Implementation of Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

National Assessment Report - Sri Lanka
Implementation of Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

NATIONAL ASSESSMENT REPORT - SRI LANKA
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<td>Active Pharmaceutical Ingredients</td>
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MESSAGE FROM
THE HON. MINISTER OF HEALTH AND INDIGENOUS MEDICINE

I am pleased to note that some important recommendations have come up through the National Consultation held in Sri Lanka towards implementing the World Health Assembly resolution 61.21 adopted in May 2008 on Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property on Promoting Innovation and Access to Health Products.

Sri Lanka has embarked on a new era of developments with the new changes in the government policies. Health sector has been identified for novel interventions in the areas of tobacco control, national medicines policies and on the burden of chronic kidney diseases. The interdependence of health with other sectors – environment, agriculture, education and international trade have opened new arenas in the management of public health. Trade factors and international agreements are influencing public health in access and development of medicines and medical products and their regulation across boundaries. Moreover, access for health and food products through e-commerce and internet have resulted in new paradigms for which we need legal instruments and capacity building in the country.

I understand that the strategy involves promoting innovation, transfer of technology and access to medical products for public health. We have just got our new Medicines Act passed by the Parliament of Sri Lanka and therefore this exercise has come up at an opportune time for our country.

I am thankful to all other Ministries and organizations that came together to one platform to discuss and make recommendations to improve the health system of our country. I fully recognize the long term collaboration with other government and private sector organizations in order to strengthen the performance of the health systems and to reach the highest attainable standards of health.

Hon. (Dr) Rajitha Senarathne
Minister of Health and Indigenous Medicine
I am pleased to note that Sri Lanka has taken a leading role towards the implementation of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property which was endorsed by the sixty-first World Health Assembly in May 2008. The strategy aims at providing a framework to secure a sustainable basis for needs-driven essential health research promotion within member countries.

The assessment process in Sri Lanka has brought together the active engagement of different ministries and institutions for the cause of public health. It has also facilitated identification of clear and implementable policy recommendations for the government to increase its effectiveness in promoting health products innovation through institutional development, investments and international coordination of areas relevant for public health. The involvement of all relevant stakeholders in the assessment process is a positive initiative to make available the medical products of the required quality, safety and efficacy for the people and also ensuring provision of the necessary information to enable the use of such products in a rational manner.

Dr D.M.R.B. Dissanayake
Secretary to the
Ministry of Health and Indigenous Medicine
MESSAGE FROM
THE DIRECTOR GENERAL OF HEALTH SERVICES

It is with immense pleasure that I send this message to the publication on the National Assessment on implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) in Sri Lanka.

Sri Lanka is committed to provide free healthcare services for every citizen of the country and has achieved remarkable progress during past few decades. These achievements have been internationally recognized by WHO and UNICEF as best in South East Asia region.

Today the world is increasingly interdependent and transforming to a global village. More changes have taken place in all spheres in the past few years than in previous decades particularly related to innovations. As it is seen in the Global strategy there are certain proposals that are core to the health sector such as engaging in policies for regulation of medical products and retention of health personnel. There are other sets of actions which call for interdisciplinary approaches for best health outcomes for the respective countries.

In Sri Lanka aligned with the global initiative many steps have been taken forward to get academia involved in research activities in relation to health products and medical devices where trade plays a primary role. Certain areas such as managing intellectual property rights to contribute to innovation and public health require information sharing among the medical sciences and legal disciplines. This may be more appropriate on the background of transition in population and disease epidemiology where non communicable diseases have come up as a major challenge in which innovation and new medical products are much needed.

In that respect initiatives taken in Sri Lanka under the guidance of WHO South East Asia Regional office, I am sure would set the platform for more regional cooperation and sharing of inter-regional experience in view of addressing present challenges.

I assure that the fullest support from the Department of Health Services to implement the recommendations of the report which I strongly believe as a need of the day.

Dr. Palitha Mahipala
Director General of Health Services
I am happy to note that Sri Lanka has completed the work on the assessment to evaluate its position on Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property. I congratulate the Ministry of Health and all other stakeholders for the work accomplished.

The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) is a comprehensive framework for addressing issues related to innovation and access to essential health technologies for developing countries and to mobilize resources for these purposes. The GSPA-PHI was endorsed by the sixty-first World Health Assembly in May 2008. The Global Strategy identified 8 main elements and 25 sub-elements spread across 108 action points. These cover important areas to improve delivery and access to health products and promote innovation, such as prioritizing and promoting research and development, building and improving innovative capacity, transfer of technology and application and management of intellectual property.

This is the first assessment on Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property conducted in a Member State in the South East Asian Region. The World Health Organization stands ready to collaborate with Ministry of Health in all of this important work and to facilitate implementation of the recommendations in the assessment report.

The national assessment findings are expected to help the Government in many ways especially at policy level for prioritization of investments in research and development for health and at managerial level for improving coordination of various research efforts. I hope this assessment exercise carried out in Sri Lanka will also be a model for other countries in the Region.

Dr Arvind Mathur
WHO Representative to Sri Lanka a.i.
MESSAGE FROM
DR. B.V.S.H. BENERAGAMA-FOCAL POINT FOR SRI LANKA FOR GSPA-PHI

It is with great pleasure I make this note on the completion of the national assessment conducted in Sri Lanka for the implementation of the World Health Assembly resolution on Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property on Promoting Innovation and Access to Health Products.

The recommendations made during the National Consultation were discussed at the Regional Meeting held in Bangkok from 16-18 December 2014. The same was considered as an important component for next steps at a global level in addition to developing our country position.

I am also happy to mention that this assessment which is the first for Sri Lanka is also the first for the South-East Asia Region of WHO. This report is based on the inputs received from all relevant Ministries and organizations. Sri Lanka has a National Science and Technology Policy and several institutions are dedicated to promote R&D in general and health R&D in particular. However, more needs to be done in coordination of R&D efforts to support public health objectives. In order to guarantee continuous access to quality medicines and other health products, existing processes need to be strengthened further.

We are concerned on the technology gap in health products and technology transfer has been an issue of concern. We need to harness new technologies such as web based platforms for sustainable development and information exchange as well as examine interventions for mainstreaming traditional health products such as in indigenous medicine.

It is my firm belief that, our coming together to work on this assessment on a common platform will help overcome many barriers in our healthcare system.

I am grateful to the Ministry of Health and Indigenous Medicine, WHO Regional Office of the South East Asia Region and to the country office in Sri Lanka for taking initiatives and supporting us throughout this project.

Dr. B.V.S.H. Beneragama
Focal Point for Sri Lanka for GSPA-PHI & Director – Maternal and Child Health
EXECUTIVE SUMMARY

The National Assessment for implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) was carried out in Sri Lanka as per the World Health Assembly Resolution 61.21. This is the first assessment carried out in the South East Asia Region (SEAR). The assessment was intended to understand the present status of Public Health, Innovation and Intellectual Property in Sri Lanka for further national action on GSPA-PHI.

A tool prepared by the World Health Organization (WHO) was used with minor modifications as appropriate in the Sri Lankan context to carry out the assessment. There were several steps in the assessment process. The tool was introduced to the stakeholder institutions at face to face meetings with high officials in the institutions and their support for the assessment was sought. The tool was then sent to the stakeholder institutions for collection of information on areas relevant to the institution. A discussion paper was prepared based on the responses received from them. Representatives of the institutions were then called for a consultative workshop in April 2014 to review and revise the discussion paper. The refined discussion paper was sent to high level officials of the institutions. The national assessment was finalized at a consultative meeting held in September 2014.

The findings of the national assessment are presented in six main sections. They are (i) Health Research and Development, (ii) Manufacturing of Pharmaceuticals, (iii) Application and Management of Intellectual Property (iv) Improving Delivery and Access, (v) Traditional Medicine and (vi) Monitoring and Reporting. Each section is divided into subsections in order to give further clarity to the assessment.

Sri Lanka has a National Science and Technology (S&T) policy. There are several institutions dedicated to promoting research and development (R&D) in general and health R&D in particular. The country, however, has much to do on co-ordination of R&D efforts to support public health objectives. In addition, the investment available for health R&D needs further prioritization. The current capacity to develop health products, particularly pharmaceuticals and related technologies is weak. The pharmaceutical sector, therefore, needs major investments to support public health objectives. Existing processes need to be strengthened further to guarantee continuous access to quality medicines and other health products.
INTRODUCTION

In response to a request made by the South East Asian Regional Office (SEARO) of the World Health Organization (WHO), the WHO country office in Sri Lanka facilitated a National Assessment on Public Health Innovations and Intellectual Property as a part of the follow up action on the World Health Assembly (WHA) resolution 61.21 of 2008 on Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI). The GSPA identified 8 main elements and 25 sub-elements spread across 108 action points to increase effectiveness in promoting innovation within the countries through institutional development, investment and coordination of areas relevant to health innovation. Each element has an intellectual property and trade (IPT) component that needs to be explored and developed in order to maximize the results under the GSPA. These elements are:

1. Prioritizing research and development needs;
2. Promoting research and development;
3. Building and improving innovative capacity;
4. Transfer of technology;
5. Application and management of intellectual property to contribute to innovation and promote public health;
6. Improving delivery and access;
7. Promoting sustainable financing mechanisms; and
8. Establishing and monitoring reporting systems.

It is envisaged that the member nations would carry out a national assessment, using an assessment tool developed by the WHO, on the baseline status of the country on research and development (R&D), innovation, intellectual property and access to medical technologies with the view to identify further national action on GSPA-PHI. By carrying out this national assessment, Sri Lanka, became the first country in the South East Asian Region to do so.

The Assessment tool for GSPA in Sri Lanka brought together active engagement of diverse institutions/ministries for the cause of public health. This analysis facilitated identification of clear and implementable policy recommendations for the government to increase its effectiveness in promoting health products innovation through institutional development, investment and coordination of areas relevant for public health. It is hoped that the understanding gained from this exercise will be useful as a road map for further progress on WHA 61.21 and health R&D at national regional and global level.
METHODOLOGY

The methodology for the national assessment was developed based on the WHA resolution 61.21. The assessment tool was developed by the WHO taking into account the eight elements stipulated in the resolution. Since element seven (7) on sustaining financing mechanisms of the resolution is being pursued separately through international discussions on innovative funding models, the other seven elements were given more emphasis in this national assessment.

The modified National Assessment Tool Kit used for the current assessment comprised of six major sections:
These sections were divided further into twenty one subsections. There were a total of sixty eight questions in the tool. Minor adjustments were made to the wording of questions in order to make the tool user friendly in the Sri Lankan context. The Ministry of Health identified a focal point to coordinate and support the national assessment. A working group with several resource persons was established to support the focal point.

The assessment was done in several steps.

1. A list of potential stakeholder institutions that could provide the necessary data was prepared by the working group in consultation with experts in different fields.

2. The questions in the assessment tool that were relevant to a particular institution were identified based on the mandate of that institution.

3. The relevant personnel in the identified institutions were consulted and the modified tool was delivered to them for submission of the required data.

