

IP AND ACCESS TO MEDICAL DEVICES IN NIGERIA: CHALLENGES AND THE LEGAL PERSPECTIVE

Temitope O. Oloko*

ABSTRACT

While access to essential medicines is a major problem for public health in Nigeria, the country confronts other significant health care problems stemming from access to other areas of medical technology, which have received less attention in the scholarly literature. Medical devices play an essential role in health care, from screening to diagnosis and treatment. Outdated medical devices and insufficient medical equipment and supplies, and lack of access to high-quality, safe and appropriate priority medical devices greatly impair health services. Addressing these shortcomings will likely require a tailored and focused approach to developing a technology transfer strategy including appropriate measures within the intellectual property system as shaped by the WTO TRIPS Agreement. As a potential contribution to future work on developing such an approach to leveraging access to these vital technologies, this article reviews the legal and policy background, and then provides a case study of priority medical devices related to the diagnosis and treatment of cancer in 13 hospitals in Lagos with consideration of availability, affordability, accessibility, appropriateness, quality and age.

Keywords: Access to Medical Devices, Public Health, Technology transfer

1. INTRODUCTION

Generally, intellectual property (IP) denotes a class of legal regimes with distinct degrees of rights of ownership

over different forms of intangible subject matter.¹ In principle, intellectual activity in the field of industry, science or art attracts legal protection.² The common categories of rights included within the general term 'intellectual property' are patents, trademarks, copyright, trade names, and indications of origin.³ Patents today are associated with economic, health, cultural and social conditions prevailing in a country. There is no doubt that patents have assisted in national development and have created benefits for humanity. Inventions have played an important part in human development and have contributed to social and economic welfare. However, patent protection in relation to public health has been extensively debated over the last 20 years due to assertions that patents constitute a barrier to access to medicines in developing countries.⁴

Public health concerns have led to the only multilateral reconsideration made so far to the World Trade Organisation's Agreement on Trade-Related Aspects of Intellectual Property Rights⁵. The Doha Declaration on Public Health⁶ addressed important points of principle at the highest political level, and led to the only amendment so far applied to the TRIPS Agreement, in the form of a Special Compulsory Licensing System to give vulnerable countries a new avenue for access to medicines.⁷ Even though there is a provision for regular review of the TRIPS Agreement,⁸ and an annual review of the Special Compulsory Licensing System, developing countries and non-governmental organisations assert that the TRIPS Agreement and in particular its patent provisions, represent a barrier to effective access to medicines.⁹ The

* Masters in Law (University of Lagos), Master in Law in Intellectual Property and Commerce and Technology (Franklin Pierce Law Center Concord, New Hampshire USA), Doctor of Law – LL.D (University of Pretoria South Africa). Currently lectures as Senior Lecturer in the faculty of law Lagos State University in Intellectual Property, Law of Trust and Contracts

¹Peter Drahos, 'The Universality of Intellectual Property Rights: Origins and Development' p. 1 www.wipo.int/edocs/mdocs/tk/en/.../wipo_unhchr_ip_pnl_98_1.doc accessed 02 February 2018; see also Paul Craig and Grainne de Burca, *EU Law Text, Cases and Materials* Oxford University Press 5th ed 2011 p. 5.

² Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to p. 21- 28 www.unsgaccessmeds.org/final-report/ accessed 02 February 2018.

³Craig and Grainne de Burca p. 5; A striking feature of intellectual property is that, despite its early historical links to the idea of monopoly and privilege, the scope of its subject matter continues to expand. See also Drahos p. 1; Intellectual property rights are also among the most controversial forms of trade and business regulation in the global economy. See Keith E. Markus *Introduction. The*

WTO, Intellectual Property Rights and the Knowledge Economy, in Keith Markus (ed) Critical Perspective on the Global Trading System and the WTO Elgar Cheltenham 2004 p. 34.

⁴ Sampat B N Academic Patents and Access to Medicines in Developing Countries. (2009) *American Journal of Public Health*, 99, 9-17.

⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organisation (WTO Agreement) Annex 1C ('TRIPS Agreement')

⁶ The 4th WTO Ministerial meeting at Doha, Qatar adopted, on the 14 November 2001, a Declaration on the TRIPS Agreement and Public Health ('Doha Declaration').

⁷ See Article 31bis of the Revised TRIPS Agreement

⁸ See Article 71 TRIPS Agreement.

⁹ Frederick M. Abbott, 'The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference' (October 2001). *FSU College of Law, Public Law Working Paper No. 36 and QUNO Occasional Paper No. 7* available at SSRN: <http://ssrn.com/abstract=285934> or <http://dx.doi.org/10.2139/ssrn.285934> accessed 05 February 2018; see also Zita Lazzarini, 'Making Access to Pharmaceuticals a Reality: Legal Options under TRIPS and the

Doha Declaration was conceived mainly as a result of apprehensions about the likely impact of the TRIPS Agreement on access to medicines.¹⁰

Yet access to essential medicines is not the only problem faced in relation to public health. Over the years the issue of access to medicines has continued to dominate the discussion in relation to public health care and despite this, the needs of the poorest countries are still not met.¹¹ This has led to the examination of other areas such as access to medical devices. The current debate is on affordable health care which include access to medicines, medical care and medical devices. The lack of access to high-quality, safe, and appropriate, priority medical devices¹² which have an essential role to play, from screening to diagnosis and treatment,¹³ may lead to an effective deprivation or deterioration of health services.

Accordingly, the World Health Assembly passed its first resolution on Health Technologies¹⁴ in May 2007.¹⁵ The resolution was based on a project called Priority Medical Devices (PMD) which was launched by the WHO at the request of the Government of the Netherlands through the Ministry of Health, Welfare and Sports to identify inequalities in the available preventive, diagnostic, therapeutic and assistive medical devices in the market by determining whether the needs of health care providers and end-users throughout the world are being met and if not, to propose remedies to resolve the inadequacies or shortcomings.¹⁶

2. RESEARCH PROBLEM

The health care sector challenge is enormous and not limited to the lack of access to medical devices. The medical system in Nigeria is largely underdeveloped and lacks modern healthcare devices, infrastructure and facilities. With the population of Nigeria growing astronomically and currently put at 180 million, it is glaring that access to required medical devices is in short fall and practically supplied by imports while new innovations in medical devices are largely unavailable.¹⁷ This has led to lack of proper diagnosis, treatment and preventive intervention culminating in countless deaths and a surge in medical tourism which costs Nigeria over \$1bn annually.¹⁸ The fact that there are negligible innovations in the country also creates a gap in easy access to medical devices and this was aptly captured in the recent Global Innovation Index which ranked Nigeria ranked 119 out of 127 countries worldwide.¹⁹ This in essence reveals that there is no capacity to develop medical devices or to maintain and repair biomedical devices in the country.²⁰

Available statistics show that cancer is the second leading cause of death globally, killing 8.8 million persons in 2015 worldwide, meaning nearly 1 in 6 deaths is caused by cancer. In Nigeria, 100,000 cases of cancer are diagnosed every year and about 80,000 people die yearly as a result of the same, meaning 4 in every 5 people die of cancer. This seems outrageous but is not farfetched as Nigeria currently has only 9 Radiotherapy Centers. The

Case of Brazil' 6 *Yale Human Rights & Development Law Journal* 2003 pp 103-138.

¹⁰The Doha Declaration explained available at http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm#trips accessed 07 February 2018.

¹¹ Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to p. 21- 28 www.unsgaccessmeds.org/final-report/ accessed 02 February 2018

¹²Medical device is defined as "An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means."

