Thailand Country Study: R&D on Health

Submitted by
SEAMEO TROPMED Network
EXECUTIVE SUMMARY

This country study on research and development for health products in Thailand is one of 5 country studies conducted in the SEA Region, as a next step to take forward the recommendations contained in two important documents which will affect the financing and coordination of health research and development in the Region. These are: (1) Regional Resolution SEA/RC65/R3 (Consultative Expert Working Group on Research and Development: Financing and Coordination) adopted during the 65th Regional Committee Meeting held in Yogyakarta, Indonesia in September 2012; and (2) the draft resolution adopted during the Open-ended Meeting of Member States on the Follow-up of the Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination which was held in Geneva on 26-28 November 2012. These country studies are conducted to document existing norms and standards followed for the classification of health R&D activities, to identify current and future priorities for R&D for health products, and to identify projects which need to be implemented in order to develop and deliver priority health products. Data were collected through the application of three methodologies: (1) conduct of an extensive literature review; (2) conduct a series of 3 consultative meetings with three groups of stakeholders as participants -- health policy makers and planners; researchers and academician; and the pharmaceutical industry; and (3) key informant interviews.

The important findings derived from the various data collection methodologies conducted in this project are as follows:

- There are several existing institutions/bodies that are involved in developing policies at the national level related to research and development. These include national bodies concerned with R&D for science, technology and innovation in general, as well as bodies/institutions primarily focused on research and development efforts on health. In addition, a number of departments in the Ministry of Public Health also develop policy guidelines for health research in the country. However, it was gathered from the different data collection mechanism utilized in this study that a weak coordination mechanism exist between and among these different bodies. It appears that there is no single body that provides the policy direction for health research in the country.

- There is no single body that identifies the priority areas for health research for the entire country. Priority areas of current research efforts are based on the policies and plans of specific institutions. In addition, availability of internal and external funding sources, opportunities for collaborative researches, as well as interests and expertise of the researchers influence decisions for the type and area of research conducted. However, it was also noted that several of the areas covered in the current research efforts are relevant to the health needs of the country.

- There is no single/common system of norms and standards for the classification of health research and development that is mandated to be utilized by research institutions and researchers in the country. However, an important output of the Consultative Meetings conducted as part of this country study was a consensus among all three groups of stakeholders (policy-making bodies, researchers and academicians, pharmaceutical groups) that a common system of norms and standards for the classification of health research and development activities should be developed and utilized for Thailand. It was further established that there have been initial efforts towards the development of a common system of norms and
standards for classification of health research in the country. The use of a modified version of the Health Research Classification System (HRCS) developed in the UK was recommended for use in Thailand in a current study done in the country, with the preliminary results having been recently presented to the policy-making bodies of health research. Another study on the classification of health R&D activities is also being done in one of the universities.

- The priority areas for medical products identified in this country identified by the 3 groups of stakeholders who participated in the Consultative Meetings include:
  - Vaccine for dengue and influenza
  - Drugs for malaria and orphan diseases such as melioidosis
  - Diagnostic kits/rapid tests for screening for cancers and markers for NCDs
  - Natural products/medicinal plants

- There is also a consensus that more efforts should be exerted on translational research so that medical products can be made more accessible and appropriate to the population in need.

- Given the current R&D activities and priorities on health of Thailand, the following projects are suggested in order to develop and deliver health products.

  1. Development/Adoption of a common norm and standard for classification of health research and development activities that can be used by everyone involved in these activities. The National Research Council of Thailand can lead the efforts on this initiative, with the process to be participated in by all groups of stakeholders. Since the development of norms and standards requires a lot of in-depth and detailed discussions among various sectors within health, it is suggested that this activity be considered as a separate project focused only on this area, rather than just a rider activity such as the current one. Activities related to information dissemination and capacity building on the use of the system should follow the development of norms and standards for R&D activities to ensure its utilization by all stakeholders.

Complementary to the development of a system of norms and standards, efforts should also be exerted to strengthen protection of intellectual property rights.

  2. Conduct of a series of Consultative Meetings among different health R&D stakeholders to discuss the role of a health R&D observatory at the national, regional and global levels, including the most effective mechanism for its establishment, management, monitoring and evaluation. In addition, the merits, acceptability and feasibility of the idea of the global health R&D Observatory acting merely as a Coordinator of a network of regional and national observatories with national level observatories taking a more major role covering different areas of health R&D must be explored. This is a deviation from the usual set-up wherein countries merely act as data providers and have very little participation in the activities of a global observatory based somewhere else, say in Geneva.