4. The resource persons visited the institutions in person to explain the assessment tool and facilitated the collection of data.

5. Data collection was completed within the planned time frame.

6. A draft document was prepared as a discussion paper for a national consultative workshop.
A two day national workshop was organized to discuss and develop consensus on a draft discussion paper in two stages.

First day (28 April 2014):
the draft document was discussed by representatives of the stakeholder institutions. The participants were divided into the following three groups:

(i) Group one consisted of representatives of academic and research institutions.

(ii) Group two consisted of representatives of institutions related to Ministry of Health.

(iii) Group three consisted of representatives of institutions representing trade related areas from both the government and the private sectors.

The draft document was modified to incorporate the information that emerged during the discussions.

Second day (29 April 2014):
the modified document was presented to high level officials from the stakeholder institutions for comments and recommendations.

The draft document was circulated again to the stakeholder institutions giving one month to submit any additional information with evidence.

The final draft report of the national assessment was prepared incorporating all submissions and comments provided by the stakeholder institutions.
10 It was circulated among the stakeholders before the final national consultation which was held on 26 September 2014.

11 The assessment report was finalized and adopted taking into consideration the final comments made by high officials at the consultative meeting.
The findings of the National Assessment are presented in six main sections. Under each section there are several subsections. Web links to additional information are provided for easy reference.

Health Research and Development

Health R&D policies and infrastructure

The National Science and Technology Commission (NASTEC) under the Ministry of Technology and Research is mandated by law to develop and monitor Science and Technology Policy of the country. The NASTEC is also responsible for establishing national priorities in R&D. This is done through stakeholder consultation and ratified at Biannual Conferences on Science and Technology (BICOST) that have been held since the year 2000. The Science, Technology and Innovation Strategy for Sri Lanka for 2011 to 2015 was formulated at the 6th BICOST held in 2012 and can be accessed at http://costi.gov.lk/index.php/en/32-uncategorised/90-five-year-strategy-ebook. The Science and Technology Investment Framework adopted at the 7th BICOST in 2014 can be accessed at http://www.nastec.lk/index.php/2014-03-11-05-08-50/bicost-report.
Ministry of Health has its own directorate for research - The Education, Training & Research (ET&R) Unit. This Unit is responsible for promotion of health research in Sri Lanka. It convenes the National Health Research Council (NHRC) which functions as an advisory body. The NHRC meets on a monthly basis and it comprises of experts from the medical field nominated by their respective institutions. It consists of representatives of seven Medical Faculties in Sri Lanka; Banadaranaike Memorial Ayurvedic Research Institute (BMARI); Institute of Indigenous Medicine, University of Colombo; Gampaha Wickramarachchi Ayurveda Institute of the University of Kelaniya; Sri Lanka Medical Association (SLMA), Post Graduate Institute of Medicine, University of Colombo; Industrial Technological Institute (ITI) and Ministry of Health (Director General of Health Services, Deputy Director General - Education, Training and Research and 3 other Deputy Director Generals). The total membership in the NHRC is 15. An Act of parliament has been drafted to setup the NHRC as an independent Council and is awaiting final legal formalities.

The NHRC has a mechanism to periodically identifying research priorities on health. In 2006 the NHRC developed a list of research priorities in health based on the 8 steps methodology presented at the Global Forum IX with the involvement of representatives from professional colleges and associations. This list of research priorities was published in 2008 on the website of the Ministry of Health. These are now being revised (started in 2013).

The NHRC has already held several workshops with professional colleges to finalise the list. The revised list will be primarily based on the burden of diseases in Sri Lanka. The list is extensive as all professional colleges and different divisions in the Ministry of Health and other groups represented in the NHRC had submitted proposals.

There is mixed perception on priority setting on R&D in relation to different public funding agencies in the country. The National Research Council (NRC) established under the Ministry of Technology and Research on a Presidential Directive issued on 24th July 2007 is dedicated purely for research funding. The basis for funding is investigator driven research of high scientific merit. NRC is solely funded by the Government of Sri Lanka.

The National Science Foundation (NSF) has identified health R&D as an important priority. However, their basis for funding is also scientific merit of the proposals. The funds are distributed among all areas of science and technology ranging from health to agriculture to engineering. In addition it has recently identified thematic areas for funding research. These thematic areas are food security, climate change, water security and energy security. Direct health topics have not been included in thematic areas as of now.

1 http://www.oecd.org/investment/globalforum/aboutthegfii.htm
2 http://www.health.gov.lk
3 http://www.nrc.gov.lk
4 http://www.nsf.ac.lk
The University Grants Commission\(^5\) (UGC), Ministry of Higher Education\(^6\) and the Ministry of Indigenous Medicine\(^7\) also provide funding for health research.

There are 42 S&T institutions and 52 university faculties in the country involved in research. The Medical Research Institute (MRI) is the only R&D institution within the Western medical system dedicated to research. The Bandaranaike Memorial Ayurveda Research Institute (BMARI) is dedicated to research on the Ayurveda system of medicine. Both these institutions have not made any major impact on research due to inadequate research funds. However, these institutions started receiving noteworthy research funding during the past two years. The majority of health-related research is done by academics in medical and science faculties of Universities, staff of different institutions and programmes under the Ministry of Health. All these institutions have their own criteria for defining research priorities depending on their mandates. These are largely dependent on operational decisions taken for institutional functioning. At present, any institution under the Ministry of Health can conduct its research on any relevant field.

There was no proper coordination mechanism between R&D in Sri Lanka and national development. The Coordinating Secretariat for Science, Technology and Innovation (COSTI)\(^8\) was established on 1 February 2013 under the Senior Minister for Scientific Affairs in order to fill this gap. COSTI’s main objectives are: a) Establishment of an Inter-Ministerial Steering Committee for Science Technology and Innovation to coordinate all activities including funding in Science Technology and Innovation, b) Setting up of National Operational and Coordinating Councils, c) Establishment of a Secretariat to centralize, institutionalize and support the coordination and monitoring activities related to Science, Technology and Innovation and d) Development and operationalization of National Science, Technology & Innovation Coordination and Monitoring System (NSTICAMS) –

\(^5\) http://www.ugc.ac.lk
\(^6\) http://www.mohe.gov.lk
\(^7\) http://www.indigenousmedimini.gov.lk
\(^8\) http://www.costi.gov.lk
a flexible, comprehensive National ICT Platform for coordination and monitoring of all activities related to Science, Technology and Innovation across more than 25 ministries and more than 70 institutions.

COSTI is looking at building virtual research clusters with the assistance of the Sri Lanka Medical Association (SLMA)\(^9\), other professional bodies and the Sri Lanka Association for Advancement of Science (SLAAS)\(^10\) to coordinate research in the health sector.

There are some research networks operating at national level at present (E.g. National Education and Research Network), regional level (E.g. Asia Pacific Action Alliance on Human Resources for Health; Forum for Ethical Review Committees in Asia and the Western Pacific) and global level (E.g. Global Influenza Surveillance Network). Sri Lanka’s participation in such networks has been constrained due to lack of funding.

Currently there are two WHO Collaborating Centres established in Sri Lanka to encourage health related research. The Department of Community Medicine, Faculty of Medicine Colombo hosts the WHO Collaborating Centre for Occupational health\(^11\) since 2012. The WHO Collaborating Centre for Primary Healthcare Development was established at National Institute of Health Science, Kalutara in 2013\(^12\).

There are few private sector organization with own research facilities at present in Sri Lanka. Contribution of those to health R&D is minimal. There are few noteworthy ventures.

The Genetech\(^13\) was founded with the vision of making the benefits of biotechnology accessible to the people of Sri Lanka. This is a venture that expects the transfer of technology of university research into commercial applications. Genetech offers paternity tests with accepted international standards at the lowest price in the world. Today, Genetech has reached the international market and has offered its services to the courts of Bhutan and Fiji Islands.

The first paternity case was requested by the Bhutan government through the Forensic Medicine Unit, National Referral Hospital Thimphu in 2007 and a total of 64 paternity cases and 2 Forensic cases have been referred to Genetech up to now from Bhutan. In addition the courts of Fiji Islands have referred 24 paternity cases to Genetech. The DNA reports submitted by Genetech for those cases have been accepted by the respective courts and they continue to send samples to Genetech laboratory for analysis.

\(^9\) http://www.slma.lk
\(^10\) http://www.slass.lk
\(^11\) http://www.med.cmb.ac.lk/index.php/who-collaborating-centre
\(^12\) http://nihs.gov.lk
\(^13\) http://www.genetechsrilanka.com
Ceygen Biotech\(^{14}\) was the second company that was formed aimed at product development for the health sector. Ceygen Biotech manufactures molecular biology reagents and diagnostic kits for the local market. It has the vision of venturing into the export market in the near future.

Credence Genomics\(^{15}\) was the latest company to enter the biotechnology space in Sri Lanka. It grew out of the Global Forum of Sri Lankan Scientists convened by the National Science Foundation in December 2011 as collaboration between Sri Lankan scientists based in Sri Lanka and the USA with investment from the private sector. This company is the first next generation sequencing company in the country.

In addition to these, there are several university based R&D institutions of international standing that have entered the diagnostic arena – these include the Human Genetics Unit, Faculty of Medicine, University of Colombo\(^{16}\) which has been in the forefront of introducing genetic diagnostic technologies to the country by themselves as well as with its commercial partner Asiri Centre for Genomic and Regenerative Medicine of the Asiri Group of Hospitals (together they are the largest providers of genetic diagnostics in the country); the Department of Microbiology, Faculty of Medical Sciences, University of Sri Jayewardenepura which has been in the forefront of introducing flow cytometry based diagnostics to the country\(^{17}\); and the Department of Oral Pathology, Faculty of Dental Science, University of Peradeniya which is engaged in cutting edge research into Oral Cancer – the commonest cancer in Sri Lanka\(^{18}\).

The Moratuwa University is the only University in Sri Lanka with a special research laboratory for biomedical technologies\(^{19}\). This laboratory is a joint
venture with a private partner and focuses on medical product development for commercialization.

**Funding for health R&D**

The total annual health expenditure in Sri Lanka is LKR 165,000 million ($1380 million) which is equal to 3.4% of the GDP in 2009 according to the latest published National Health Accounts. Government spending accounted for 1.8% of the GDP. However, National Health Accounts does not provide detailed information on health R&D spending.

The National Research Council (NRC) and the National Science Foundation (NSF) are the main public funding agencies for research in Sri Lanka. The National Health Research Council (NHRC) has limited funding and can only support small research projects. Universities have been provided with limited funds for research by the government. Different divisions of the Ministry of Health allocate limited funds from their general allocation for operational research. The Medical Research Institute (MRI) which comes under the Ministry of Health also provides funds for health research for employees of the Ministry of Health, and others who collaborate with them. The Ministry of Health and the Universities provides a research allowance amounting to 25% of the salary for employees who engage in research. The government has allocated special funds for the initiation of research projects at BMARI since 2013 to promote R&D in the Ayurveda sector.