¹³WHO, Medical Devices, Priority medical devices available at http://www.who.int/medical_devices/access/en/ accessed 12 March 2018.

¹⁴This term refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life. It is used interchangeably with 'health care technology'. Resolution WHA60.29. Health Technologies. In: Sixtieth World Health Assembly. Geneva, 23 May 2007. Available at http://www.who.int/medical_devices/resolution_wha60_29

[-en1.pdf](#) accessed 12 March 2018. See also WHO, Local Production and Technology Transfer to Increase Access to Medical Devices Addressing the barriers and challenges in low- and middle-income countries 2012 available at http://www.who.int/medical_devices/1240EHT_final.pdf accessed 16 March 2018.

¹⁵WHO Sixtieth World Health Assembly Health Technologies WHA60.29 available at http://www.who.int/medical_devices/resolution_wha60_29_-en1.pdf accessed 12 March 2018.

¹⁶WHO. Medical Devices, Priority medical devices.

¹⁷ 2016 ITA Top Markets Report Medical Devices Country Case Study https://www.trade.gov/topmarkets/pdf/Medical_Devices_Nigeria.pdf accessed 02 February 2018.

¹⁸ Omatseye C. Nigeria loses \$1bn annually to medical tourism Vanguard 23 August 2017 <https://www.vanguardngr.com/2017/08/nigeria-loses-1bn-annually-medical-tourism-omatseye/> accessed 02 March 2018.

¹⁹ Global Innovation Index 2017 https://www.globalinnovationindex.org/UploadedFiles/Indepths/Files/Indepths_9db22f7962064f1282db29c9aec30365_PDF accessed 05 March 2018.

²⁰ Towards improving access to medical devices through local production Phase II Report of a case study in four sub-Saharan countries

available of devices is way below the WHO requirement of 1 radiotherapy machine per 1 million population²¹ and grossly inadequate for a population of 180 million.

DEFINITION OF TERMS

Public Health: public or privately organised measures used to prevent disease, promote health, and prolong life among people generally with the aim of offering people healthy living conditions as well as the eradication of disease.²²

Harmonized definition of “medical device”: any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article:

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical or diagnostic purposes by means of *in vitro*
- examination of specimens derived from the human body;

and

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.²³

Medical Device: any instrument, apparatus or contrivance (including components, parts and accessories thereof) manufactured, sold or advertised for internal or external use in the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof, in man or in animal²⁴

Access to Medical Devices: defined in terms of the various factors that determine the extent of a patient’s access to medical devices and services. These factors include the availability, affordability, accessibility, appropriateness, acceptability and quality of the medical device.

Medical Products covers pharmaceuticals, vaccines and diagnostics but does not include medical devices and other health services.

The following are six crucial components to improve access to medical devices²⁵

Availability: when a medical device can be found on the medical device market; it may also mean whether medical devices are physically available at health care facilities and are usable by medical providers to treat patients.

Affordability: the extent to which the intended clients of a health service or product can pay for its utilization.

Accessibility: people’s ability to obtain the technology and use it appropriately when needed; it may also refer to whether households or individuals are geographically able to reach health care facilities that offer necessary medical devices for a specific health condition.

Appropriateness: medical methods, procedures, techniques and equipment that are scientifically valid, adapted to local needs, acceptable to both patients and health care personnel, and that can be utilized with resources the community or country can afford; appropriateness should include the consideration of available infrastructure and human and financial requirements.

Acceptability: households’ or individuals’ attitudes and expectations towards the use of medical devices, specifically whether those devices are socially and culturally appropriate to meet local demands.

²¹ Adeyanju Adekunle Joseph. Radiotherapy Technical Challenges In Nigeria, LUTH.

²² WHO, Public health, available at <http://www.who.int/trade/glossary/story076/en/#> accessed 16 March 2013.

²³ Global Harmonization Task Force, Information Document Concerning the Definition of the Term “Medical Device” GHTF/SG1/N29R16:2005

www.imdrf.org/.../ghtf/.../sg1/.../ghtf-sg1-n29r16-2005-definition-medical-device-05... accessed 02 April 2018

²⁴ Section 13 Food, Drugs and Related Products Act 1993 Cap F33 LFN 2004.

²⁵ Local Production and Technology Transfer to Increase Access to Medical Devices Addressing the barriers and challenges in low- and middle-income countries 2012 http://www.who.int/medical_devices/1240EHT_final.pdf 17 April 2018;

Quality: whether the medical devices found in health care facilities and used by medical providers meet regulatory standards for effective and safe use.

Age: how long the device has been in use in the facility.

LITERATURE REVIEW

Innovation and research and development are fundamental to strategic and sustainable growth. Innovation cuts across the boundaries of various subjects and disciplines and is essential for the development of knowledge and technology. Scientific innovation and commercial innovation create competitive advantage that is vital for economic development.²⁶

Almost 25 years into the TRIPS Agreement regime, questions are still being raised in relation to innovation and R&D with reference to the effects of patents. Do patent rights impede innovation and research, or does patenting encourage research and development? Patent rights are given as a result of R&D carried out in a particular field that results in an innovation. Without R&D, there can be no innovation that leads to an invention and, thus, there would be no patent right. Whether the knowledge of the grant of a patent inspires R&D or if the target of R&D and the entire patent system is based on mere economics has been subject to significant debate. Patent protection and economic incentives play a role in innovation²⁷ although the statement is supported by little empirical evidence.²⁸

Torrance and Tomlinson, using a multi-user interactive simulation of patent and non-patent systems (PatentSim) compare the rates of innovation, productivity and societal utility. The study showed that patent protection did not spur innovation.²⁹ On the other hand, Moser, using nineteenth-century exhibition data to determine the effects of patent laws on innovation, resolved that weak patent laws encourage innovation where effective

alternative methods of protection exist and concludes that patent laws chart the course of innovative production.³⁰

In terms of the level of patent protection in Nigeria, there may be a correlation with the study that claims that patents do not stimulate innovation and R&D.³¹ Since 1970, the Nigeria Patent and Designs Act (PDA) has provided a term of protection for 20 years and allows products and process patents with little examination yet, there are not many registered patents, both locally and by foreign applicants.³² Therefore, stronger patent protection alone does not stimulate innovation and R&D, other variables still need to be taken into consideration.

Strong patent protection may not necessarily lead to increased innovation and R&D. Thus, according to Boschiero, in practice the exclusive right in patents operates as a commercial tool coupled with the erosion of the balance of the public interest and patent holder's right, with the society shifting towards possessive mechanism for proprietary benefit as opposed to the general good.³³ The exercise of maximum patent right, however, may create a strangle-hold on people's lives as a result of their inability to acquire the necessary knowledge to use such technologies or products. Especially, in relation to innovations in the treatment of diseases that require medical devices that are necessary for preventive, diagnostic, therapeutic and assistive treatment. If these devices are beyond the reach of people who need them, then innovation fails to have a positive impact on society. Innovation and health care go hand in hand, the improvement of health care is mainly dependent on advancement in technology. Diaconu *et al.* while examining the procurement process of medical devices in low and middle incomes countries, notes that the lack of basic medical devices seriously compromises the provision

²⁶ Sadi Koray Demircan. The Role of R&D and Innovation in Us Economy as a Benchmark for Turkish Economy the Eli Broad College of Business Michigan State University available at http://www.ekonomi.gov.tr/upload/bf09ae98-d8d3-8566-520b0d124e5614d/koray_demircan.pdf accessed 23 April 2018.