  3. Consolidate efforts on the following priority R&D areas where demonstration projects can be implemented:

    - Communicable disease: collaborative project on dengue vaccine development
• Drugs/medicines for an orphan disease: Collaborative project on melioidosis
• Natural products that address a priority public health need of the country
• Diagnostic kit for screening.

More detailed discussions on these priority areas should be organized to maximize efficiency and collaboration among the different groups of stakeholders.

4. If possible, WHO should facilitate sourcing of funds for projects on the priority areas since products on these priority areas can also meet the needs of the region.

5. Knowledge gained and products of these projects can be shared throughout the region to ensure equitable access of the needy population.
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1. BACKGROUND OF THE PROJECT

1.1 Rationale

This project is conducted as a next step to take forward two important documents which will affect the financing and coordination of health research and development in the Region:

a. Regional Resolution SEA/RC65/R3 (Consultative Expert Working Group on Research and Development: Financing and Coordination) adopted during the 65th Regional Committee Meeting held in Yogyakarta, Indonesia in September 2012. This resolution recognized the need of Member States in the Region to implement recommendations of the CEWG in phases [1].

b. The draft resolution adopted during the Open-ended Meeting of Member States on the Follow-up of the Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination which was held in Geneva on 26-28 November 2012 [2]. SEA/RC65/R3 was a major input in drafting this resolution, which was presented in the 66th World Health Assembly Meeting in May 2013.

A plan of action for SEA/RC65/R3 and the draft WHA resolution needs to be developed which would enable the prioritization of activities for SEA Region, as well as define global norms and standard setting appropriately for the CEWG process in WHO. The development of this strategic work plan will be the agenda of an expert group meeting to be held in Bangkok on 25-26 July 2013.

As inputs to the expert group meeting, country studies are conducted for Thailand, India, Bangladesh, Sri Lanka and Indonesia, to document existing norms and standards followed for the classification of health R&D activities, to identify current and future priorities for R&D for health products, and to identify projects which need to be implemented in order to develop and deliver priority health products.

This paper presents the results of the country study for Thailand the conduct of which was contracted out to SEAMEO-Tropmed under an APW. Results of the country study will be presented and discussed together with those of other countries during the Expert Group Meeting to be held in Bangkok on 25-26 July, 2013.

1.2 Historical perspective

Global initiatives to analyse intellectual property rights, innovation and public health, as well as to provide adequate funding, incentive mechanisms and promote R&D for the development of new products and technologies against diseases that disproportionately affect developing countries started more than a decade ago. A landmark document was Resolution WHA56.27 (Intellectual Property Rights, Innovation and Public Health) which was adopted by the 56th World Health Assembly in May 2003 [3]. This was the basis for the establishment of the Commission on
Intellectual Property Rights, Innovation and Public Health (CIPIH) in 2004 which made an in-depth analysis of the issues, and presented 60 recommendations in its report which was published in 2006 [4].

From 2003 onwards, several resolutions have been adopted by the World Health Assembly and several bodies have been formed to fine-tune the original recommendations of the CIPIH Report. From the global level, it was finally brought to the regional and national levels in 2012 with the adoption of Resolution WHA65.22 (Follow up of the Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination) during the 65th World Health Assembly. This resolution urged member States “to hold national level consultations among all relevant stakeholders in order to discuss the CEWG report and other relevant analyses, resulting in concrete proposals and actions” [5].

During the 66th WHA in May 2013, Resolution WHA66.22 was adopted which identified more concrete actions implementable at the regional and national levels, including, amongst others [6]:

a. the development of norms and standards for classification of health research and development in order to systematically collect and collate information;

b. the establishment of a global health research and development observatory within WHO’s secretariat in order to monitor and analyse relevant information on health R&D, building on regional and national observatories and existing data collection mechanisms; and

c. facilitating through regional consultations and broad engagement of relevant stakeholders the implementation of a few health R&D demonstration projects to address identified gaps that disproportionately affect developing countries, and for which immediate action can be taken.