Private sector and external funding for research is obtained mainly through individual efforts of researchers. This has become a major part of the funding for R&D for health. However, there is scarcity of information on the funding sources and amounts. The NSF carries out Science & Technology surveys from time to time. It also collects information on research funding. However, there is very limited information publicly available on disbursement of research funding and its utilization in Sri Lanka.

**Discovery science and clinical research**

Legislation to facilitate clinical trials is in the draft form at present. Currently there are several industry sponsored clinical trials conducted by individuals, few university units, and private organizations. There are no major publicly funded clinical trials conducted at present in Sri Lanka. The major healthcare provider in the country is the government and it is free of charge at the point of delivery. No assessments have been conducted in the country to explore whether the present organization of healthcare in the public sector has the capacity to conduct clinical trials on par

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with globally acceptable standards addressing ethical and safety issues. There are very few multicentre international trials conducted in Sri Lanka. The majority of them are Phase III trials, mostly on anti-cancer agents, anti-diabetics and immunosuppressants. Very few investigator initiated clinical trials are conducted in the country. The regulator has granted permission to conduct four international trials in 2012 and five trials in 2013.

The Sri Lanka Clinical Trials Registry (SLCTR) established and managed by the SLMA has been operational since November 2006. It was the first functioning clinical trials registry in South Asia. The details of registered trials are available for the public from the website of SLCTR\(^{22}\). In March 2008 the SLCTR was recognised as a Primary Registry in the Registry Network of the International Clinical Trials Registry Platform of the WHO (WHO-ICTRP).

The Cosmetic Devices and Drugs Authority (CDDA) of the Ministry of Health is the regulator of clinical trials in Sri Lanka. A Sub Committee on Clinical Trials (SCOCT) was established under the CDDA in January 2009\(^{23}\).

It is mandatory that all clinical trials involving medicines including medical devices and cosmetics are approved by the CDDA. According to the guidelines of the Sub Committee on Clinical Trials (SCOCT), Phase I clinical trials are not allowed in Sri Lanka for foreign chemical entities and Phase II and III trials are allowed only if they are multi-centre studies approved by reference regulatory authorities (from USA, Canada, European countries governed by regulations of European Medicines Agency, Australia, New Zealand, Japan and Singapore,) or they are WHO sponsored trials. SCOCT has identified 8 Ethics Review Committees to grant ethics approval for regulatory purposes. Approval from one of those committees is compulsory to obtain regulatory approval to conduct clinical trials in Sri Lanka. There are many ethics review committees operating independently, affiliated to universities and few academic institutions. However, there is no legal framework for establishment and functioning of ethics review committees in Sri Lanka at present.

The Forum for Ethics Review Committees in Sri Lanka (FERCSL) convened by the Sri Lanka Medical Association\(^{24}\) has published a comprehensive set of guidelines for Ethics Review Committees (ERC). It does not have any legal authority as yet. The ERC of the Faculty of Medicine of the University of Colombo (in 2009), the ERC of the Faculty of Medical Sciences of the University of Sri Jayewardenepura (in 2012), and the ERC of the Faculty of Medicine of the University of Colombo (in 2014) have been recognised under the Strategic Initiative for Developing Capacity of Ethical Review (SIDCER) of the World Health Organisation. The majority of the committees are however, are not recognised under the SIDCER programme nor

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22 http://www.slctr.lk
23 http://www.cdda.gov.lk
24 http://www.fercsl.net
confirm to global standards. The FERCSL is constantly working with all ethics review committees to train ERC members on ethics review and to improve the standards and procedures adapted by ERCs. The CDDA, the regulator, is also working on improving its standards. It had sought expertise of the Health Science Authority, Singapore (HSA) for training in Good Clinical Practices (GCP) and evaluation of clinical trial protocols. In the year 2013, three Medical Consultants of the Sub Committee on Clinical Trials (SCOCT) and one Pharmacist of the CDDA underwent training at the HSA. Apart from the HSA training opportunity, international collaboration on capacity building for clinical trials has been limited.

**Access to knowledge**

Limited access to medical/health literature is a major concern for researchers. There is also concern about underutilization of available databases by researchers.

Medical libraries in the country are connected through the Health Literature Libraries and Information Services (HELLIS) network that facilitates access to available literature in local libraries to scientists. HELLIS network coordinates among member libraries to share available literature when a request is made by a scientist. The National Science Foundation provides a document delivery service through which anyone can gain access to articles not freely available through institutional subscription.

The Medical Research Institute (MRI) in Colombo has set up a Library Information Network in their library to deliver user friendly service using the KOHA open source integrated library information software suite.

The scientists request wider availability of literature at their institutions by improving access. There is a need to provide access to online portals such as ATHENS and Science Direct to all universities and research institutions.
The lack of international visibility for Sri Lankan research has also been of concern. A major new initiative the Sri Lanka Journals Online\textsuperscript{25} has overcome that issue. Sri Lanka Journals On-Line (SLJOL) is a service to provide access to Sri Lankan published research, and increase worldwide knowledge of indigenous scholarship. It is a part of the Journals Online Project supported by INASP an international development charity working with a global network of partners to improve access, production and use of research information and knowledge\textsuperscript{26}. As of November 2014 there were 59 journals listed on SLJOL. There are 556 Tables of Contents listing 5217 articles. 5052 of the articles were available in full text (PDF).

**Building and improving innovative capacity**

The Ministry of Higher Education is responsible for training the health workforce in medical, dental, and veterinary disciplines. University Grants Commission (UGC) is responsible for devising higher education strategies.

The Ministry of Health conducts training for nursing and other para-medical staff at diploma and certificate level. The training of such categories of staff has been upgraded to bachelor’s level with the establishment of allied health science courses in nursing, physiotherapy, pharmacy, and medical laboratory sciences in universities during the past decade. The Ministry of Health is the main employer of healthcare personnel. The human resource strategic plan 2009-2018 of the Ministry of Health has not identified any capacity building of health workforce on R&D. Projections on health related Human Resources (HR) are done by the Ministry of Health from time to time with the assistance of the Ministry of Finance and Planning. The National Human Resources and Employment Policy (2013 NHREP) of the Government of Sri Lanka sets out the overarching policy framework to provide full, decent and productive employment to all Sri Lankans.

\textsuperscript{25} http://www.sljol.info
\textsuperscript{26} http://www.inasp.info
The Health Master Plan includes policies on human resource development on health, but does not specifically address HR development for R&D in health. From the available information it is not possible to disaggregate investment on HR development on health R&D training as the expenditure is recorded under different budget headings at different institutions. The current National Health Accounts does not look at this area in detail.

The local pharmaceutical manufacturing industry is relatively small in Sri Lanka. Hence, expertise of industrial pharmacy, technology management and other related areas of pharmaceutical manufacturing are limited. There are university courses on pharmacy, business management, project management and accounting. Apart from general pharmacology and pharmacy no specific university courses are available on drug manufacture, product development or related subjects at present. Records at the National Intellectual Property Office (NIPO) show that applications received for patents and other intellectual property rights (IPR) from local scientists are scarce. In the pharmaceutical sector very few applications have been received from local scientists during the past decade. There are limited training opportunities in Sri Lanka on Intellectual Property (IP) management and those are mostly restricted to the legal profession. Trade Related Aspects of Intellectual Property Rights (TRIPs) flexibilities have not been used in Sri Lanka as yet. Only one study has been conducted on IP status and medicinal drugs during the past 5 years. The University of Moratuwa, the only Engineering University in Sri Lanka has a Department of Management of Technology which offers several undergraduate and postgraduate courses on Technology Management. This is the only department in a Sri Lankan University to have such courses.

There is limited dialogue between education institutes and industrial sector on requirements of HR. Although there are few training programmes established between engineering and business management fields with industry, such linkages are almost nonexistent in relation to health sector. It should be noted that health is framed mainly as a public good in Sri Lanka since the major service provider is the government. Further, business development/entrepreneurship divisions in health related research institutes/faculties in universities are nonexistent in Sri Lanka at present.

Incentives for health innovation

The National Policy Documents envisage a growth in local innovations adding value to the local economy. There are few incentives provided by the government to promote research and development targeting new innovations. They are in the form of individual incentives like consideration for promotions and special

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28 http://www.mot.mrt.ac.lk
allowances, and fiscal incentives to institutions and priority consideration in research grant schemes. Individual R&D contributions are considered for promotions to the next level at research institutions and universities. Published research, patents and ability to attract research grants from outside sources are allocated marks in promotion schemes. Institutions provide limited opportunities for local and foreign training, scholarships, foreign leave and sabbatical leave to enhance the knowledge and for career advancement. Research Scientists are eligible for research allowance as a part of their salary.

The National S&T policy encourages all researchers, including health related researchers, to tie up with business partners at the outset of the research project. The two funding bodies functioning under the Ministry of Technology & Research, NSF and NRC, also consider alliance with business partners as a criterion in funding research proposals in certain grant schemes. At present, NRC is supporting one medical product development project through a Public Private Partnership (PPP). Industrial Technology Institute (ITI) is a technology provider to industries including medium size and small enterprises. ITI is engaged in R&D projects in collaboration with industries. ITI has also established PPP with industry. They are mainly on non-health products.

The Sri Lanka Institute of Nanotechnology (SLINTEC) is a company established with investment from the Government of Sri Lanka and six blue chip Sri Lankan companies. SLINTEC has gained a reputation for product innovation in a short period of time. Almost the entire capital investment on the company was recovered recently when they sold their first patent to a foreign company. At present they are not involved in health related R&D. The Sri Lanka Inventors Commission (SLIC) coming under the purview of the Ministry of Technology & Research has created a platform for collaboration between the inventors and those having such needs from the industry. This could be extended to cover the Public Health Services Sector in Sri Lanka with appropriate fine tuning.

There are some inventions in the medical sphere by Sri Lankan inventors which have secured National, Presidential and International Awards which are yet to be commercialized. They include a diabetes early warning toilet urinal system, a hospital infection control hand sanitation system, an improvised condom catheter with a draining channel, and a modified retractor for surgical operations which give a large field of view. The SLIC sees the following as the main barriers to commercialization of local inventions: lack of access to capital, lack of access to markets, lack of access to technology, and underdeveloped entrepreneurial and business management skills.

29 http://slintec.lk
30 www.slic.gov.lk
Support Scheme for Supervision of Research Degrees (SUSRED) is an award given by the National Science Foundation to Supervisors of post graduate research degrees (MPhils and PhDs) and institutions that support post graduate research in Sri Lanka, in recognition of the service to the nation. This scheme was implemented in 2011 to motivate, support and recognize the scientists in all areas of Science and Technology.

The President’s Awards for Scientific Publications was started in 2001 by the NRC to recognize scientists whose work reached international standards. Under this scheme Sri Lankan scientists based in Sri Lanka who publish papers in Science Citation Index (SCI) indexed journals receive a certificate of appreciation. The criteria for making this award were made more stringent recently by restricting the award to those who publish in SCI journals with an impact factor of one or more.