²⁷ Petra Moser, How Do Patent Laws Influence Innovation? Evidence from Nineteenth-Century World Fairs Working Paper 9909 National Bureau of Economic Research <http://www.nber.org/papers/w9909>; Organisation for Economic Co-Operation and Development (OECD) Patents and Innovation: Trends and Policy Challenges p.1 available at <http://www.oecd.org/science/sci-tech/24508541.pdf> accessed 21 May 2018.

²⁸ Andrew W. Torrance & Bill Tomlinson, Patents and the Regress of Useful Arts, Colum. Sci. & Tech. L. Rev. 10 (2009) 130-168 p.130.

²⁹ Andrew W. Torrance & Bill Tomlinson, Patents and the Regress of Useful Arts, 10 Colum. Sci. & Tech. L. Rev. 4 (2009) 130-168 p.131.

³⁰ Petra Moser, 'How Do Patent Laws Influence Innovation? Evidence from Nineteenth-Century World Fairs' National Bureau of Economic Research Working Paper No. 9909 2003 available at <http://www.nber.org/papers/w9909> accessed 21 May 2018.

³¹ Andrew W. Torrance & Bill Tomlinson, 'Patents and the Regress of Useful Arts', (2009) Columbia Science and Technology Law Review 10 130-168 p.130.

³² Get statistic on current patent application.

³³ Nerina Boschiero Intellectual property rights and public health: an impediment to access to medicines and health technology innovation? https://www.statoechiese.it/images/uploads/articoli_pdf/Boschiero_2_Intellectual.pdf accessed 09 April 2018.

of health care services.³⁴ Not only is there a dearth of medical devices; access to new innovations is not available and this was evident in the visits to various hospitals.

It is against this broad background that the present paper analyses the specific situation confronting Nigeria's serious, systemic access issues. A survey of the availability of certain key technologies in Nigeria may contribute an empirical foundation for further work on shaping and implementing appropriate policy initiatives to address these challenges, including considering specific measures for local innovation, technology transfer and the application of IP measures towards these ends.

NATIONAL REGULATIONS ON MEDICAL DEVICES

The Federal Ministry of Health (FMOH) is the supervising ministry for all Federal health institutions and it is responsible for all health-related policy formulation. The National Agency for Food and Drug Administration and Control (NAFDAC) is an agency under the FMOH which regulates food, drugs and related products which include medical devices in Nigeria.³⁵ NAFDAC operates through the legislation which prohibits manufacturing, importing, exporting, advertising, selling or distribution of medical devices in Nigeria without registration in accordance with the provisions of the Act or Regulations.³⁶

For registration, a medical device must meet the prescribed standards for quality, safety and efficacy. Registration may be cancelled if the medical device is unsuitable for what it is intended.³⁷ In addition, the agency provides registration guidelines for imported medical devices.³⁸ Other regulatory agencies, such as the Standard Organisation of Nigeria (SON), Bureau of Public Procurement (BPP) and Nigeria Nuclear Regulatory

Authority (NNRA), may also be involved in ensuring conformity with expected quality and safety standards.

Following their registration, access to medical devices is an important component of the right to health. Although the Nigerian Constitution does not expressly provide for the right to health care, it is presumed that under section 17(3) (d) ³⁹ claim can be laid to such right. The right to health - like all human rights - is indivisible, universal, interdependent and interrelated. Mark and Bendent are of the view that access to medicines and devices finds a foothold in the right to health and they further state that it can be affirmed as human rights based on the right to health set out in the International Covenant on Economic Social and Cultural Rights.⁴⁰

Registration of medical devices under this regulation is a prerequisite for their intended use in Nigeria, but it does not in itself ensure or improve access to medical devices that are important for public health needs. There is still a need for policy analysis, technical assistance and capacity-building at the national level focussed on leveraging improved actual access to these technologies.

TECHNOLOGY TRANSFER

The developed countries were offered technology transfer as an incentive during the negotiation of the TRIPS Agreement⁴¹ in maintaining the protection of IP rights in developing and least-developed countries (LDCs).⁴² The expectation of developing countries was that stronger IP protection would encourage technology transfer, but this perception has shifted dramatically.⁴³

According to the United Nations Conference on Trade and Development (UNCTAD): 'technology transfer is the process by which commercial technology is disseminated'.⁴⁴ Access to the right technology is vital to

³⁴ Karin Diaconu, Yen-Fu Chen, Semira Manaseki-Holland, Carole Cummins and Richard Lilford, 'Medical Device Procurement In Low- And Middle-Income Settings: Protocol For A Systematic Review', *Systematicreviewsjournal.Biomedcentral.Com/Articles/10.1186/2046-4053-3-118* Accessed 09 April 2018.

³⁵ Section 1 Food, Drugs and Related Products Cap F33 LFN 2004.

³⁶ Ibid.

³⁷ Ibid.

³⁸ NAFDAC/RR/007/00

<http://www.nafdac.gov.ng/index.php/guidelines/medical-devices-guidelines> accessed 19 April 2018.

³⁹ Chapter II 1999 Constitution of the Federal Republic of Nigeria.

⁴⁰ Stephen P Marks and Adrianna L Benedict Access to Medical Products, Vaccines and Medical Technologies in Jose M Zuniga, Stephen P Marks and Lawrence O Gostin (ed) *Advancing Human Right to Health*, Oxford University Press, 2013, pp. 305-324.

⁴¹ Tú Thanh Nguyễn Competition Law, Technology Transfer and the TRIPS Agreement: Implications for Developing Countries Edward Elgar Cheltenham 2010 p. 29-30; see also Poku Adusei 'Regulatory Diversity as Key to the 'Myth' of Drug Patenting in sub-Saharan Africa' (2010) 54 *Journal of African Law* 26-27.

⁴² WTO Technology transfer

http://www.wto.org/english/tratop_e/trips_e/techtransfer_e.htm accessed 19 April 2018.

⁴³ Tana Pistorius 'The Impact of Intellectual Property Law and Policy on Sustainable Development' 32 (2007), *South African Yearbook of International Law* 376-395 p.381; See also Du Plessis 'Perspectives from a 33 developing country' Extraordinary Session I: IP and the global economy AIPPI Lisbon (Exco Meeting) (17 21 June 2002):

http://www.aippi.org/reports/Vortrag_DuPlessis.pdf accessed 19 April 2018.

⁴⁴ United Nations Conference on Trade and Development (UNCTAD) Series on issues in international investment agreements UNCTAD/ITE/IIT/28

the growth of any nation. Correa has noted that the North-South technological gap is widening and there has been no increase in technology transfer to the developing countries. Instead he observes, big companies are forming 'strategic alliances'⁴⁵ which increase their dominance in the generation and use of technology⁴⁶ whereas developing countries are still struggling to obtain technology transfer that enhances economic development. It has been observed that technology transfer is a major global economy challenge⁴⁷ and economic advancement will be realised only if ideas, experience and practice are borrowed from more advanced countries.⁴⁸

Unlike the specific steps taken in relation to public health, which arose as a result of protest that the TRIPS Agreement impeded access to essential medicines, an expectation of transfer of technology was in the TRIPS Agreement from its entry into force.⁴⁹ The promotion of technology transfer is said to be an important objective of the TRIPS Agreement; however, it acts only as a platform and does not actually transfer technology from developed to developing countries.⁵⁰ That said, Article 66.2 of the TRIPS Agreement does require developed country WTO Members to "provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base".⁵¹

Technology transfer is vital for developing a strong technological base necessary for economic growth. Access

to technology transfer has been underscored as an approach of achieving indigenous inventiveness.⁵² For this reason, NOTAP is significant, as it renders services which include preparation of technology transfer agreements, IP right promotion and provision of state of the art technological information, commercialisation of R&D results, research-industry linkage, monitoring, consultancy and extension services and technology advisory services.⁵³ Technology transfer will be one of the ways to ensure access to medical devices needed for diagnosis and treatment as this would assist patients to enjoy better health care provision. This article therefore reviews the current situation in Nigeria, and in particular considers critical unmet needs, as a potential contribution to further consideration of suitable technology transfer strategies tailored to this field.