A detailed listing of significant milestones and corresponding decision which led to the conduct of country studies to inform the development of a strategic work plan for the SEA region for financing and coordinating health R&D activities is shown in Box 1.
## BOX 1: MAJOR MILESTONES ON THE ROAD TO THE THAILAND COUNTRY STUDY

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<th>MILESTONE</th>
<th>IMPORTANT DECISIONS/HIGHLIGHTS</th>
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<tr>
<td>1. Resolution WHA56.27 (Intellectual Property Rights, Innovation and Public Health) adopted by the 56th World Health Assembly; May 2003 [3]</td>
<td>1.1 &quot;...to establish the terms of reference for an appropriate time-limited body to collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries.&quot; [3]</td>
</tr>
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<td>1.1 Establishment of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) in 2004</td>
<td>1.2 Recommendation 6.1 of the CIPIH Report: &quot;WHO should develop a Global Plan of Action to secure enhanced and sustainable funding for developing and making accessible products to address diseases that disproportionately affect developing countries&quot; [4]</td>
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<td>1.2 Publication of the CIPIH Report in 2006</td>
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<td>2.1 Resolution WHA59.24 (Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action) adopted by the 59th World Health Assembly: May 2006 [7]</td>
<td>To establish an intergovernmental working group (IGWG) to &quot;draw-up a Global Strategy and Plan of Action in order to provide a medium-term framework based on the recommendation of the Commission&quot;. Such a strategy and plan of action would aim at (a) securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries; (b) proposing clear objectives and priorities for research and development; and (c) estimating funding needs in this area&quot;. [7]</td>
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<td>2.2 Establishment of the Inter-governmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) which met from Dec. 2006 to May 2008</td>
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<td>3.1 Resolution WHA61.21 (Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property) adopted by the 61st World Health Assembly: May 2008 [8]</td>
<td>Global Strategy and Plan of Action has 8 elements, of which the 7th element covers promoting sustainable financing mechanisms. Among the key actions to be taken is to &quot;establish a result-oriented and time-limited expert working group under the auspices of WHO and linking up with other relevant groups to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of financing to stimulate R&amp;D related to Type II and Type II diseases and the specific R&amp;D needs of developing countries in relation to Type I diseases&quot; [8].</td>
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<td>4.2 Establishment of the CEWG in 2010. Final Report entitled &quot;Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination&quot; was submitted to the 65th WHA in May 2012</td>
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<td>MILESTONE</td>
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<td>5.1</td>
<td>Urged member States “to hold national level consultations among all relevant stakeholders in order to discuss the CEWG report and other relevant analyses, resulting in concrete proposals and actions” [11]</td>
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<td>5.2</td>
<td>Requested the Director General “to hold an open-ended meeting of member States that would thoroughly analyse the report and the feasibility of the recommendations proposed by the Consultative Expert Working Group, and taking into account discussion during regional committee meetings and regional and national consultations” [11]</td>
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<td>6.1</td>
<td>Regional technical discussion of the CEWG Report conducted during the 65th SEA Regional Committee Meeting in Yogyakarta, Indonesia on 7 Sept. 2012</td>
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<td>6.2</td>
<td>Regional Resolution SEA/RC65/R3 (Consultative Expert Working Group on Research and Development: Financing and Coordination) adopted during this meeting [1]</td>
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<td>6.2</td>
<td>“To engage actively in the negotiations in an open-ended meeting of Member States in November 2012, inter alia, by supporting the development of the Global Health R&amp;D Observatory, effective global R&amp;D coordination, adequate and sustainable funding for R&amp;D on diseases of Type II and III and specific R&amp;D needs of diseases of Type I in developing countries” [1]</td>
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<td>7.1</td>
<td>The Open-ended meeting of Member States on the follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination was held in Geneva on 26-28 November 2012 [2]</td>
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<td>7.1</td>
<td>• Chaired by Dr. Viroj Tangcharoensathien of Thailand</td>
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<td>8.1</td>
<td>Requested the Director General to [6]:</td>
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<td></td>
<td>a. “develop norms and standards for classification of health research and development, building on existing sources, in consultation with Member States and relevant stakeholders, in order to collect and collate information systematically”</td>
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<td></td>
<td>b. “facilitate through regional consultations and broad engagement of relevant stakeholders the implementation of a few health research and development demonstration projects to address identified gaps that disproportionately affect developing countries, particularly the poor, and for which immediate action can be taken”</td>
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<td>9.1</td>
<td>Conduct of country studies in Thailand, India, Bangladesh, Sri Lanka and Indonesia</td>
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<td>9.1</td>
<td>Terms of reference for the country studies:</td>
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<td>a. Suggest methodologies to develop norms and standards for the classification of health R&amp;D needs of developing countries based on systematically collected and collated information</td>
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<td>b. Identify priorities for R&amp;D for health products based on public health needs for developing countries; and</td>
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<td>c. Identify projects in order to develop and deliver health products</td>
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1.3 Project Terms of Reference

