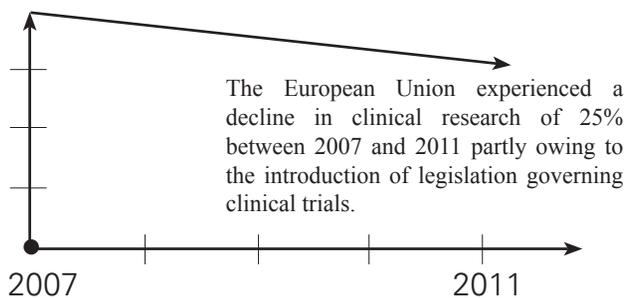
¹⁰ Health research for disease control and development High Level Meeting: Accra Ghana 15th – 17th June, 2006

¹¹ Chanda-Kapata, P., Campbell, S., Zarowski, C., 2012

Earley *et al* (2013), 25% of the sample of clinical trials examined resulted in death. The step by government to regulate this area is thus vital and consistent with legislation in other countries such as the United States and Europe. There has however been debate about the possible negative effect of this legislation on the number of clinical trials undertaken.

The House of Commons in Britain for instance observed that the number of clinical trials between 2007 and 2011 fell by 25% in the European Union (See Table 2) and 22% in Britain partly due to clinical trial directives in legislation¹². Caution must therefore be exercised so that researchers are not discouraged from conducting research.

Table. 2 Clinical Trials in the European Union between 2007 & 2011



The procedural regulations and acquisition of approvals could also cause delays in commencement of research if processes of registration and approval are prolonged. Bureaucratic regulations have for instance been cited as inhibiting innovation and delaying the rate at which life-saving medications reach the market in the United States¹³.

Another challenge arising from regulation could be the high cost to Government, the public, researchers and research institutions. The establishment and operation of systems to monitor health research and enforce the requirements of the Act are likely to increase public expenditure in health by Government. These costs usually translate into higher taxes and user fees for individuals while researchers and research institutes must pay fees for registration and other procedural fees. Conover (2004) for instance vehemently argues that the cost of health regulation in the USA has tended to exceed the benefits. The cost of regulation was estimated at US\$ 1 trillion in 2004 and costs are said to have exceeded benefits by US\$ 169 billion. This represented 1.8% of GDP. The Zambian government must thus devise a strategy to reduce costs of regulation while

¹² House of Commons Science and technology Committee: Clinical trials written evidence 6 March 2013

¹³ (Conover, 2004) Health Care Regulation: A \$169 Billion Hidden Tax. Policy Analysis, No.527

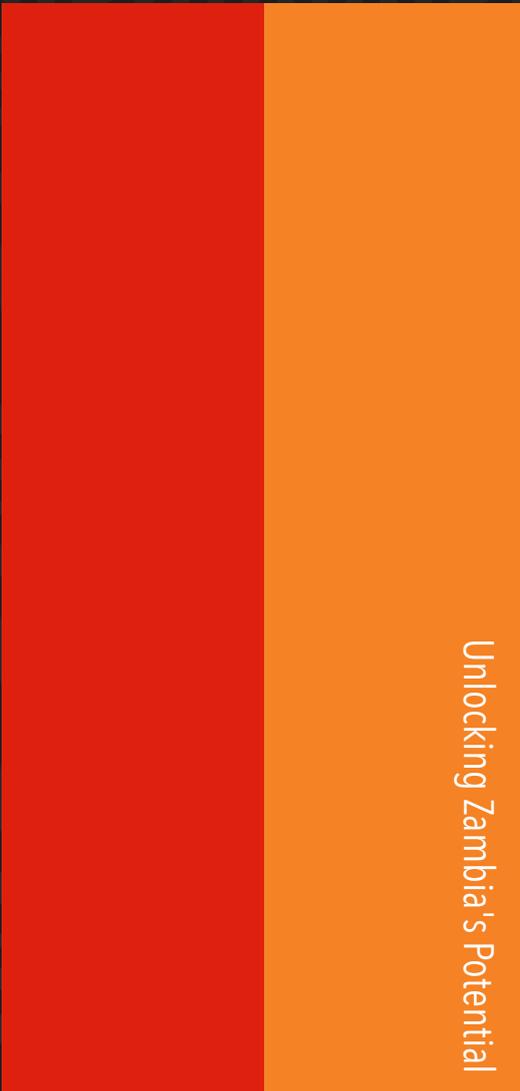
retaining its benefits.

PMRC therefore believes that the enactment of the National Health Research Act No. 2, 2013 by the Zambian government is both timely and of great importance. The Act on one hand recognizes the highlighted benefits of research and seeks to promote its advancement; but also seeks to protect the public from abuse arising from unethical practices in health research.

In conclusion, the Act has the potential to improve public health, labour productivity, create employment and promote economic growth. The Act lays a foundation for strategic policy action to promote and facilitate research and development in health. Furthermore, it establishes provisions for monitoring ethical conduct in research for public protection. The challenges likely to be faced in implementation of the Act include the high costs of implementation and creation of lengthy, bureaucratic processes, which may discourage researchers from carrying out work and delay delivery of life saving drugs to patients.

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