METHODOLOGY

This study employed both a situation analysis based on a literature review of available relevant research, survey, data, statistical analyses as well as a questionnaire-based survey research strategy and it is purely descriptive in nature. Current information relating to healthcare in Nigeria is extracted from various analysis done by the WHO and by other scholars. Data on access to medical devices in 12 tertiary hospitals in Lagos⁵⁴ was used as a pilot to collect through questionnaire developed for that purpose. The questionnaire is based on the WHO list of PMD for cancer management⁵⁵ which was collated as part of a medical device technical series. This study gives an overview of access to priority medical devices ranging

<http://unctad.org/en/Docs/psiteitd28.en.pdf> accessed 19 April 2018.

⁴⁵ For example, Ranbaxy Laboratories (a leading Indian pharmaceutical company) and Bayer AG, (a German pharmaceutical company) for the development of a new generation of antibiotics called ciprofloxacin. See also UNCTAD/UNDP, Transfer of Technology for Successful Integration into the Global Economy UNCTAD/ITE/IPC/2003/6 p.18 available at http://unctad.org/en/Docs/iteipc20036_en.pdf accessed 20 October 2013.

⁴⁶ Carlos M. Correa Review of the TRIPS Agreement: Fostering the Transfer of Technology to Developing Countries, TWN Trade & Development Series 13 p.21- 22; The Journal of World Intellectual Property (Vol. 2, No. 6), <http://www.twinside.org.sg/title2/t&d/tnd13.pdf> accessed 19 April 2018.

⁴⁷ David B. Audretsch, Erik E. Lehmann, Albert N. Link, Alexander Starnecker (eds) (introduction) Technology Transfer in a Global Economy Springer Group 2012 p. 2.

⁴⁸ UNCTAD/UNDP, Transfer of Technology for Successful Integration into the Global Economy UNCTAD/ITE/IPC/2003/6 p.6 http://unctad.org/en/Docs/iteipc20036_en.pdf accessed 24 April 2018.

⁴⁹ Article 7 TRIPS Agreement.

⁵⁰ Tú Thanh Nguyễn Competition Law, Technology Transfer and the TRIPS Agreement: Implications for Developing Countries Edward Elgar Cheltenham 2010 p. 29-30.

⁵¹ Implementation of this provision is surveyed in Watal, Jayashree; Caminero, Leticia (2017), Least-developed countries, transfer of technology and the TRIPS Agreement, WTO Staff Working Paper, No. ERSD-2018-01, World Trade Organization (WTO), Geneva, <http://dx.doi.org/10.30875/412bee53-en>

⁵² Adejoke Oyewunmi, The Patent System and Transfer of Technology in Nigeria Olanrewaju Fagbaohun and Bambo Adewopo (ed.). *Developments and Reform, Nigeria's Commercial Law s Essays in honour of Chief Dr Chris Ogunbanjo* The Law Center LASU Lagos, 1998, 78-92 p.79.

⁵³ NOTAP website <http://notap.gov.ng/content/technology-transfers> accessed 09 September 2013.

⁵⁴ This is because Lagos is cosmopolitan and people from every state in Nigeria empty themselves there.

⁵⁵ WHO list of Priority Medical Devices for cancer management

www.who.int/medical_devices/publications/priority_med..._ancer_management/en/ accessed 15 April 2018.

from consumables to routine medical equipment and devices which are typically considered essential for the prevention, diagnosis and treatment of cancer. The questionnaire was structured and defined in the format of close-ended questions or statements represented with medical devices or apparatuses.

The article gives a summary of the regulation that is of significance to MD. The study draws together materials regarded as priority medical devices in cancer management. To determine each question, under each construct there is a set of six kinds of measurement scales, viz. availability, affordability, accessibility, appropriateness, quality and age of the device with different response categories to verify access to MD. The response categories with their respective codes of each of the measurement scales are given as follows:

Availability: 1: yes; 2: no

Affordability: 1: not at all; 2: low extent; 3: some extent

Accessibility: 1: not at all; 2: low extent; 3: some extent

Appropriate: 1: 0–25% (low); 2: 26–50% (medium);
3: 51–75%; (high); 4: 76–100% (optimal).

Quality of MD: 1: low; 2: medium; 3: high

Age: 1: < 1 year; 2: 1–5 years; 3: 6–10 years

Out of thirteen questionnaires administered to the selected medical centres in Lagos State (South-West of Nigeria), twelve were filled and returned while one was returned but not filled. This was the questionnaire sent to Badagry general hospital. Thus, it was excluded from this analysis. Since the nature of the study is descriptive, frequency tables were prepared showing the numbers and percentages of responses.

DESCRIPTIVE ANALYSIS

The frequency distribution of each kind of device with respect to its availability, affordability, accessibility, appropriateness, quality and age is discussed below, with reference to the tables of data provided at the end of this article.

CANCER MEDICAL DEVICES

Table 1 presents the descriptive frequency distribution of responses on the items for *General Medical devices for Clinical Assessment and Minor Procedures*. Of the twelve medical centres surveyed, item 1 (Aneroid sphygmomanometer Stethoscope) is available in 11 (92%) centres and 1 centre (8%) lacks it. 5 (42%) respondents indicated that the item is affordable to low extent while 6 respondents indicated that it is affordable to a large extent. Accessibility is low in 7 (58%) centres and

substantial in 4 (33%). Its appropriateness is considered moderate, high and optimal in 5 (42%) centres, 5 (42%) centres and 1 centre respectively. Its quality is low in 6 (50%) centres and high in 4 (33%). The age of the device in 1 (8%) is less than 1 year, while in 1 centre (8%) and 8 (67%) centres, its age falls within the ranges 1–5 years and 6–10 years respectively.

Item 1 (Thermometer) is available in 11 (92%) of the surveyed centres and not in the remaining one. It is not affordable in 1 centre, affordable in 3 (25%) centres to a low extent while it is affordable to large extent in 7 (58%) centres. Accessibility in 6 (50%) centres is low while in 5 (42%) centres accessibility is substantial. The appropriateness of the device is moderate in 4 (33%) centres, high in 5 (42%) centres and optimal in 2 (17%) centres. The device is of low, medium and high quality in 4 (33%) centres, 1 centre (8%) and 5 (42%) centres respectively. The device is less than 1 year old in 1 (8%) between 1–5 years and 6–10 years in 1 centre (8%) and 8 (67%) respectively.

Examination table resuscitation trolley

Examination table resuscitation trolley equipped, with medicines and defibrillator fixed examination/treatment light is available in 11 (92%) of the centres surveyed and is not available in 1. The device is not affordable in 1 centre, affordable in 4 (33%) to a low extent and to large extent in 6 (50%) centres. Accessibility is low in 8 (67%) centres, and substantial in 3 (25%). Appropriateness is moderate in 4 (33%) centres, high in 5 (42%) centres and optimal in 2 (17%). In 6 (50%) centres, 1 centre (8%) and 3 (25%) centres, the devices are of low, medium and high quality respectively. The age of the device in 2 (17%) centres is less than 1 year and between 1–5 years in 8 (67%).