This project has four terms of reference as follows:

1. Suggest methodologies to develop norms and standards for classification of health R&D needs of developing countries based on systematically collected and collated information. For this purpose, it would be necessary to examine:
   a. Current norms and standards for classification of health R&D in developed and developing countries
   b. Classification of health R&D by health and non-health sectors
   c. Based on the above suggest possible methodologies for norms and standards for classification of health R&D needs of developing countries

2. Identify priorities for R&D for health products based on public health needs of developing countries

3. Identify projects in order to develop and deliver health products

4. Participate in the regional meeting in July 2013 and present their findings to the meeting

Based on the above terms of reference, the project has the following deliverables:

1. Copy of the project final report highlighting:
   a. methodology used;
   b. results of each consultation;
   c. analysis of the data and data triangulation;
   d. overall conclusions of the findings; and
   e. recommendations

2. Powerpoint presentation for the CEWG regional consultation in July 2013

3. Copy of the literature review findings which should include the:
   a. literature search strategy;
   b. list of appropriate articles identified;
   c. summary of the articles identified; and
   d. overall conclusions and recommendations
2. METHODOLOGY

In order to achieve the terms of reference of the project, it was undertaken in three phases, namely:

1. Data collection
2. Analysis; and
3. Documentation and report writing

Each of these phases was covered by a specific set of activities which are described in the following sections.

2.1 Data Collection Phase

The data collection phase consisted of the following 3 sets of activities:

a. conduct of an extensive desk/literature review;

b. series of Consultative Meetings with different groups of stakeholders; and

c. key informant interviews

The literature review was conducted primarily to provide the data needed to answer the first term of reference for this project. The conduct of consultative meetings and key informant interviews were conducted to address the second and third terms of reference.

2.1.1 Conduct of Extensive Literature Review

The objectives of doing an extensive literature review were:

a. to establish and examine the:
   - norms and standards for classification of health R&D in both developed and developing countries;
   - norms and standards of international pharmaceutical companies in relation to health R&D;
   - norms and standards of both health and non-health sectors of Thailand, and

b. to determine the current status of research and development for health products in Thailand.

The main sources of the literature reviewed for this project were peer-reviewed publications available online, as well as reports of government agencies, international organizations, academic institutions, NGOs, pharmaceutical industries and other bodies and institutions involved in health and health-related research. At the start of the project, websites of the various health and health-related institutions were accessed to get their profiles, determine their mission statements and objectives, and the listing of their roles and responsibilities. This was done to identify the health and health-related institutions conducting R&D activities for health products in Thailand, whose representatives will be invited to attend the Consultative Meetings which will be conducted as part of this project.

While the focus of the literature review was the current status of health research and development for health products in Thailand, the documents reviewed covered three geographic levels: global, regional and country-specific. This was done to provide a wider and more comprehensive perspective of R&D activities for health products at all levels.
For purposes of this project, health products were defined to include vaccines, diagnostics and medicines. This is based on resolution WHA 59.24 on public health, innovation, essential health research and intellectual property rights which was adopted during the 59th World Health Assembly in May, 2006 [7].

2.1.2 Consultative Meetings with different groups of stakeholders

A series of three consultative meetings were conducted as part of this project, with the following objectives:

a. to identify norms and standards for classification of health R&D utilized by different health and health-related organizations in Thailand;

b. to list current R&D activities conducted for health products, in relation to the country’s public health needs;

c. to identify priorities for R&D for health products based on the country’s public health needs; and

d. to identify projects in order to develop and/or deliver health products

The first Consultative Meeting was conducted with health policy makers and planners as participants. They included officials and representatives of the different departments of the Ministry of Public Health (MoPH) whose activities are related to R&D for health products like the Food and Drug Administration, National Vaccine Institute, and the Department of Disease Control. Also in attendance were officials of institutions mandated to set the country’s research agenda, set priorities or allocate research funds like the National Research Council of Thailand (NRCT), National Science and Technology Development Agency (NSTDA), the National Science Technology and Innovation Policy Office and Thailand Centre of Excellence for Life Sciences (TCELS).