The NASTEC initiated an award system in year 2006 in order to encourage young scientists and to recognize their achievements. These awards are presented under two categories; Scientific research and Popularization and promotion of science. The awards are open to members of the Young Scientists Forum (YSF). Various arrangements such as Technology Transfer Offices (TTOs) are in place with the institutions of the Ministry of Technology and Research (e.g. Vidatha) but they are not specifically designed for health innovations. The NASTEC has taken the initiative to formulate policies and mechanisms to establish TTOs like entities within the institutions coming under the Ministry of Technology and Research.

Budget 2012 announced a range of tax incentives including reduction of income tax on research income, reduction in personal income tax of all those engaged in research and technology and reduction in income tax on all institutions engaged in research and technology.

Such institutions were also exempt from Value Added Tax (VAT). The budget further proposed a triple tax deduction in relation to research and development expenditure undertaken by private enterprises through Government institutions, to promote private institutions to use Government research facilities. Under this scheme for every rupee invested in R&D in the government sector by a private company, the company is entitled to a wave off 3 rupees from their corporate taxes. The private sector does not appear to have made use of this in the health sector.

The National Intellectual Property Office (NIPO) is in-charge of implementing IPR related activities in the country. Sri Lanka does not have any legislation comparable to Bayh-Dole Act or the Patent and Trademark Law Amendments
Act in the USA. Steps have been taken to develop similar legislation for Sri Lanka by the Ministry of Industries with assistance from the World Intellectual Property Office (WIPO). Adequate safeguards should be incorporated into such legislation in order to protect public health objectives because restrictive legislation may be counterproductive to the population at large.

Currently there are hardly any north-south or south-south partnerships for capacity building in the area of health innovation established in Sri Lanka. This is mainly due to restricted capacity in the industrial sector for original research and new product development. Most industries focus on replicating already available technologies and products. The National Science Foundation however, has two funding schemes that are aimed at facilitating such collaborations. The Overseas Special Training Programme (OSTP) to financially assist scientific and technical personnel, (science administrators, science educators, S&T policy makers & science communicators) as well as full time research students to acquire overseas training up to 12 months\(^{31}\) and the International Partnerships for Science and Technology (IPSAT) programme to facilitate Sri Lankan scientists, engineers, science and technology policy makers and research personnel to undertake collaborative R&D/S&T service assignments with foreign based scientists for stipulated periods in Sri Lanka\(^{32}\). These are mainly utilised by those in non-health related R&D field.

\(^{31}\)http://www.nsf.ac.lk/index.php/researchers-a-academics/overseas-training
\(^{32}\)http://www.nsf.ac.lk/index.php/researchers-a-academics/ipsat
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International transfer of technology

There is no comprehensive documented national strategy directly focused on acquiring technologies from other countries to assist local manufacturers. However, there are some initiatives aimed at obtaining international collaboration on technology transfer (e.g. for production of anti-snake venom serum, and for production of large volume parenterals). These are also aimed at encouraging foreign investment in Sri Lanka.

The Ministry of Health recently decided to purchase the entire production of local pharmaceutical manufacturers (if they wish to sell) for requirements of the government sector health care institutions on a negotiated price. This is a buy back guarantee for local manufacturers, encouraging them to go for joint ventures/partnerships with foreign manufacturers to acquire new technologies.

There was no information available on north-south or south-south technology transfer partnerships in the pharmaceutical sector. There was a request from the local manufacturing industry, to bring in foreign technical expertise and train local scientist on modern technologies.

There is no formal process for technology assessment in Sri Lanka at present. The expertise available to undertake such an exercise also appears to be limited. As such there was no evidence of a formal assessment being made of the neither technology available in Sri Lanka for health R&D nor the technology available within the pharmaceutical industry. This is identified as an urgent need to plan the way forward.

Local production policies, capacity and legislation

The Ministry of Finance and Planning has a separate department for trade and investment policy. The mission of the Department is to, “promotion and facilitation of international economic integration for the benefit of the economy and the

people of Sri Lanka”. This mission is a crosscutting mission for all sectors. It does not specifically mention the pharmaceutical sector. As stated in an earlier section of this document, Sri Lanka has an S&T policy in which health is also included. However, specific provisions for pharmaceutical ingredients, biologicals, etc. are not mentioned in it. The scope of the policy should be updated and broadened.

Public spending on R&D in Sri Lanka is less than 0.2% according to the report of the National Survey on Research and Development and Innovation published by NSF in 2012. Government research institutions do not have funding to sponsor clinical trials. Some facilities are available for toxicology studies (e.g. MRI animal house).

However, the facilities do not confirm to international standards. There is a level 2 bio-safety facility at the MRI and there are no satisfactory bio-safety facilities available at national level. At present a national bio-safety policy is being established.

The Ministry of Finance and Planning recommends all the tax rates to the parliament. Pharmaceutical raw materials (both active pharmaceutical ingredients and excipients) are free of import duties at present. However, importers have to pay Port and Aviation Levy (PAL) of 2% on the CIF price on raw materials which is not applicable to finished products. Therefore, local manufacturers who totally depend on imported raw materials are at a disadvantage compared to importers of finished products.

Although customs look into counterfeit pharmaceuticals, those controls are not effective unless specific confidential information is received. There are shortcomings in the detection of counterfeit drugs. There are no anti-dumping polices in place for pharmaceuticals. There is a report on donation of pharmaceuticals to the country following the tsunami disaster that highlights this issue. Although there are several recommendations on donations, the legal framework is not in place to enforce it. There is a new regulation enforced to release only products that have 75% or more shelf life from customs to the market.

**Industry capacity for local production of existing products**

Pharmaceutical firms are able to undertake formulation, process and scale-up of generic drugs. However, pharmaceutical manufacturing industry is extremely small in Sri Lanka. A limited number of products is manufactured at present. The government has a single manufacturing plant with extremely limited capacity. All others are imported as finished products. Hence, pharmaceutical manufacturers are a small entity in pharmaceutical industry in Sri Lanka. Most manufactures
produce the same pharmaceutical products. Number of locally manufactured products as of June 2014 was 131. These includes tablets, capsules, liquids, dry powder for suspensions, and external preparations such as creams, ointments and lotions. Injectables or any other sterile products are not manufactured in Sri Lanka. All Active Pharmaceutical Ingredients (API) are imported and manufacturers only manufacture the finished product. No vaccines are produced in Sri Lanka at present. There is very limited capacity for manufacturing other pharmaceuticals too. In addition there is very limited laboratory capacity for testing APIs and finished products. Currently R&D is minimal in the pharmaceutical sector in the country.

As pharmaceutical market size of Sri Lanka is comparatively small and marketing activities on branded products are very strong, manufacturing of generics is not commercially viable, unless the country can venture into foreign markets. At present the Sri Lankan producers of pharmaceuticals cannot supply the local demand and there is almost no export market. However, local manufacturers will get some relief in this regard with the implementation of the new government policy to purchase government requirements from local manufacturers on agreed prices with priority being given to the State Pharmaceutical Manufacturing Corporation. Due to issues of scaling up of production as stated above, the unit price of pharmaceuticals produced locally is generally higher than the imported ones. Hence the above mentioned buy back guarantee would help to expand production.

The licensed manufacturers can comply with the requirements of the CDDA for registration of their products. There are 10 manufacturing plants conforming to local regulations. However, they do not have the capacity at present to comply with WHO/Good Manufacturing Practices (GMP) standards. This is a major issue that they have to address if they are to enter the export market. There is limited expertise in the country on GMP standards. Major improvements are needed in the manufacturing industry to comply with WHO/ GMP requirements.

The local pharmaceutical firms produce dossiers as a registration requirement. However, there is limited expertise within the industry to submit a complete data set. At present there is limited capacity within the country to conduct bio availability studies. The first facility to conduct bioequivalence studies was established in the Department of Pharmacology, Faculty of Medicine, University of Colombo recently and has commenced operations.

In the Ayurveda medicines sector, the BMARI is taking steps to establish a GMP compliant drug manufacturing unit with modern machinery. This however depends on the availability of financial support from the government.
Public and/or private sector manufacturers are able to prepare regulatory dossiers for clinical trial authorization and drug registration using data from their own clinical studies. Public and/or private sector manufacturers are able to design and implement clinical development plans for drugs.

In the Ayurveda field many private sector companies have flourished and some of them have GMP compliant facilities and export products to foreign markets, notable among them is Link Natural Products (Pvt) Ltd. This company is the only company conducting clinical trials in Sri Lanka in collaboration with clinical departments in universities to support the medicinal claims that they make for their products. The results of their clinical trials have been published in indexed journals and have enabled the company to increase the market share of their products locally and export to Western markets.

34 http://linknaturalproducts.com
Trade agreements and intellectual property

Sri Lanka is a member of the World Trade Organisation (WTO) from 1994. Sri Lanka has not entered into any bilateral or regional agreement going beyond TRIPs. Public health impact assessment has not been done on TRIPs plus commitments as it is not applicable at present.

The Department of Commerce is the focal point for international trade agreements in Sri Lanka. Depending on the nature of topics covered in trade negotiations, representatives from the health sector are invited for such consultations. However, there is no legal or administrative requirement for inviting health representatives.

An advisory committee was established within the Ministry of Health in 2007 to examine issues related to trade and health. The committee has not been convened since 2011. There is no mechanism at present to coordinate policies on public health, intellectual property and trade within or among different ministries.

There is very little coordination between health and national intellectual property office on IPR issues related to protecting public health.
Patents and clinical trials data exclusivity

There is a National Patent Office. It is not a member of any regional organization. A basic electronic database on patent application and patent registry is maintained. This information is not publically available. There is ongoing work to improve the electronic database on patent information. The Sri Lankan Patent Act does not have provisions for data exclusivity. Currently the clinical test data of the first registered product is used to register subsequent products except for biotechnology products. Drug regulation maintains a clear distance from the IPR protection in the drug registration process. This is with the intention of improving accessibility and affordability of pharmaceuticals to the general public. Provisions for compulsory licensing available in the Sri Lankan Patent Act have not yet been enforced.
Access to quality medicines

The Cabinet of Ministers approved the National Medicinal Drug Policy (NMDP) for Sri Lanka in 2005\(^{36}\). It was primarily based on the principles of essential medicines and use of generic name in procurement to prescribing. The policy included “need” clause where price of the product can be considered in registration. This was included to uphold affordability of drugs to the population. The policy provides directives to uphold and maintain quality of medicines imported and manufactured in Sri Lanka. However, preparation and implementation of the legal framework to facilitate NMDP has been delayed. A draft bill is now presented for discussion.

There is a National Drug Quality Assurance Laboratory (NDQAL) with limited capacity. The laboratory needs to be upgraded with improved human resources capacity and equipment to provide better service.