Pulse oximeter

A pulse oximeter is available in 9 (75%) of the centres surveyed. It is affordable in 3 (25%) centres to a low extent and affordable to large extent in 7 (58%) centres. The accessibility is low in 6 (50%) centres and substantial in 4 (33%). Appropriateness of the device is moderate in 3 (25%) centres, high in 5 (42%) and optimal in 2 (17%). In 4 (33%) centres, 3 (25%) centres and 2 (17%) centres, the device is of low, medium and high quality respectively. The device less than 1 year old in 1 centre, and between 1–5 and 6–10 years in 2 (17%) and 6 (50%) centres respectively.

Electrocardiography system

An electrocardiography system) is available in 10 (83%) centres while it is not available in 2 (17%) centres. The device is affordable in 4 (33%) centres to a low extent while it is affordable to large extent in 6 (50%) centres. The level of accessibility in 7 (58%) centres is low, while in 3

(25%) centres there is a substantial (to some extent) level of accessibility. The appropriateness of the device in 4 (33%) centres, 3 (25%) centres and 3 (25%) centres falls within the ranges 26% – 50%, 51% – 75% and 76% – 100% respectively. In 5 (42%) centres, 2 (25%) centres and 2 (17%) centres, the device are of low, medium and high quality respectively. The ages of the device in 2 (17%) centres and 7 (58%) centres, the ages of the device are within the ranges 1–5 years and 6–10 years respectively.

Colposcopy

Table 2 presents the descriptive frequency distribution of the respondents' responses to the item for *Colposcopy*. This item is available in 2 (17%) of the 12 surveyed centres while 10 (83%) centres do not possess such item. 17% of respondents indicated that the affordability of the item is low in their centres while others could not respond to this measure. Only two respondents indicated the level of accessibility: in one there is a low level of accessibility while in the other there is a substantial level. The appropriateness of the device in 2 (17%) centres falls within 76% – 100%. Only two respondents indicated the quality and age of the device. In each case, the devices are of low and high quality respectively while the age of the device are within the range 1–5 years and 6–10 years respectively.

Cryotherapy

Table 3 presents the descriptive frequency distribution of the respondents' responses to the item for *Cryotherapy*. Of the twelve medical centres surveyed, item 1 (Cryosurgery unit) is available in 2 (17%) centres while 10 (83.3%) centre do not possess it. Two respondents indicated that affordability is low in their centres while others could not respond. Only 2 respondents indicated the level of accessibility, which is low both cases. The appropriateness of the device in 2 centres falls within 76% – 100%. Only two respondents indicated the quality and age of the device: in both cases, the devices are of high quality and the device falls within the range 6–10 years.

Endocervical curettage

Table 4 presents the descriptive frequency distribution of the respondents' responses to the items for *Endocervical curettage ECC*. Of the twelve medical centres surveyed, items 1 and 2 (Cryosurgery unit and Endocervical curettage) are available in 11 (92%) and 2 (17%) centres respectively while the remainder lack this item. Both items are affordable to a low extent while only item 2 (Endocervical curettage) is affordable to a large extent in just one centre. Both items are accessible to some extent in 1 centre (8%) and in 2 (17%) centres respectively. The device is optimally and highly appropriate in 1 and 2 centres respectively. They are of high quality in just 1

centre, each while endocervical curettage (item 2) has a medium quality in 1 centre. The age of each of the devices falls within 1–5 years in only 1 centre while the age of Endocervical curettage (item 2) falls within the range of 6–10 years in just one centre.

Electrocautery system electrode for LEEP

Table 5 presents the descriptive frequency distribution of the respondents' responses to the item (Electrocautery system electrode for LEEP) for *Large loop excision of transformation zone (LEEP/LLETZ) - Electrosurgical unit*. Of the twelve medical centres surveyed, item 1 (Electrocautery system electrode for LEEP) is available in 2 (17%) centres while 10 (83.3%) centres lack this item. Two respondents reported low affordability in their centres while others could not respond. Two respondents indicated that accessibility was low. Appropriateness was high in 1 centre and optimal in one other centre. The devices are of low and high quality in two centres while device is newer than 1 year in one centre and between 1–5 years in another.

Papanicolaou Test

Table 6 presents the descriptive frequency distribution of the respondents' responses to the item (Vaginal speculum, reusable) for Papanicolaou Test. The table depicts that out of the twelve medical centres surveyed, item 1 (Vaginal speculum, reusable) is available in 11 (92%) centres while 1 centre lacks this item. 6 (50%) respondents indicated that the item is affordable to a low extent while 3 (25%) respondents indicated that it is affordable to large extent. Accessibility is low in 7 (58%) centres and substantial in 2 (17%) centres. The appropriateness of the device in 6 (50%), 2 (17%) and 1 centres is medium, high and optimal respectively. The devices are of low, medium and high quality in 6, 1 and 2 centres respectively. The device is between 1–5 years in 2 centres and between 6-10 years in 7 (58%) centres.

MEDICAL IMAGING & NUCLEAR MEDICINE (IMAGING DEVICES)

Table 7 presents the frequency distribution of the respondents' responses to the items 1 to 5 for *All Cancers*. Of the centres surveyed, item 1 (Ultrasound scan preferably with capacity for colour Doppler imaging system and accessories X-ray imaging) is available in 2 (17%) centres and not the remainder (83.3%). The device is not affordable at all in 1 centre and affordable to a low extent in 1 other. It is accessible to some extent in 2 centres. It is optimally appropriate in 2 (17%) centres. The device is of medium and high quality in just 1 centre in both cases. The device's age falls within 1–5 years in 1 centre and 5 – 10 years in the other.

Item 2 (CT scan) is available in 3 (25%) centres while the device is not available in the remaining 9. It is not affordable at all in 1 centre and only affordable to a low extent in 2 centres. The device is not accessible at all in 1 centre and accessible to a low extent in 2 centres. It is highly appropriate in 1 centre and optimally in one other. The age of the device (item 2) falls within the range 5 – 10 years in 1 centre (8%).

MRI Scan

Item 4 (MRI scan: Magnetic Resonance Imaging (MRI) Scan) is available in 1 centre (8%) surveyed and not in the remaining 11. The device is affordable and accessible to a large extent in the centre where it is optimally appropriate. The device is of high quality and its age falls within the range 5 – 10 years.

Item 4 (Biopsy procedures) is available in 1 centre and not in the remaining 11. In that centre, it is affordable at a low level and only moderately accessible, despite its optimal appropriateness. The device is of high quality and its age falls within the range 5 – 10 years.

Fluoroscopic scanning

Item 5 (Fluoroscopic scanning for image guided procedures Image guided procedures to place catheter for chemotherapy) is available in 2 (17%) centres and not in the remaining 10. Its affordability is low in 1 centre and moderate in the other. The device is accessible to some extent in 2 (17%) centres. The device is optimally appropriate and one and highly in the other. Its quality is medium quality in 1 centre and high quality in the other. The device is between 1–5 years old in 1 centre and 5 – 10 years in the other.