Box 2 presents a description of the various units/institutions whose Heads/and or representatives were invited to attend the first Consultative Meeting,

The second Consultative Meeting was attended by researchers and academicians. Invited to the meeting were the Heads and/or representatives of various Departments in the Faculties of Science, Tropical Medicine, Medicine, and Pharmacy of Mahidol University. Also invited were officials and/or representatives from various research institutes like the Chulabhorn Research Institute, the Armed Forces Research Institute of Medical Sciences (AFRIMS), Thai Red Cross AIDS Research Centre, Medical Molecular Biology Research Unit (BIOTEC), the Health Systems Research Institute and the Office of the National Research Council of Thailand.

A description of the various institutions whose officials and/or representatives were invited to attend the second Consultative meeting is shown in Box 3.
<table>
<thead>
<tr>
<th>UNIT/INSTITUTION</th>
<th>DESCRIPTION/ROLES AND FUNCTIONS</th>
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| Food and Drug Administration (FDA), MoPH | FDA is one of 3 departments under the Public Health Service Support of the Ministry of Public Health. Its main function is quality and standard control of manufacturing, imports and distribution of food, drugs, cosmetics, hazardous substances, psychoactive substances, narcotics, medical equipment, and volatile substances. Its operations include business licensing for operation and use of products or active ingredients in production, in accordance with eight Acts, and six international conventions and agreements. There are five aspects to Its mission, namely [12]:  
  - Regulate and monitor health products to meet quality and efficacy standards.  
  - Promote Good Manufacturing Practice in the production and quality control of health products to ensure consumer safety and to encourage exports.  
  - Research and develop the effectiveness of the consumer protection system for health products.  
  - Promote and support the capability of health product consumers and society to be able to protect themselves and be self-reliant.  
  - Encourage and enable all stakeholders and non-government parties to share in the consumer protection role.  
   
To undertake this mission, FDA is divided into two division groups: the Health Product Control Division group which consists of the Bureau of Cosmetic and Hazardous Substances Control, and the Divisions of Drug Control, Food Control, Medical Devices Control, Narcotics Control and Import and Export inspection. The second group is the Support Division Group which consists of 3 divisions: Public and Consumer Affairs; Rural and Local Consumer Health Products Protection Promotion, Technical and Planning; and the Office of the Secretary. |
| Department of Medical Sciences, MoPH | The Department of Medical Sciences, together with the FDA is another department under the Public Health Service Support of the Ministry of Public Health. Its main functions are [13]:  
  - to study, analysis and conduct research to control quality and safety of food, drugs, narcotics, cosmetics, hazardous substances and medical equipment to reach international standards and for export;  
  - technical and technological development in medicinal plants, medical sciences;  
  - laboratory diagnostic services;  
  - laboratory standards; and  
  - enforcement of laws on infectious agents and zoonotic toxins and other related areas  
   