The CDDA is responsible for regulatory work on medicinal drugs including maintenance of GMP by the local industry. Sri Lanka follows WHO/GMP Guidelines. Some of the imported products are prequalified by the WHO. They include

\(^{36}\) http://apps.who.int/medicinedocs/documents/s17121e/s17121e.pdf
Expanded Programme on Immunization (EPI) vaccines and anti Tuberculosis (TB) Drugs. If Sri Lanka is targeting the export market, it should upgrade its manufacturing facilities to international standards. Sri Lanka therefore needs more trained human resources to managing GMP requirements.

**Delivery infrastructure and incentives**

Approximately 20% of the annual health budget is allocated for medical supplies. The per capita government expenditure on medicines has been steadily increasing over the years. There is a well-established procurement procedure for pharmaceuticals, and surgical consumables as well as equipment. There is no pooled procurement of drugs for Sri Lanka by the government. The procurement process is based on a worldwide tender process. There have been several changes to the procurement system in recent years. However, due to many reasons medicine shortages occur at times in public sector facilities. The Medical Supplies Division (MSD) of the Ministry of Health is responsible for the delivery mechanism of medicinal drugs and surgical supplies to the government health institutions. Each district has a Regional Medical Supplies Division (RMSD). Bulk stocks are sent from the central MSD to regional stores. From RMSD supplies are distributed to the hospitals. MSD and RMSD have capacity to store and distribute medicinal drugs in the prescribed manner. However, there is an urgent need to establish good storage and good distribution practices to overcome shortcoming in the supply chain. A study that assessed MSD drug issues\(^\text{37}\) has highlighted the limited capacity for drug storage and the need to expand capacity urgently.

\(^{37}\text{http://apps.who.int/medicinedocs/en/d/Jh17994en}\)
Regulation of safety and efficacy

The expertise available within the CDDA is limited for regulation of safety and efficacy of pharmaceutical products. The CDDA requires more human resources, space, and training. Legislation has been prepared for the establishment of a National Medicinal Drugs Regulatory Authority and for its legal enactment a bill has been already submitted for approval with the hope of strengthening the medicine regulatory system. At present the CDDA is not a part of any inter-country regulatory harmonization programme.

The policy of the government is to promote the use of generics. Tenders are always called by generic names for government requirements and the government always encourages practitioners to prescribe in generic names. The Ministry of Health is conducting programmes to promote the use of generics all over the country. It is a legal requirement that that all prescriptions should be written in generic name. If needed a brand name can be written within brackets. However, this is not monitored and prescribers do not comply with these requirements. Regular workshops for medical officers, pharmacists and the general public are being conducted. Every product should be price marked and it is being monitored by the Consumer Affairs Authority under the Ministry of Commerce and Internal Trade. Several surveys on prices of pharmaceuticals have been conducted. There is no price control for pharmaceuticals. However, the approval of the Consumer Affairs Authority is required to increase prices. There is no import duty on medicines, but for medical devices and equipment a VAT is levied.
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5 Traditional Medicine

The National S&T Policy has recognized the value of indigenous knowledge including traditional medicine. It recommends that the scientific basis of the traditional knowledge should be researched. There is a separate Ministry dedicated to traditional medicines (Ayurveda, Siddha, Unani and ‘Deshiya Chikithsa’) in Sri Lanka – the Ministry of Indigenous Medicine. There are several institutions under the Ministry. They include the Department of Ayurveda, Bandaranaike Memorial Ayurvedic Research Institute (BMARI), Ayurvedic Drug Corporation, and the National Institute of Traditional Medicine. There are four state run indigenous medical institutions for training of practitioners. These institutions are under the University Grants Commission.

The BMARI has established needs based priorities for health R&D, viz. research on Cancer, Diabetes, Chronic Kidney Diseases, Cardio Vascular Diseases and Dengue. These research areas have been prioritized in keeping with the national health research policy.

Although there has been limited R&D work done in the past, BMARI is planning to improve the capacity to work on medicines development and production.

Apart from the government facility to manufacture Ayurvedic medicines, many private sector industries are involved in manufacturing of medicines. However, R&D is extremely limited. Most of the private sector and government facility manufacture limited amount of selected preparations. There is very limited capacity for clinical research in traditional medicines in Sri Lanka. Both human resources to undertake such studies and institutional capacity are extremely limited at present. The exception, as mentioned above, has been Link Natural Products Pvt Limited.

Regulation of traditional medicines is vested with the Department of Ayurveda. Registration and market authorization of traditional medicines is done by this department. However, the process is not adequately based on scientific grounds. Mainly desk reviews are done by the formulary committee. There is no system for pharmacovigilance in traditional medicines at present. In addition certain legal

38 http://www.ayurveda.gov.lk
provisions in the country also limit access to some commonly used ingredients of Ayurvedic drugs such as Cannabis and Opium.

Although several attempts have been made to protect traditional knowledge from misappropriation, still a proper legal framework is not in place. Anecdotal evidence suggests that large amounts of traditional knowledge, particularly related to medicinal use, is exploited and taken out of the country through illegal means.
Sri Lanka has an established Health Information System to monitor service delivery, epidemiological information, maternal and child health and vital statistics. In addition human resource surveys and facility surveys are conducted in a periodical manner. Periodic surveys are carried out by the Department of Census and Statistics, the Central Bank and other government institutions to collect additional information.

Epidemiology Unit of the Ministry of Health receives weekly returns on communicable diseases from all health units in the country. This is analysed and published in the Weekly Epidemiological Report and Quarterly Epidemiological Bulletin. Maternal and child health information is collected from health units in each quarter.

This is available in the Reproductive Health Management Information System (RHMIS) in digital form. The Family Health Report is published based on these data. Annual Health Bulletin provides the basic health statistics and service delivery information.

Demographic and Health Survey (DHS) and consumption surveys done by the Department of Census and economic related surveys done by the central bank also provide information related to the health sector. Information on R&D
carried out by institutions and individuals of the Ministry of Health are published on the website of the Ministry. The S&T surveys done by the NSF include health sector information. However, detailed information is not available. The Health Development Committee (HDC) of the Ministry of Health is a system established for monitoring and reporting.
FUTURE CONSIDERATIONS

The areas that need attention in any future R&D road map were highlighted by the participants during the group discussion. The intention was to raise important issues rather than go into details. Hence, the points listed below are presented as important issues to be considered in any future deliberation.

HEALTH RESEARCH AND DEVELOPMENT

- The Science and Technology policy of Sri Lanka should be updated and the scope of the policy should be broadened. There should be specific provisions for pharmaceutical products which are not mentioned in the policy.

- A high level multi stakeholder committee should be established to identify the national developmental agenda for health. Health innovations should be considered from both provider and industry point of view for prioritisation. Health sector research and development should include indigenous systems of health in Sri Lanka.

- Investment done on health research should be results oriented. All the sectors should support more on capacity building on health innovations.

- A central agency to coordinate the Research and Development (R&D) process should be established and health sector R&D should be streamlined.

- Access to public health literature and scientific data bases need to be improved in both academic and research institutions to facilitate and encourage young researchers.

- A consortium of academic and research institutions should be established to improve collaboration between research teams.

- Development of innovative proposals should be encouraged to attract the private sector while identifying their commercial needs. Mechanisms should be created to collaborate and coordinate to access the private sector funding and government funding for such proposals. New funding sources also should be explored to increase funding for R&D linking research institutes with industry.
Enactment of National Health Research Council Act, the Clinical Trials Act and implementation of accreditation processes should be expedited to facilitate internationally accepted research in Sri Lanka.

Improve the collaboration with WHO for technical assistance to ensure health research ethics training and to assist ethics committees to comply with SIDCER (Strategic Initiative for Development of Capacity in Ethics Review) requirements in Sri Lanka.

Develop a mechanism to integrate different organizations under different Ministries to set up an observatory organization.

**Manufacturing of pharmaceuticals**

The Ministry of Health and the Ministry of Indigenous Medicine should identify the areas and prioritize areas for transfer of technology.

Board of Investment of Sri Lanka should promote and offer concessions to joint ventures in manufacturing of pharmaceuticals.

Opportunities should be explored for local manufacturers to export. Concessions should be provided for the manufacturers who totally depend on imported raw materials to match the imported finished products within the current tax structure. The present system needs revision with the involvement of all stakeholders.

A National Pharmaceutical Industry Development Plan should be prepared and implemented. Fiscal measures should be taken to expand viable local manufacturing industry.

Capacity of the Cosmetics Devices and Drugs Authority on Good Manufacturing Practices inspection and management should be improved to ensure quality of pharmaceuticals imported to the country and at local manufacturing sites.

National Drug Quality Assurance Laboratory should be upgraded to meet the demand and ensure the quality of the medicine imported and manufactured.

An assessment should be carried out on national medicines regulatory system of Sri Lanka and encourage in building inter-country harmonization programmes with the support of WHO.
A list of WHO certified manufacturers should be available to assist pharmaceutical firms to identify certified suppliers for active pharmaceutical ingredients.

**Application and management of intellectual property**

- Public and/or private sector manufacturers are not able to access rights to original drugs and registration data for further development at present. Further awareness and discussion with the National Intellectual Property Office (NIPO) is recommended to facilitate the process on this subject.

- Establish a permanent mechanism to coordinate between the NIPO, Ministry of Health, Department of Ayurveda and Ministry of Trade and Commerce with regard to trade agreements.

**Improving delivery and access**

- High-level coordinating mechanism should be established to coordinate the activities relevant in improving access to medicinal drugs with the participation of Ministries of Health, Industry and Finance.

- Good distribution practices and good storage practices should be established at all levels of the pharmaceutical supply chain.

**Traditional medicine**

- Digitalization of traditional medicine literature should be explored to support research.

- More research should be promoted to strengthen evidence based medicine in Ayurveda and traditional medicine in relation to products, practices, efficacy and safety.

**Monitoring and reporting**

- A monitoring and reporting system should be established to cover all institutions engaged in R&D.
STAKEHOLDER MEETING PARTICIPANTS

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2. Dr Sunil de Alwis, Deputy Director General of Health Services (Education, Training & Research)
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27. Dr K.G. Surangi, Bandaranaike Memorial Ayurveda Research Institute
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32. Ms. R.M.D.N. Rathnayake, National Intellectual Property Office
33. Prof W. Abeywickrama, Chairman, Industrial Technology Institute
34. Dr Radhika Samarasekera, Industrial Technology Institute
35. Dr S. Chelvendran, Industrial Technology Institute
36. Mr Deepal Sooriyaarachchi, Commissioner, Sri Lanka Inventors Commission
37. Mr. D. C.A. Sattrukalsinghe, Director, Sri Lanka Inventors Commission
38. Dr D.A. Tantrigoda, Chairman, National Science and Technology Commission
39. Prof Sirimalee Fernando, Chief Executive Officer, Co-ordinating Secretariat for Science Technology and Innovation
40. Dr. Sachie Panawala, Co-ordinating Secretariat for Science Technology and Innovation
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42. Mrs S. Sivayogarajan, President, Sri Lanka Pharmaceutical Manufacturers Association
43. Mrs. Ruwanthi Murage, Sri Lanka Pharmaceutical Manufacturers Association
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45. Ms. Vajrapani De Silva, Genetech Research Institute
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INSTITUTIONS PARTICIPATED IN THE ASSESSMENT

Bandaranaike Memorial Ayurvedic Research Institute (BMARI)
(www.indigenousmedimini.gov.lk/Research_institute.html)

The Bandaranaike Memorial Ayurvedic Research Institute (BMARI) which was established in October 1962 functions under the jurisdiction of the Ministry of Indigenous Medicine. The BMARI is the National Centre of Excellence in Medical Research related to Ayurveda, Siddha, Unnani and other Medicine systems identified by the Institute. BMARI has established a project with main focus on four Non-communicable diseases prevalent in Sri Lanka (Cardio Vascular Diseases, Chronic Kidney Diseases with known and unknown aetiology, Cancers and Diabetes and one communicable disease (Dengue). However, it is also expected to pay attention on other important areas if and when the BMARI research committee finds any area worth researching. A special attention will also be paid to endorse health research regulatory processes, collaborative links with stakeholders and health research ethics.