Breast Cancer

Table 8 presents the frequency distribution of the respondents' responses to the items 1, 2, 3, 4 and 5 for *Breast Cancers*. Item 1 (Mammographic X-ray system) is available in 4 (33%) centres and not in the other 8. The item is affordable to low extent in three centres. Accessibility is low in 1 medical centre. Three report appropriateness as medium, high and optimal in their centres, where it is of low, medium and high quality respectively. The age of the device in 2 (17%) centres falls within 1–5 years while in 1 (8%) it falls within the range 6–10 years.

Mammographic stereotactic biopsy

Of the twelve medical centres surveyed, item 1 (Mammographic stereotactic biopsy system) is available in only 2 (17%) centres and is lacking in the remaining 10. It was reported as of low affordability, low accessibility, low

quality but high appropriateness and recent age in one centre.

Ultrasound scan

Ultrasound scan is available in 3 (25%) centres and not the remaining 9 (75%). The device is unaffordable in 1 centre and affordable to a low extent in 2 others. It is inaccessible in 1 centre (8%) and accessible to a low extent in 2 others. The device is highly and optimally appropriate in two separate centres, of high quality in 2 centres, and with an age in the range 6–10 years in 1 centre.

Breast Tomosynthesis

All 12 respondents indicated that item 5 (Breast Tomosynthesis) is not available in all.

Cervical Cancer

Table 4 presents the descriptive frequency distribution of the respondents' responses to the items for *Cervical Cancer*. Of the twelve medical centres surveyed, items 1 and 2 (Ultrasound scan TVUS (transvaginal ultrasound scan) and Image guided procedures to place catheter for chemotherapy) are available in 3 (25%) centres and 1 centre (8%) respectively while 9 (75%) centres and 11 (92%) centres do not possess such item respectively. Both items are affordable to a low extent in 2 (17%) centres and 1 centre (8%) respectively while item 1 (Ultrasound scan TVUS (transvaginal ultrasound scan) is affordable to a large extent in 1 centre (8%)., both items are accessible to a low extent in 2 (17%) centres and 1 centre (8%) respectively while item 1 (Ultrasound scan TVUS (transvaginal ultrasound scan) is accessible to a large extent in 1 centre (8%). The appropriateness of both devices fall within 26% – 50% in 1 centre (8%) and 1 (17%) centre respectively, item 1 is appropriate within the range 26% – 50% in 1 centre (8%) as well as appropriate within 76% – 100% in 1 centre (8%). Also, each of the two devices are of low quality in just 1 centre (8%) and 1 (8%)centre respectively while item 1 has a medium quality in 2 (17%) centres. The age of each of the devices falls within 1–5 years in only 1 centre (8%) each while the age of Endocervical curettage (item 2) fall within the range of 6–10 years in just one centre.

TRUS (transrectal ultrasound scan) for leukaemia

Table 10 presents the frequency distribution of the respondents' responses to the item (TRUS (transrectal ultrasound scan) Image guided procedures to place catheter for chemotherapy) for *Leukaemia*. The table depicts that out of the twelve medical centres surveyed, the item (Ultrasound scan CT scan) is available in 2 (17%) centres while the device is not available in 10 (83.3%) centres., the device is affordable to a low extent in 2 (17%) centres. The device is accessible to low extent in 1 centre

(8%) while it is accessible to some extent in 1 centre (8%). The appropriateness of the device is high in 1 centre (8%) and optimal in another. In 2 (17%) centres, the device is of high quality. The age of device the ages fall within the range 5 – 10 years in 2 (17%) centres.

Ultrasound scan CT scan for leukaemia

Table 11 presents the frequency distribution of the respondents' responses to the item (Ultrasound scan CT scan) for *Leukaemia*. The table depicts that out of the twelve medical centres surveyed, the item (Ultrasound scan CT scan) is available in 3 (25%) centres while the device is not available in 9 (75%) centres. , 2 (17%) respondents indicated that the item is affordable to low extent in their respective centres while it is affordable to some extent in 1 centre (8%). The device is accessible to some extent in 3 (25%) centres. The appropriateness of the device falls within 51% – 75% in 1 centre (8%) while it falls within the range 76% – 100% in 2 (17%) centres. In 2 (17%) centres, the device is of medium quality while it is of high quality in 1 (8%). As indicated by 1 respondent, the age of the device 1 centre (8%) falls within 1–5 years while the ages fall within the range 5 – 10 years in 2 (17%) centres.

TRUS for prostate cancer

Table 12 above presents the frequency distribution of the respondents' responses to the item (TRUS (transrectal ultrasound scan)-guided prostate biopsy) for *Prostate cancer*. The table depicts that out of the twelve medical centres surveyed, the item (transrectal ultrasound scan)-guided prostate biopsy) is available in 3 (25%) centres while the device is not available in 9 (75%) centres. , 1 (8%) respondent indicated that the item is affordable to low extent in his/her centre while it is affordable to some extent in 1 centre (8%). The level of accessibility in 1 (25%) of the medical centres is of low extent while it is accessible to some extent in 1 (8%). The appropriateness of the device falls within 51% – 75% in 1 centre (8%) while it falls within the range 76% – 100% in 1 centre (8%). In 2 different centres, the device is of medium and high quality respectively. As indicated by 2 respondents, the ages of the device in 2 (17%) centres fall within 1–5 years.

PROCEDURES

Mammographic X-ray

Table 13 presents the frequency distribution of the respondents' responses to the item (Mammographic X-ray system) for Mammography. Item 1 (Mammographic X-ray system) is available in only 4 (33%) centres. 3 (25%) respondents indicated that the item is affordable to low extent in their respective centres. The level of accessibility in 1 (25%) of the medical centre of low extent while to

some extent, the device is available. In 3 different centres, the device is of low, medium and high quality respectively. As indicated by 2 respondents, the ages of the device in 2 (17%) centres fall within 1–5 years while in 1 (8%) fall within the range 6–10 years.

Mammographic stereotactic biopsy system

Table 14 presents the descriptive frequency distribution of the respondents' responses to the item (Mammographic stereotactic biopsy system) for *Stereotactic guided Core Needle Biopsy of Primary Tumor or Metastatic Lesions*. Of the twelve medical centres surveyed, item 1 (Mammographic stereotactic biopsy system) is available in 2 (17%) centres while 10 (83.3%) centre do not possess such item. , only one respondents indicated that the affordability of the item is low in the centre while others could not respond to this measure. , only 1 (8%) respondent indicated the level of accessibility is of low level in the centre. The level of appropriateness of the device in 1 centre (8%) falls within 51% – 75%. Also, exactly one respondent indicated that the quality of the device is of low in the centre and likewise just one respondent indicated that the age of the device is less than 1 year in the centre.

Biopsy gun

The biopsy gun (ultrasound probe or transducer/Linear array) for Ultrasound Guided Biopsy of Regional Lymph and Sentinel Nodes (FNA) is unavailable in all the centres surveyed.

Fine Needle Aspiration

The item single use devices/ disposables/medical Supplies for Fine Needle Aspiration (FNA) is available in only 4 (33%) centres. It was affordable to a low extent in 1 centre and to a large extent in 2, accessible at a low level in 3 centres, highly appropriate in 1 centre and optimally appropriate in 2. The ages in three centres range between less than one year, 1–5 years and 6–10 years respectively.