Under the Dept. of Medical Sciences is the Bureau of Drugs and Narcotics. It is designated as the national quality control laboratory for testing the quality of medicines as well as testing of narcotics, illicit drugs and substance abuses in Thailand. The Bureau’s activities include pre-marketing assessment, post-marketing surveillance, laboratory testing service, production of reference substances, bioequivalence study, Thai pharmacopoeia and Thai Herbal pharmacopoeia establishment, research and training. |
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<tr>
<th>UNIT/INSTITUTION</th>
<th>DESCRIPTION/ROLES AND FUNCTIONS</th>
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<tr>
<td>Bureau of Emerging Infectious Diseases, MoPH</td>
<td>The Bureau of Emerging Infectious Diseases is one of the bureaus under the Department of Disease Control of the MoPH. It has the following roles and responsibilities [14]:</td>
</tr>
<tr>
<td></td>
<td>1. Study, analyze, research, and coordinate emerging infectious diseases knowledge development and prevention and control technology.</td>
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<td></td>
<td>2. Set guidelines and develop standards, criterion and operational format for emerging infectious diseases prevention and control.</td>
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<td>3. Transfer the knowledge and technology in the field of emerging infectious diseases prevention and control.</td>
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<td></td>
<td>4. Coordinate and support the emerging infectious diseases prevention and control mechanism and network system development.</td>
</tr>
<tr>
<td></td>
<td>5. Analyze and follow up emerging infectious diseases situations.</td>
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<td>6. Set strategic plans, objective plans, budget and support for emerging infectious diseases prevention and control operation.</td>
</tr>
<tr>
<td></td>
<td>7. Follow up and evaluate emerging infectious diseases prevention and control overall achievements.</td>
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<td></td>
<td>8. Conduct training on preparedness for public health emergencies particularly in infectious diseases and biological weapon in every region for both the government and private sector and primary public utility.</td>
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<td></td>
<td>9. Coordinate activities related to emerging infectious diseases under the bilateral and multilateral cooperation, for example with ASEAN, APEC, BIMSTEC, etc.</td>
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<td></td>
<td>Under the Bureau are 4 sections which are the General Administrative Section; Technical Development and Emergency preparedness Section; Strategy and Corporate Development; and Risk Communication and Information System Development</td>
</tr>
<tr>
<td>Bureau of Non-communicable Diseases, MoPH</td>
<td>The Bureau of Non-communicable Diseases is under the Department of Disease Control of the Ministry of Public Health of Thailand. The Bureau is further sub-divided into 8 Sections namely strategies management; general management; organizations development; injury prevention; risk behaviour surveillance system; academic development group for the prevention of non-communicable chronic diseases; risk communication; and NCD control development group. The mission of the Bureau covers the following [15]:</td>
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<tr>
<td></td>
<td>1. Knowledge technology innovation in non-communicable disease surveillance, prevention and control of injuries, surveillance data and risk behaviour;</td>
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<td>2. Promote the transfer and exchange of knowledge; surveillance technology to prevent NCDs and injuries;</td>
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<td>3. Advocate for public policies and measures related to NCDs and injuries; monitoring and enforcement</td>
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<td></td>
<td>4. Monitoring and evaluation of NCD surveillance, prevention and control; and</td>
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<td></td>
<td>5. Support capacity building and collaboration</td>
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<tr>
<td>UNIT/INSTITUTION</td>
<td>DESCRIPTION/ROLES AND FUNCTIONS</td>
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| **National Vaccine Institute (NVI)** | The National Vaccine Institute was originally the Office of the National Vaccine and was formally elevated into an Institute in 2011, under the Department of Disease Control of the Ministry of Public Health. NVI has a 3-fold mission, namely [16]:

  a. To strengthen and push the necessary infrastructure which will be mutually beneficial for research development and vaccine production;

  b. Coordinate and drive the implementation of policies and strategies of the NVI aimed at integrated vaccine development; a

  c. Develop staff, and manage the transfer of technology and knowledge related to vaccines (through its Technology Transfer and Training Center)

  The NVI acts as the Secretariat of the National Vaccine Committee and is tasked to prepare the vaccine agenda, as well as coordinate and monitor the implementation of the resolutions of the Committee. |
| **International Health Policy Program (IHPP), MoPH** | The International Health Policy Program, Thailand (IHPP) is a semi-autonomous program conducting health policy and health system research to address priority health problems in Thailand and at the international level. The program, which is part of the Bureau of Policy and Strategy in the Ministry of Public Health, aims to improve the national health care system, through generating reliable evidence and integrating this evidence into policy processes in order to encourage evidence-based policy decisions. The aim of the program is to strengthen the capacity of Thai researchers to conduct high-quality and policy-relevant research through five strategies [17]:

  1. Conducting policy-relevant research;

  2. Participating in interface; policy

  3. Building-up partnerships and networks;

  4. Providing opportunity for researchers; and

  5. Publication of articles on domestic and international journals

  Its priority areas are research on health care financing, economic evaluation, public health insurance and health policy analysis. |
| **National Research Council of Thailand (NRCT)** | The Office of the National Research Council of Thailand was established in 1956 and is an independent public agency operating under the direct supervision of the Prime Minister. Its main function is to formulate and implement national research policy and strategies. The administrative functions of the NRCT are carried out by the Office of the National Research Council of Thailand which was institutionalized in 1959. The major activities of the NRCT are concerned with [18]:

  - the adoption of the national research policy guided by the present need for research as directed by the government;

  - the promotion of research work in the form of research grants to both government and private sectors

  - coordination with national and international organizations on research projects, as well as exchange of research information