Consumer Affairs Authority (CAA)
(http://www.caa.gov.lk/web/)

The Consumer Affairs Authority (CAA) is the apex government organization mandated to protect consumers’ interests and ensure fair market competition in Sri Lanka. It has been established under the Consumer Affairs Authority Act No.09 of 2003. The act has laid down the legal provisions empowering the CAA to take necessary actions to safeguard the interests of consumers while maintaining effective competition among suppliers of goods and services. The Consumer Affairs Authority functioning under the Ministry of Commerce and Internal Trade consists of a Chairman and Members representing different fields of expertise, such as industry, law, economics, commerce, administration, accountancy, science and health, in order to assist the policy making in meeting the goals and objectives of the Authority under the Act.
Cosmetics Devices and Drugs Authority (CDDA)  

The Cosmetics Devices and Drugs Authority (CDDA) of the Ministry of Health is responsible for the regulation of manufacture, importation, sale, and other related activities with respect to medicines, medical devices and cosmetics. The Cosmetics, Devices & Drugs (CDD) Act 1980 is the legislative framework that provides the legal authority to carry out these regulatory activities. The Directorate of the Medical Technology and Supplies is functioning as the CDDA under the delegated powers of the Director General of Health Services. The CDDA is supported by the Technical Advisory Committee (TAC) appointed under the CDD Act for the implementation of the provisions of the Act and it comprises of representatives of all relevant stakeholders.

Coordinating Secretariat for Science, Technology and Innovation (COSTI)  

The Coordinating Secretariat for Science, Technology and Innovation (COSTI) was established on February 1, 2013 as mandated by a cabinet decision of September 9, 2011 with the specific aim of coordination and monitoring of Science, Technology and Innovation activities in the country. It is expected to work towards promoting value addition and commercialization in line with the National Science Technology and Innovation (STI) Strategy of Sri Lanka approved by the Cabinet in August 2010.

Industrial Technological Institute (ITI)  
([http://iti.lk/en/](http://iti.lk/en/))

The Industrial Technological Institute (ITI) is a wholly owned institute of the Government of Sri Lanka that functions under the jurisdiction of the Ministry of Technology & Research. It is a statutory board incorporated on the 1st April 1998, under the Science and Technology Development Act No. 11 of 1994 and as per its mandate the objective of ITI is to elevate the level of technology in Sri Lanka to the level required for rapid industrialization. ITI supports the industry by undertaking contracts, on testing, investigation and research for improving product quality, technical processes and methods used in industry, and for discovering new processes and methods to be used in industry.
Medical Research Institute (MRI)
(http://www.mri.gov.lk/en/)

The Medical Research Institute (MRI) is the premier institute established under the Ministry of Health for bio-medical and applied health research. MRI conducts research in diversified areas in the fields of Virology, Bacteriology, Parasitology, Nutrition, Biochemistry, Histo-Pathology, Haematology, Immunology, Entomology, Molecular Biology, Pharmacology, Mycology, Health Informatics and Animal Studies. MRI is a major service provider for all hospitals in Sri Lanka with special and specific diagnostic laboratory tests. It also functions as a National Laboratory for Japanese encephalitis, measles, rubella and influenza and as the regional reference laboratory for poliomyelitis.

National Science and Technology Commission (NASTEC)
(http://www.nastec.lk/)

The National Science and Technology Commission (NASTEC) is the apex policy formulating and advisory body to the government of Sri Lanka on Science and Technology matters. It was created by an act of parliament, and came into operation in August 1998. NASTEC is most effective in the prioritization of areas of national importance of Science and Technology, and in advising the Government with regard to the rational allocation of funds for research and development.

National Health Research Council (NHRC)

National Health Research Council (NHRC) functions as an advisory body to the Education, Training and Research (ET&R) unit of the MOH to promote health research in Sri Lanka. NHRC consists of 15 members including representatives of six medical faculties of Sri Lanka, Sri Lanka Medical Association, Post Graduate Institute of Medicine and officials from Ministry of Health. Awarding of NHRC research grants is one of the major activities performed by the council. The research proposals submitted for funding are scrutinized for suitability by the NHRC and grants are made available for the approved proposals through the consolidated fund of the Ministry of Health.
National Intellectual Property Office (NIPO)
(http://www.nipo.gov.lk/)

The National Intellectual Property Office of Sri Lanka (NIPO) established under the Intellectual Property Act No 36 of 2003 is mandated with the administration of the intellectual property system in Sri Lanka. Main functions of the NIPO include administration of intellectual property, collection and dissemination of intellectual property information and promotion of the use of intellectual property system in the development process by the intellectual property owners, enterprises & industries.

National Research Council (NRC)
(http://www.nrc.gov.lk/)

The National Research Council (NRC) was established under the Ministry of Technology and Research to plan and co-ordinate the research efforts of researchers and to facilitate their research in public sector scientific research and development organizations in Sri Lanka so as to build, strengthen and derive the maximum benefit to the country from a vibrant research community. The NRC has a wide range of activities that brings together academics and professionals of the country, and brings about public and private sector participation in achieving scientific advance through collaborative research. NRC is the apex body for government research funding in Sri Lanka.

National Science Foundation (NSF)
(http://www.nsf.ac.lk/)

National Science Foundation (NSF) is a state funded institution under the Ministry of Technology and Research was established in 1998 by Act No. 11 of 1994 as the successor to the Natural Resources Energy & Science Authority of Sri Lanka (NARESA). The National Science Foundation, mandated to serve and strengthen the Science and Technology sectors in Sri Lanka and its activities conform to the National Science & Technology Policy. Accordingly, the National Science Foundation facilitates research, development and innovation to create a knowledge economy. It also facilitates capacity building, infrastructure development, technology transfer, knowledge creation and sharing in all fields of science & technology to improve the quality of life of the people.
Sri Lanka Inventors Commission (SLIC)
(http://slic.gov.lk/)

Sri Lanka Inventors Commission (SLIC) is functioning under purview of the Ministry of Technology and Research and is governed by a board consist of a commissioner and two assistant commissioners. The SLIC provides technical assistance to inventors after examination of their inventions to determine their patentability and to help them prepare patent applications and also grants financial aid enabling them to develop, perfect and produce their patented inventions.

Sri Lanka Institute of Nanotechnology (SLINTEC)
(http://slintec.lk/)

Sri Lanka Institute of Nanotechnology (SLINTEC) is a private company formed through a public-private partnership between the Government of Sri Lanka and five leading private sector companies. SLINTEC specializes in nanotechnology research & development to make innovative products and add value to natural resources. Currently focuses on five primary research areas, namely agriculture, apparel, water purification, healthcare and mineral resources. SLINTEC has advance laboratory facilities to perform a wide range of nano science related testing activities.
PROMOTING INNOVATION
AND IMPROVING ACCESS

The World Health Organization (WHO) is working with Member States to implement the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI).

The GSPA-PHI is very broad in scope. It recommends specific actions across multiple sectors and at multiple levels (global, regional and national) to promote innovation in, and access to, essential medical technologies in low- and middle-income countries. While the WHO is working to implement the GSPA-PHI at all levels, the most important effort must be at the national level.

The strategy is based on specific actions that several stakeholders, mainly WHO and countries, should implement in various areas to ensure that capacity is developed to generate innovation in medical technologies, sufficient research is conducted to address needs of developing countries in terms of medical technologies and access to new, needed technologies is promoted in these countries.

As part of its efforts to implement the GSPA-PHI, the WHO has developed a National Assessment Tool (NAT) based on country-specific action items in the strategy. This tool facilitates a systematic assessment of the conducive environment to innovation for medical technologies, helping Member States to analyse their situation in terms of policies, regulations, legislations, infrastructure and funding. Furthermore, countries can benchmark their own strengths and weaknesses in implementing the GSPA-PHI and identify where policy interventions are needed. Specific actions to be undertaken at global and regional levels have been excluded, and specific actions that name the WHO as the key stakeholder have also been excluded unless those actions require information to be collected from countries, in which case a question has been formulated and included in this tool.

The development of this National Assessment Tool has benefitted from several recent complementary initiatives including: Strengthening Pharmaceutical
Innovation in Africa, the Innovation Union Scoreboard, and the Draft HAI Africa Pilot Monitoring Tool. Information collected through this tool will be retained in a web-based monitoring and evaluation platform developed by PHI as an integral part the WHO’s contribution to GSPA-PHI implementation (Element 8). This database will assist in:

- drafting GSPA-PHI country progress reports and reports to WHO governing bodies;
- tailoring WHO technical assistance to meet the needs of Member States; and - identifying gaps and opportunities to be addressed by development partners.

**STRUCTURE AND USE:**

This National Assessment Tool takes the form of a semi-structured questionnaire. It is designed to guide the collection and assessment of all relevant information. However, low- and middle-income countries are so diverse that a one-size-fits-all approach is unlikely to succeed. This tool should be adapted as needed to fit each national context.

In general, the structure of this assessment tool follows the order of Elements in the GSPA-PHI. Similar questions have been grouped together under topics derived from Elements with one exception: references to traditional medicine in Elements 1, 3 and 5 have been formulated as questions and grouped together in a separate section.

At the end of each question in this assessment tool, relevant specific action items in the GSPA-PHI are noted. When such numbers are not provided, this means that while no specific action item is linked directly to the question the information is still required to complement or clarify other questions and complete the picture.

Responses to questions in this assessment tool are not expected in the form of “yes” or “no.” In most cases, explanation and supportive documentation are required. WHO might already have collected some of the information requested by this questionnaire: in such cases, the information is provided and the respondent should either update it or confirm it. Those using this tool should be thoroughly briefed about its use. Regarding this last aspect, the WHO recommends the establishment of a National Task Force on implementation of GSPA-PHI comprised of relevant stakeholders from the public and private sectors including civil society organizations.
National Task Force: Members may include, but need not be limited to, representatives from ministries of health, science & technology, trade & industry and finance; national research councils and research institutions; the national regulatory authority; non-profit civil society organizations involved in health care delivery and economic development; trade associations and for-profit firms. Diverse membership will facilitate the collection of accurate information needed by policy makers and development partners and to coordinate national effort in implementation of GSPA-PHI.