CONCLUSION

It can be inferred from the analysis that some of the apparatuses or devices required for diagnoses or treatments of certain illnesses such as cancer etc. are available in a few medical centres in Lagos State (the South-western geopolitical zone of Nigeria) with respect to certain levels of accessibility and appropriateness. Apparatuses or devices such as aneroid sphygmomanometer stethoscopes, thermometers, examination tables, resuscitation trolleys, and defibrillators. Fixed examination/treatment lights, pulse oximeters, electrocardiography systems, colposcopes and vaginal speculums are available in at least 75% of the surveyed centres. Comparatively, apparatuses or devices

such as cryosurgery units, endocervical currettes, electrocautery systems, ultrasound scans, CT scan, biopsy procedures, mammographic X-ray systems, mammography stereotactic-guided core needle biopsy of primary tumour or metastatic lesions, ultrasound scan TVUS (transvaginal ultrasound scan), image-guided procedures are available in at most 33.3% of the surveyed medical centres.

On the contrary, breast tomosynthesis biopsy guns are not available in all the surveyed medical centres while only one of the surveyed medical centres has magnetic resonance imaging (MRI) System in Lagos State. Clearly there is a problem of access to these medical devices.

In addition to the conclusion based on the questionnaire, in most of the hospitals the ratio of patients per device is high leading to overuse of these devices, with frequent breakdowns leaving the patients with no options. This survey therefore suggests that further work should be done on improved clinical evaluation and investigation for medical devices as a crucial opportunity to improve the rules about the conduct of clinical investigations and the collection of clinical data for medical devices.

There are numerous challenges and systemic issues which are attached to the lack of access to medical devices that should also be considered in the development of an overarching policy for enhanced access: these include power failures, environment, policy, safety, product development and technology transfer, maintenance and preventive maintenance and training.

The health care situation in Nigeria is in a state of emergency and there is need to overcome the barriers to accessing medical devices. There is also a need to improve, promote, and accelerate the transfer of technology between developed and developing countries through cooperation and coherence at the international level (promoting access) and the adoption of a holistic approach by government policy makers, healthcare providers, researchers to create an efficient, effective regulatory system tuned to the realities of the Nigerian situation. This article has mapped out in concrete terms the nature of the challenge and the needs to be practically addressed through such an approach.

BIBLIOGRAPHY

2016 ITA Top Markets Report Medical Devices Country Case Study
https://www.trade.gov/topmarkets/pdf/Medical_Devices_Nigeria.pdf

Abbott F M 'The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference' (October

2001) FSU College of Law Public Law Working Paper No 36 and QUNO Occasional Paper No 7

Adejoke Oyewunmi, The Patent System and Transfer of Technology in Nigeria, Olanrewaju Fagbaohun and Bambo Adewopo (ed.). *'Developments and Reform, Nigeria's Commercial Law - Essays in honour of Chief Dr Chris Ogunbanjo* The Law Center LASU Lagos, 1998, 78-92 p.79.

Adeyanju A J Radiotherapy Technical Challenges In Nigeria, LUTH.

Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organisation Annex 1C.

Audretsch D B et al, Introduction: Technology Transfer in a Global Economy in Audretsch D B et al *Technology Transfer in a Global Economy* 2012 Springer Group

Boschiero N, Intellectual property rights and public health: an impediment to access to medicines and health technology innovation?

https://www.statoechiese.it/images/uploads/articoli_pdf/Boschiero.2_Intellectual.pdf

Constitution of the Federal Republic of Nigeria.

Correa C M 'Review of the TRIPS Agreement: Fostering the Transfer of Technology to Developing Countries' (1999) 2 *The Journal of World Intellectual Property* 939

Craig P and de Burca G (2011) *EU Law Text, Cases and Materials* (5th ed) Oxford: Oxford University Press

Demircan S K, *The Role of R&D and Innovation in Us Economy as a Benchmark for Turkish Economy*, Eli Broad College of Business Michigan State University
http://www.ekonomi.gov.tr/upload/bf09ae98-d8d3-8566-520b0d124e5614d/koray_demircan.pdf

Diaconu K et al, *Medical device procurement in low- and middle-income settings: protocol for a systematic review*
<https://systematicreviewsjournal.biomedcentral.com/articles/10.1186/2046-4053-3-118>

Drahos, Peter, 'The Universality of Intellectual Property Rights: Origins and Development', *Intellectual Property and Human Rights*, World Intellectual Property Organization, 1999, Geneva,
www.wipo.int/edocs/mdocs/tk/en/.../wipo_unhchr_ip_pnl_98_1.doc

Du Plessis 'Perspectives from a developing country' *Extraordinary Session I: IP and the global economy*, AIPPI Lisbon (17 21 June 2002) available at:
http://www.aippi.org/reports/Vortrag_DuPlessis.pdf

- Food, Drugs and Related Products Act 1993 Cap F33 LFN 2004.
- Global Harmonization Task Force, Information Document Concerning the Definition of the Term "Medical Device" GHTF/SG1/N29R16:2005
www.imdrf.org/.../ghtf/.../sg1/.../ghtf-sg1-n29r16-2005-definition-medical-device-05...
- Global Innovation Index 2017
https://www.globalinnovationindex.org/UploadedFiles/Indepths/Files/Indepths_9db22f7962064f1282db29c9aec30365.PDF
- Lazzarini Z 'Making Access to Pharmaceuticals a Reality: Legal Options under TRIPS and the Case of Brazil' (2003) 6 *Yale Human Rights and Development Law Journal* 103
- Local Production and Technology Transfer to Increase Access to Medical Devices Addressing the barriers and challenges in low- and middle-income countries 2012
http://www.who.int/medical_devices/1240EHT_final.pdf
- Marks S P and Benedict A L Access to Medical Products, Vaccines and Medical Technologies in Zuniga JM *et al* (ed) (2013) *Advancing Human Right to Health*, Oxford University Press,
- Markus, K E, Introduction. The WTO, Intellectual Property Rights and the Knowledge Economy, in Keith Markus (ed) (2004) *Critical Perspective on the Global Trading System and the WTO* Cheltenham: Elgar p. 34.
- Moser P, 'How Do Patent Laws Influence Innovation? Evidence from Nineteenth-Century World Fairs,' *Working Paper 9909 National Bureau of Economic Research*
<http://www.nber.org/papers/w9909>
- Nguyãen T (2010) *Competition Law Technology Transfer and the TRIPS Agreement: Implications for Developing Countries*, Cheltenham: Edward Elgar
- Omatseye C, 'Nigeria loses \$1bn annually to medical tourism', *Vanguard* 23 August 2017 at
<https://www.vanguardngr.com/2017/08/nigeria-loses-1bn-annually-medical-tourism-omatseye/>
- Organisation for Economic Co-Operation and Development (OECD), *Patents and Innovation: Trends and Policy Challenges* <http://www.oecd.org/science/sci-tech/24508541.pdf>
- Pistorius T, 'The Impact of Intellectual Property Law and Policy on Sustainable Development' *South African Yearbook of International Law* 376 (2007)
- Poku Adusei 'Regulatory Diversity as Key to the 'Myth' of Drug Patenting in sub-Saharan Africa' (2010) 54 *Journal of African Law* 26-27.
- Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Medicines
www.unsqaccessmeds.org/final-report/
- Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to p. 21- 28
www.unsqaccessmeds.org/final-report/
- Resolution WHA60.29. Health Technologies. In: Sixtieth World Health Assembly. Geneva, 23 May 2007.
http://www.who.int/medical_devices/resolution_wha60_29-en1.pdf
- Sampat B N, 'Academic Patents and Access to Medicines in Developing Countries' *American Journal of Public Health*, 99 (2009), 9-17.
- Torrance A W & Tomlinson B, 'Patents and the Regress of Useful Arts', *Colum. Sci. & Tech. L. Rev.* 10 (2009) 130-168 p.130.
- Towards improving access to medical devices through local production Phase II Report of a case study in four sub-Saharan countries
- UNCTAD/UNDP, Transfer of Technology for Successful Integration into the Global Economy UNCTAD/ITE/IPC/2003/6
http://unctad.org/en/Docs/iteipc20036_en.pdf
- UNCTAD/UNDP, Transfer of Technology for Successful Integration into the Global Economy UNCTAD/ITE/IPC/2003/6
http://unctad.org/en/Docs/iteipc20036_en.pdf
- United Nations Conference on Trade and Development (UNCTAD) Series on issues in international investment agreements UNCTAD/ITE/IIT/28
<http://unctad.org/en/Docs/psiteiit28.en.pdf>
- Watal, Jayashree; Caminero, Leticia (2017): Least-developed countries, transfer of technology and the TRIPS Agreement, WTO Staff Working Paper, No. ERSD-2018-01, World Trade Organization (WTO), Geneva, <http://dx.doi.org/10.30875/412bee53-en>
- WHO list of Priority Medical Devices for cancer management
www.who.int/medical_devices/publications/priority_med...cancer_management/en/
- WHO Sixtieth World Health Assembly Health Technologies WHA60.29
http://www.who.int/medical_devices/resolution_wha60_29-en1.pdf
- WHO, Local Production and Technology Transfer to Increase Access to Medical Devices Addressing the