  The NRCT also serves as a Research Documentary Centre where research works in both natural and social sciences are compiled and disseminated to all researchers. |
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<tr>
<th>UNIT/INSTITUTION</th>
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<tr>
<td>National Science and Technology Development Agency (NSTDA)</td>
<td>NSTDA was established in December 1991 under the Ministry of Science and Technology by the special national Science and Technology Development Act of 1991. It is an autonomous entity reporting to the Governing Board chaired by the Minister of Science and Technology. It is an umbrella organization which plans and executes four mandated missions [19]: 1. research and development; 2. technology transfer; 3. human resource development; and 4. Infrastructure development NSTDA is comprised of 4 national R&amp;D centers: the National Center for Genetic Engineering and Biotechnology (BIOTEC); the National Metal and Materials Technology Center (MTEC); the National Electronics and Computer Technology Center (NECTEC); and the National Nanotechnology Center (NANOTEC). Under the Strategic Planning Alliance II (2011-2016), NSTDA focuses on five targeted sectors: agriculture and food; energy and environment; health and medicine; resources, communities and the underprivileged; and manufacturing and service industries critical to the economic and social development of Thailand.</td>
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<td>National Science Technology and Innovation Policy Office</td>
<td>The National Science Technology and Innovation Policy Office (STI) was established under the National Science Technology and Innovation Act, promulgated on 13 February 2008. The office is an autonomous government agency that operates under the policy guidance of the National Science Technology and Innovation Policy Committee (NSTIC), chaired by the Prime Minister of Thailand. The Office principally works with industries, government, the academe, and local communities. Collaborative networking is an essential part its strategy and is emphasized by the creation and promotion of active collaboration through strong linkages and exchange programs with local, overseas, and international organizations [20]. The responsibilities of the National Science Technology and Innovation Office are: 1. To produce policies and plans regarding science, technology and innovation at the national level; 2. To provide support and advice to other governmental agencies in formulating their own implementation plans; 3. To develop standard measurements, indicators, database, and conduct policy research in support of science, technology and innovation; and 4. To facilitate and monitor the development of human resources in science and technology.</td>
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Thailand Center of Excellence for Life Sciences (TCELS)

Thailand Center of Excellence for Life Sciences is one of 7 independent organizations under the umbrella of the Office of Knowledge Management and Development which was established on 18 June 2004 under a royal decree. The objective of the organisation is to build the country’s life sciences infrastructure, select and develop the necessary technology, and to manage and stimulate the life sciences industry. It is envisioned that TCELS will be a focal point to develop the manufacturing process, quality products, and services in the life sciences [21].

The mission statement of TCELS covers 6 areas as follows:

a. Undertake strategic planning for life sciences business and investment in Thailand;

b. Support development of life sciences pharmaceuticals and other products and services;

c. Create a network of government agencies, organisations, institutes, and private sector interests inside and outside the country;

d. Monitor industry progress and identify life sciences business and investment opportunities for government agencies, organisations and institutes;

e. Support capacity building for Thailand's life sciences and professionals;

f. Serve as a centre for life sciences coordination in Thailand

Among the TCELS projects which are already seeking patent protection are the skin whitening project which develops products from natural latex serum and the development of a CD4 test kit for people with HIV/AIDS.

Health Intervention Assessment Program (HiTAP)

The Health Intervention and Technology Assessment Program (HiTAP), was established in 2007 as a non-profit organization, in order to take responsibility for appraising a wide range of health technologies and programs, including pharmaceuticals, medical devices, interventions, individual and community health promotion and disease prevention as well as social health policy. HiTAP is an associate organization, coming under the auspices of the International Health Policy Program (IHPP), Thailand. Its mission statement covers the following areas [22]:

a. To efficiently and transparently appraise health interventions and technologies by using international, standard and qualified research methodologies;

b. To develop systems and mechanisms in order to promote the optimal selection, procurement and management of health technology as well as appropriate health policy determination;

c. To distribute research findings and educate the public in order to make the best use of health interventions and technology assessment results.

Examples of research projects completed by HiTAP are: "Value of Information: An Application in Health Economic Evaluation of Renal Replacement Therapy in Thailand" and "Cost-utility Analysis of Recombinant Human Erythropoietin in Cancer Patients with Anemia Induced by Chemotherapy in Thailand".
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<tr>
<th>UNIT/INSTITUTION</th>
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| Mahidol University (MU) | Mahidol University (MU) is a government research University in Thailand. It was established in 1888 as School of Medical Practitioners, Siriraj Hospital (now Siriraj Medical School) and was reorganized in 1943 as University of Medical Sciences. The university originally focused on health sciences but expanded to other fields in recent decades. MU hosted the first medical school of Thailand, the Siriraj Medical School, from which the university traced its origins. Today, MU offers a wide range of graduate (most are international programs) and undergraduate programs from natural sciences to liberal arts. MU is comprised of 17 faculties and 6 colleges, and offers a wide range of academic programs in 3 core academic areas; health science, science & technology and social science & humanity [22].