**GSPA - PHI NATIONAL ASSESSMENT TOOL**

NOTE ON “INNOVATION”: The Global Forum for Health Research has defined “innovation” as “encompassing the entire process from the generation of new knowledge, to the transformation of that knowledge into useful products or services, to the implementation of those services or products.” For the purpose of this tool, “innovation” involves policies and practices that enable and encourage the development, production and delivery of existing and new drugs, vaccines, diagnostics and other medical devices to people who need them. are presented as important issues to be considered in any future deliberation.

NOTE ON NATIONAL POLICIES/STRATEGIES: This tool contains questions about national policies or strategies in multiple sections including health research policy, S&T (or innovation) policy, ethical review policy, human resources for health policy, local publicprivate R&D partnerships policy, North-South technology transfer policy, trade and investment policy, industrial policy, anti-dumping policy, poverty reduction policy, medicines policy, and traditional medicines policy.

**PRELIMINARY QUESTIONS**

1: Are you aware of any other assessments of your country’s health innovation capacity?
2: Does your country have a National Task Force on the GSPA-PHI?
HEALTH R&D POLICIES AND INFRASTRUCTURE

1. National strategy(ies) and priority setting: Does your country have a national health research policy or strategy? If yes, please comment on the strategy’s goals and describe the mechanisms for intra-ministerial coordination. Please provide links to sources of information.

2. Domestic support and leadership: Does your country have a national health research council or equivalent domestic funding body/agency? What is its structure? Please provide links to sources of information.

3. Research institutions, capacity and accreditation: What are the key publicly-funded R&D centres/institutes in your country? (Element 3.1.b) What is the balance of publicly-funded research taking place in universities, government research institutions, hospitals, field sites and non-governmental organizations? Does your country have systems to accredit universities, courses and other training, including research training? Please list WHO collaborating centres in your country, and provide links to sources of information.

4. Priority setting: Has your country established needs-based priorities for health R&D? What was the process for their definition (e.g. did it include relevant stakeholders)? How often are these priorities reassessed? (Element 1.2.a) Has your country included health system research in the national health research policy/strategy or in any other equivalent document? (Element 1.2.c) Please provide links to sources of information.

5. Research networks: Do researchers and/or research institutions in your country participate in national, regional and/or global health research networks or groups? (Element 3.1b) Please provide links to sources of information.

Funding for Health R&D

6. Public spending: What is the national health budget? What is the public budget for health R&D? How much does the private sector spend on health R&D? (Element 1.2e) If possible, provide trends in such funding over the past 5-10 years. (Element 1.2e) [POSSIBLE SOURCE: National Health Accounts]

7. External support: Provide information related to donor funding for public sector health research programs including health-related innovation. (Element 2.1.b,c)
8. Tracking and transparency: Does your country have publicly accessible information on sources of financing for health R&D? If yes, please provide details.

Discovery Science and Clinical Research

9. Clinical trials capacity: Are there any public and/or private efforts in your country to build capacity to conduct clinical trials? Does your country maintain a publicly available clinical trials registry? Please provide a brief description of clinical trials capacity in your country, both public and private (e.g., contract research organizations), as well as links to sources of information.

10. Ethical review: Is there a national ethical review policy for clinical trials? Does it cover the composition and functions of institutional ethical review committees? Where have such committees been established, and are they linked to other similar committees through national, regional and/or global networks? (Elements 2.2.f, 3.3.b, 3.3.c) Please provide links to sources of information.

11. International collaboration: Does your country participate in international efforts to build capacity and improve information in this area, e.g., International Clinical Trials Registry Platform (ICTRP) or European and Developing Countries Clinical Trials Partnership (EDCTP)? (Elements 2.2.f, 3.3.b, 3.3.c, 6.2.f)

Access to Knowledge

12. Scientific literature: Does your country make available public health literature in local languages for health researchers in national academic and government research institutions?

13. Compound libraries: Does your country maintain compound libraries? (Element 2.2a,b) If yes, please provide a list, description, and note whether your country provides open access to these. Do researchers in your country have access to compound libraries established abroad? Please provide details. (Element 2.2a,b)

14. Relevance to product development: If such open-access is available (as explained above), has it led to any new medical products? (Element 2.2.a)
BUILDING AND IMPROVING INNOVATIVE CAPACITY

Human Resource Needs

15. National policy: Does your country have a national policy or strategy focusing on human resources for health? If yes, does this policy include health researchers? Does it include incentives to retain health professionals including researchers? Please provide details. (Element 3.2.b,c)

16. Public investment: How much does your country invest in education and training of researchers and public health workers? (Element 3.1.a)

17. Future workforce, general: What disciplines are taught at university level related to public health, health research and health innovation? How many doctoral students per discipline does your country have? What has been the trend over the last 5-10 years? (Element 3.1a) Please provide links to sources of information. [POSSIBLE SOURCE: UNESCO]

18. Local production: Do universities in your country provide education in industrial pharmacy, technology assessment, technology management, business management and entrepreneurship, project management and accounting? Do they have basic and applied tertiary science education and research training relevant to drug manufacture (e.g., medicinal chemistry, pharmacology, biostatistics, target identification, etc.) and vaccine manufacture (e.g., antigen development, vaccine formulation and industrial engineering education covering biologics manufacturing)? Please provide links to sources of information.

19. IP management: Has there been any assessment of education and training needs for IP management, drafting and negotiating licenses, drafting patent applications, patent management, claims interpretation, how to manage IP “creatively” to promote both innovation and access, how to use TRIPS flexibilities and how to draft IP-related legislation that is sensitive to public health needs? (Element 5.1.a,e) Please provide links to sources of information.

20. Dialogue with industry: Do educational institutions and the education ministry in your country have mechanisms for continuing dialogue with representatives from industry to match curricula with industry needs? If yes, please provide details.
Incentives for Health Innovation

21. “Putting fuel in the tank” (rewarding academics): Is there a policy or mechanism in your country to encourage health researchers to contribute to technological innovation (e.g., career advancement linked to patenting and/or industry collaboration)? (Element 3.5b) Describe these mechanisms.

22. “Engaging the gears” (local public-private R&D partnerships): Does your country have national policies to encourage R&D partnerships between publicly funded research institutions and local industry (e.g., Bayh-Dole-like legislation)? Please list examples of such partnerships, if any, and describe outcomes. Do academic and government research institutions in your country have Technology Transfer Offices (TTOs) to facilitate such partnerships to translate publicly funded research knowledge into products? If so, have they developed institutional policies to encourage access to inventions that arise from public investments? Please provide links to sources of information.

23. “Driving innovation” (with push and pull incentives): What incentives exist in your country to encourage and reward local entrepreneurs and manufacturers in order to strengthen local innovation and production of health products (Element 3.5a)? Examples may include R&D grants, tax breaks for R&D, business incubators, recognition and/or monetary prizes, soft-loans, preferential pricing for procurement from local manufacturers, restrictions on importation, grants to local public-private R&D partnerships and for Small Business Innovation Research (SBIR) to help local industry attract private capital and encourage the creation of spin-off companies from academic and government research institutions. Please distinguish between domestic incentives and those (if any) from external development partners. Please provide sources and examples.

24. “Steering” innovation toward affordability and access: Are any such incentives specifically designed to promote affordability and access for medicines that are a high priority to the national health system? Please provide sources and examples.

25. Understanding national health information system: Provide details about national health surveillance and information systems (Element 3.1c). Are there any assessment reports on the national health information system of your country? North-South and South-South Cooperation for Building Innovation Capacity

26. Partnering: Are there any North–South and/or South–South partnerships and programs for capacity building in the area of health innovation? (Elements 3.3b, 2.2f, 4.2a) Please provide links to sources of information.
MANUFACTURING OF PHARMACEUTICALS

NOTE: Questions 26-30 are drawn primarily from GSPA-PHI Element 4. Questions 31-50 are based on legislative and industry sections of “Strengthening Pharmaceutical Innovation in Africa,” a project of the New Partnership for Africa’s Development (NEPAD) and the Council on Health Research for Development (COHRED).

International Transfer of Technology

27. National strategy: Is there a national strategy or policy to encourage and assist local manufacturers to acquire technologies from other countries for local production of health care products (“North-South” technology transfer)? Please provide links to sources of information.

28. Technology assessment: Is there a capacity for technology assessment in your country? Is there any recent assessment of technologies needed for health R&D and for local production of health products? (Element 4.3.b) Please provide links to sources of information. (See Q: 20, 43)

29. Tracking collaboration and outcomes: Does your country have a system for recording initiatives to facilitate technology transfer for local production of health products including: national, South-South and North-South cooperation? (Element 4.2.b) Does your country measure the contribution of local production to access to health products? Please provide links to sources of information.

30. Case studies: Does your country have examples of success stories or failures in North–South and South–South technology transfer for local production of health products? Please provide links to sources of information. (Elements 4.2.a, 3.3.b, 2.2.f)

31. External private investment: What is the level of foreign private investment (FDI and other financial flows) in pharmaceutical and other essential health technologies in your country? Please provide links to sources of information.

Local Production: Policies, Capacity and Legislation

32. National policies: Does your country have a national trade and investment policy? Does that policy cover active pharmaceutical ingredients (APIs) and biologics? Does your country have a national industrial policy? Does it cover the biotechnology and pharmaceuticals sectors? Does your country have a national science and technology (or innovation) policy or strategy? Does
it include the health sector? Does it balance economic aspirations with improvements in well-being, including public health? What mechanisms are in place for intra-ministerial coordination of the S&T/innovation policy? Please provide links to sources of information.

33. Publicly funded research institution capacities: Are academic and government research institutions in your country able to act as sponsors for clinical trials? Do they have facilities (e.g., animal facilities) and the technical capacity to meet international licensure standards (Good Laboratory Practice) for drug discovery and for preclinical studies including preclinical vaccine studies (e.g., toxicity)? Do they have access to vaccine delivery systems and adjuvants? Please provide links to sources of information.

34. Biosafety: Do biosafety facilities exist?

35. Border controls: Does your country minimize tariffs and duties on imported APIs? Describe. Can customs controls distinguish genuine from counterfeit API imports and exports? Does your country have anti-dumping policies (e.g., punitive tariffs)? Please provide links to relevant sources of information.

Industry Capacity for Local Production of Existing Products

36. Good Manufacturing Practice: Are pharmaceutical firms able to comply with Good Manufacturing Practice (GMP) in the manufacture of health products? Please provide links to sources of information.

37. Importing Active Pharmaceutical Ingredients (APIs): Are pharmaceutical firms able to identify API certified suppliers and test identity, quality and safety of procured APIs? Are they able to specify and test API requirements, e.g., formulation design, which can affect stability and bioavailability of finished drugs? Are they able to conduct bioequivalence studies of generic formulations? Please provide links to sources of information.