barriers and challenges in low- and middle-income countries 2012

http://www.who.int/medical_devices/1240EHT_final.pdf

WHO, Medical Devices, Priority medical devices

http://www.who.int/medical_devices/access/en/

WHO, Public health,

<http://www.who.int/trade/glossary/story076/en/#>

WHO. Medical Devices, Priority medical devices.

WTO, Technology transfer

http://www.wto.org/english/tratop_e/trips_e/techtransfer_e.htm

TABLES

Source throughout: Field survey, 2018

CANCER MEDICAL DEVICES

Table 1: General Medical devices for Clinical Assessment and Minor Procedures

	Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
		1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
1	Aneroid sphygmomanometer Stethoscope	11	1	-	5	6	-	7	4	-	5	5	1	6	-	4	1	1	8
2	Thermometer	11	1	1	3	7	-	6	5	-	4	5	2	4	1	5	1	1	8
3	Examination table Resuscitation trolley	11	1	1	4	6	-	8	3	-	4	5	2	6	1	3	2	8	-
4	Pulse oximeter	9	3	-	3	7	-	6	4	-	3	5	2	4	3	2	1	2	6
5	Electrocardiography system	10	2	-	4	6	-	7	3	-	4	3	3	5	2	2	-	2	7

Table 2: Colposcopy

Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
	1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
Colposcope	2	10	-	2	-	1	1	-	-	-	2	-	1	1	-	1	1	1

Table 3: Cryotherapy

Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
	1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3

Cryosurgery unit	2	10	-	1	1		2	-	-	-	-	2	-	-	2	-	-	2
------------------	---	----	---	---	---	--	---	---	---	---	---	---	---	---	---	---	---	---

Table 4: Endocervical curettage ECC

	Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
		1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
1	Colposcope	11	1	-	1	-	-	-	1	-	-	-	1	-	-	1	-	1	-
2	Endocervical curette	2	10	-	1	1	-	-	2	-	-	-	2	-	1	1	-	1	1

Table 5: Large loop excision of transformation zone (LEEP/LLETZ) - Electrosurgical unit

Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age			
	1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3	
Electrocautery system electrode for LEEP	2	10	-	1	1	-	-	2	-	-	1	1	-	1	1	1	1	1	-

Table 6: Papanicolaou Test (Pap smear)

Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
	1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
Vaginal speculum, reusable	11	1	-	6	3	-	7	2	-	6	2	1	6	1	2	-	2	7

MEDICAL IMAGING & NUCLEAR MEDICINE (IMAGING DEVICES)

Table 7: All Cancers

	Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
		1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
1	Ultrasound scan preferably with capacity for colour Doppler imaging system and accessories X-ray imaging	2	10	1	1	-	-	-	2	-	-	-	2	-	1	1	-	1	1
2	CT scan	3	9	1	2	-	1	2	-	-	-	1	1	-	-	2	-	-	1
3	MRI scan: Magnetic Resonance Imaging (MRI) System (1.5 T)	1	11	-	-	1	-	-	1	-	-	-	1	-	-	1	-	-	1
4	Biopsy procedures (including stereotactic biopsy)	1	11	-	1	-	-	-	1	-	-	1	-	-	-	1	-	-	1
5	Fluoroscopic scanning for image guided procedures Image guided procedures to place catheter for chemotherapy	2	10	-	1	1	-	-	2	-	-	1	1	-	1	1	-	1	1

Table 8: Breast Cancer

	Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age					
		1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3			
1	Mammographic X-ray system	4	8	-	3	-	-	1	2	-	1	1	1	1	1	1	1	-	2			
2	Mammography Stereotactic-guided core needle biopsy of primary tumour or metastatic lesions	2	10	-	1	-	-	1	-	-	1	-	-	1	-	-	1	-	-	1	-	-
3	Ultrasound scan	3	9	1	2	-	1	2	-	-	-	1	1	-	-	2	-	-	1			
4	Ultrasound guided biopsy of regional lymph and sentinel nodes	1	11	1	-	-	-	1	-	-	1	-	-	1	-	-	-	-	-	1		
5	Breast Tomosynthesis	12	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Table 9: Cervical Cancer

	Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age				
		1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3		
1	Ultrasound scan TVUS (transvaginal ultrasound scan)	3	9	-	2	1	-	2	1	-	1	1	1	1	2	-	-	2	1		
2	Image guided procedures to place catheter for chemotherapy.	1	11	-	1	-	-	1	-	-	1	-	-	1	-	-	-	-	1		

Table 10: Colorectal Cancer

Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
	1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
TRUS (transrectal ultrasound scan) - Image guided procedures to place catheter for chemotherapy.	2	10	-	2	-	-	1	1	-	-	1	1	-	-	2	-	2	-

Table 11: Leukaemia

Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
	1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
Ultrasound scan - CT scan	3	9	-	2	1	-	-	3	-	-	1	2	-	2	1	-	1	2

Table 12: Prostate cancer

	Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
		1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
1	TRUS (transrectal ultrasound scan)-guided prostate biopsy	3	9	-	1	1	-	1	1	-	-	1	1	-	1	1	-	2	-

PROCEDURES

Table 13: Mammography

	Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age			
		1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3	
1	Mammographic X-ray system	4	8	-	3	-	-	1	2	-	1	1	1	1	1	1	1	-	2	1

Table 14: Stereotactic guided Core Needle Biopsy of Primary Tumour or Metastatic Lesions

Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
	1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
Mammographic stereotactic biopsy system	2	10	-	1	-	-	1	-	-	1	-	-	1	-	-	1	-	-

Table 15: Ultrasound Guided Biopsy of Regional Lymph and Sentinel Nodes

	Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age			
		1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3	
1	Biopsy gun (Ultrasound probe or transducer/Linear array)	12	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Table 16: Fine Needle Aspiration (FNA)

Item	Availability		Affordability			Accessibility			Appropriateness				Quality			Age		
	1	2	1	2	3	1	2	3	1	2	3	4	1	2	3	1	2	3
Single use devices/ disposables/medical supplies	4	8	-	1	2	-	-	3	-	-	1	2	-	-	3	1	1	1

<http://www.parliament.gov.zm/sites/default/files/documents/acts/Trade Marks Act.pdf>