38. Manufacturing and distributing generic drugs: Are pharmaceutical firms able to undertake formulation, process and scale-up of generic drugs? Are they able to produce APIs to GMP standards and pharmacopoeia requirements? Are they able to undertake small to large-scale manufacturing, commercialize appropriately for local markets and link to local distribution networks?

39. Vaccine production: Do firms have facilities specifically tailored to undertake large scale GMP-standard vaccine production (e.g., sealed fermentation, aseptic production and purification, and large-scale harvesting)?
40. Vaccine quality control and assurance: Are vaccine producers able to maintain and demonstrate a completely controlled production process (i.e., carry out stability and potency studies; maintain potency and yield during sterile filtration of particle-containing solutions; carry out full tracking of manufacturing batches and lot-by-lot release of vaccines)? Do firms have dedicated in-house quality control laboratories for assay development and processing?

41. Meeting regulatory requirements: Are pharmaceutical firms able to prepare drug master files for registration with the National Regulatory Authority? Are they able to prepare regulatory dossiers for generic drug registration, using both data from their own studies and referencing quality, safety and efficacy data from original drug regulatory files?

Industry Capacity to Develop New Products

42. Improving known products: Are public and/or private sector manufacturers able to access rights to original drugs and registration data for further development (e.g., combination therapies and new formulations)?

43. Preclinical testing: Are public and/or private sector manufacturers able to conduct drug and/or vaccine discovery and preclinical studies, bioequivalence studies and complex drug and vaccine clinical trials to international licensure standards? Are they able to access compound libraries and screening facilities? Are they able to access adjuvants and vaccine delivery technologies, and to conduct feasibility studies for large scale vaccine manufacturing?

44. Meeting regulatory requirements for new products: Are public and/or private sector manufacturers able to prepare regulatory dossiers for clinical trial authorization and drug and biologics (vaccine) registration using data from their own clinical studies and referencing quality, safety and efficacy data from original drug regulatory files?

45. Clinical trials: Are public and/or private sector manufacturers able to design and implement clinical development plans for drugs and biologics (vaccines), and to sponsor drug and vaccine trials?
APPLICATION AND MANAGEMENT OF INTELLECTUAL PROPERTY

Trade Agreements and Intellectual Property (IP)

46. WTO, WIPO and TRIPS flexibilities: Is your country a member of the World Trade Organization (WTO)? Is your country a member of the World Intellectual Property Organization (WIPO)? Does national patent legislation incorporate flexibilities available under TRIPS? If yes, which ones? Please provide link to relevant legislation.

47. Regional and bilateral agreements: Is your country a member of a relevant regional organization? Has your country entered into bilateral or regional trade agreements which have resulted in IP protection going beyond what is required by the TRIPS agreement? Does your national legislation go beyond what is required by the WTO TRIPS agreement with respect to pharmaceutical products? Do health representatives in your country participate in bilateral and multilateral trade and IP negotiations? (Element 5.1.g) Please provide links to sources of information.

48. Assessment of IP legislation: Has there been any assessment of national IP legislation with regard to public health? (Elements 5.2.a,c,d, 6.3.a) Please provide links to sources of information.

49. Intra-ministerial coordination: What mechanism does your country use to coordinate policies on public health, intellectual property and trade? (Element 5.1.h) Please provide links to sources of information.

50. National patent office: Does your country have a national patent office? Does your country maintain a national database on patent applications and patents’ legal status (patent registry) and is it available online? Please provide links to sources of information.

51. Protection of data disclosed to regulatory authorities: Does your country provide for protection of clinical test data submitted to the national regulatory authority (as required by TRIPS to prevent unfair commercial use)? If yes, how? Please provide links to sources of information.

52. Research exemption: Does legislation in your country provide a research exemption to ensure that research involving patented inventions is not considered infringement? (Element 2.4.e) Please provide links to sources of information.
IMPROVING DELIVERY AND ACCESS

Access to Quality Medicines

53. Policies: Is there a national poverty reduction strategy in your country, and does it address the health sector? (Element 6.1.f, 6.3.b) Is there a national medicines policy in the country, and a national essential medicines list? Does the national medicines policy include improving access to affordable medicines as one of its objectives? (Element 6.3.b, 6.1.f) Please provide links to sources of information.

54. Product quality: Are any of the following standards/guidelines available in your country: Good Manufacturing Practices (Element 6.2.c); Good Clinical Practice (Elements 2.2.f, 3.3.b, 3.3.c, 6.2.f); and Good Laboratory Practice? Is there a national quality control laboratory in your country? Are any medical products from your country prequalified by the WHO? (Element 6.2.d) If yes, please list them.

Delivery Infrastructure and Incentives

55. Procurement mechanisms: What is the per-capita expenditure on medicines by government in your country, and what have been the trends over the past 5-10 years? (Element 6.1.a) Is your country part of any pooled procurement program for health products? (Element 6.1.g) If yes, please list them.

56. Delivery infrastructure: What are the strengths and weaknesses in the health delivery infrastructure in your country? Has there been any formal assessment of this infrastructure? (Element 6.1.a) Please provide links to relevant sources of information.

57. Local incentives for delivery innovation: What mechanisms are in place to create incentives for local delivery innovation, and for the adoption and adaptation of cost-effective health product and service delivery approaches from other countries or other sociocultural contexts?

Regulation of Safety and Efficacy

58. Regulatory framework: Are legal provisions that establish the functions and responsibilities of the national regulatory authority in place? Does the NRA have a website? Does the NRA participate in harmonization or collaboration initiatives? Does the NRA use an electronic information management system to keep and recover all information relative to product licensing, registration, inspections, etc.? If yes, please provide link and relevant documents.
59. Marketing authorization (licensing): Does the NRA have a legal provision that requires a marketing authorization (registration) for all pharmaceutical products on the market? Are there legal provisions that require the NRA to make publicly available registered pharmaceutical products with defined periodicity? Are there legal provisions requiring the NMRA to publish the Summary Product Characteristics (SPCs) of the pharmaceuticals registered? If yes, please provide link to relevant legislation (or provide article number).

60. Inspections: Are there legal provisions that exist permitting inspectors to inspect premises where pharmaceutical activities are performed? Are there legal provisions that require manufacturers to implement adequate GMPs? If yes, please provide link to relevant legislation (or provide article number).

61. Import controls and licensing: Are there legal provisions that exist requiring authorization to import medicines? Are there legal provisions that exist allowing the sampling of imported products for testing? Are there legal provisions that exist requiring manufacturers to be licensed?

62. Market control and quality control: Are there legal provisions for quality control of the pharmaceutical market? Does a national laboratory exist in the country for quality control testing? If yes, please provide link to relevant legislation (or provide article number).

63. Clinical trials: Are there legal provisions that exist requiring NRA authorization for conducting clinical trials? Are there legal provisions that exist requiring the agreement by an ethics committee/institutional review board of the clinical trial to be performed? Are there legal provisions requiring the sponsor and investigator to comply with Good Clinical Practices (GCP)? If yes, please provide link to relevant legislation (or provide article number).

64. Pharmacovigilance: Are there legal provisions that provide for pharmacovigilance activities as part of the NMRA mandate? Does a national Adverse Drug Reactions database exist in the country? Does a routine and crisis communication strategy exist? If yes, please provide link to relevant legislation (or provide article number).

65. Capacity and practice: What are the staff numbers, budget and other capacity measures for the national regulatory authority (NRA) of your country? Is there any formal assessment report available on the NRA? Does the NRA regulate clinical trials? If so, does it require that all clinical trial data must be obtained from ethically approved trials? (Elements 3.2.a, 6.2.a)

66. Harmonization or creation of regional authorities: Is your country’s NRA part of any regional or sub-regional regulatory harmonization program? (Element 6.2.e) Is your country involved in negotiations that could lead to the creation of a regional regulatory authority to improve economies of scale, transparency and governance?
Affordability of Medical Products

67. Promoting generics: Are users, doctors and pharmacies in your country encouraged to use generic medicines. (Element 6.3.g) Please provide details. Does the national patent law in your country have a regulatory exception (“Bolar” type provision) by which generic versions can be introduced immediately after the expiration of a patent? (Element 6.3.a, 5.2.a,c,d)

68. Understanding costs: Has there been any medicine price survey in your country? Is there a price monitoring mechanism? (Element 6.3.e) Has any study been conducted to understand different price components (e.g., tariffs, whole-sale and retail-sale margins, etc.)? Does the government impose import duties on raw materials and finished products? (Element 6.3.c) Please provide links to sources of information.

PROMOTING SUSTAINABLE FINANCING MECHANISMS

Public-Private R&D Partnerships (PDPs)

69. Global PDPs: Is your country involved in partnerships with any global public-private product development partnership (PDP, e.g., International AIDS Vaccine Initiative, Medicines for Malaria Venture, Global Alliance for TB Drug Development, DNDi)? (Element 7.2a) If yes, please provide details on the partnership(s).

70. Domestic support for global PDPs: Does your country give either financial or inkind support to global PDPs? Please, provide details. (Element 7.2c) Does your country periodically assess the performance of local collaboration with global PDPs? If yes, please provide details and methodology. (Element 7.2b)

New sources of funding

71. Revenue generation: Has your country considered any of the options reviewed by the WHO Expert Working Group on R&D Financing, or its successor the WHO Consultative Expert Working Group on R&D Financing, for revenue generation to support domestic health innovation?
TRADITIONAL MEDICINE

Health, health research and health innovation policies

72. National policies: Does your country have a national policy on traditional medicine? If yes, does it cover issues related to innovation in the field of traditional medicine? (Element 3.4 a,b,c) Has your country included traditional medicine in its national health R&D strategy, and are there any R&D priorities identified in traditional medicine? (Element 1.3.a) Please provide links to sources of information.

Production, Regulation and Protection

73. Production and development: Is there any local production of traditional medicines in your country? If yes, do publicly funded research institutions and/or private manufacturers have an ability to systematically evaluate and screen traditional medicines for successful compounds to be identified, developed and marketed?

74. Regulation: What is the status of regulation of traditional medicine in the country? Are there any national standards for quality production and R&D for tradition medicine? (Element 3.4.c) Please provide links to sources of information.

75. Protection of traditional knowledge: What mechanism does your country use to prevent the misappropriation of traditional (medicinal) knowledge? Are there digital libraries for traditional medical knowledge, and do patent examiners have access to such information when examining patent applications? (Element 5.1.f.e) Please provide links to sources of information.

MONITORING AND REPORTING

76. Health metrics and health information system: How are health and health system related data and information collected in your country? In what form are such data and information available? Are there any on-going or planned national surveys on health-related issues in your country? Does your country participate in international initiatives to monitor progress in achieving the Millennium Development Goals? If yes, please list them.

77. Domestic M&E profession: Does your country have professional associations or organizations of experts in monitoring and evaluation (M&E) in the social sector? If yes, please provide a list.