MU has implemented a policy of building-up academic excellence and developing research that leads to new body of knowledge, technology to the government/community, private and the industrial sectors and introducing commercialization of innovation. Such policy closely responds to the national research strategy. Among the current research priority areas of the university for goal-oriented and multidisciplinary research projects are post-genomic medicine, tissue engineering, bio-engineering, stem cell research, system biology, aging, food security, material science and engineering, nanotechnology and nanoscience, the control and prevention of major diseases, global warming and environment and water resource management.

In 2010, MU established 4 research clusters and 5 research centers (Centers for Emerging and Neglected Diseases Research; Research in Complex Systems Sciences; Thalassemia Research; Aquatic Animals Research; and Biopharmaceutical Development and Innovative Therapy) in line with the National Research University Project of the Ministry of Education [23]. |
| Faculty of Science, Mahidol University | The Faculty of Science, Mahidol University was founded as a Premedical School in 1958, and took the name of Faculty of Science in 1969, with the following objectives [24]:  
  a. To continuously develop graduates, scientific and technological personnel who have the highest expertise and ethical standards to serve the societies and the country,  
  b. To generate research of international standard and offer services of international quality and standard to every level of educational institution, as well as to transfer knowledge and appropriate technology to the public for the benefit of sustainable development of every community and all mankind,  
  c. To instigate in students as well as faculty staff discipline, ethics, professional codes of conduct, and maintenance of the country's cultural heritage. |
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<th>UNIT/INSTITUTION</th>
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<tr>
<td>Faculty of Science, Mahidol University (continuation from previous page)</td>
<td>The Faculty of Science has 12 departments (anatomy, biochemistry, biology, biotechnology, chemistry, mathematics, microbiology, pathobiology, pharmacology, physics, physiology and plant science. It offers undergraduate degree programs in 7 disciplines, 20 masters programs and 20 doctoral programs. It places a strong emphasis on research, not only as part of the thesis work of the students, but also as an ongoing commitment to international scientific advancement and national development.</td>
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| Chulabhorn Research Institute (CRI) | The mission of Chulabhorn Research Institute (CRI) is the application of science and technology to improve the quality of life. It has four specific objectives, namely [25]:
   a. To promote and conduct applied and basic research of national importance, in particular, that which will improve the quality of life;
   b. To act as a center for education in developing high calibre personnel in the field of science and technology;
   c. To bring together local and foreign scientists to discuss and solve emerging problems, to promote scientific exchange, and act as a center for international cooperation; and
   d. To identify, catalyze, and mobilize resources for research and development in science and technology

   Research is the core activity of CRI and its current priority research areas are natural products, medicinal chemistry and organic synthesis; biomedical research; environmental toxicology; and biotechnology |
| Armed Forces Research Institute of Medical Sciences (AFRIMS) | AFRIMS was originally founded as the South East Asian Treaty Organization (SEATO) Laboratory to help combat a cholera outbreak. It was renamed AFRIMS in 1977. It has a dual Royal Thai Army and US Army Command, with the American component in the form of a special foreign activity of the Walter Reed Army Institute of Research in Washington DC [26].

   The current research programs of AFRIMS include enteric diseases, malaria vaccine and drug research, viral diseases especially dengue fever and hepatitis. Among its departments are the Entomology Department which is involved in the study of disease vectors and the Retrovirology Department which was established to conduct vaccine studies for HIV-AIDS. A recently initiated program to monitor new and emerging disease threats as part of a Global Emerging Diseases Surveillance System is now underway. |
<p>| Thai Red Cross AIDS Research Center | Since 1985, people with HIV/AIDS have been receiving treatment and care from Chulalongkorn Memorial Hospital which is affiliated with the Thai Red Cross. Since 1987, the Thai Red Cross has been educating the public about the disease and conducting research on it. In December 1989, The Thai Red Cross AIDS Research Center was officially established. |</p>
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<tr>
<td>Thai Red Cross AIDS Research Center (Continuation from previous page)</td>
<td>The Thai Red Cross AIDS Research Centre has the following responsibilities [27]: 1. Co-ordinating with the government in campaigning against AIDS and alleviating its impact 2. Setting up projects to provide care for HIV-infected patients both at home and in many provincial communities 2.1 Setting up projects to campaign against AIDS in slum communities 3. Raising funds to support the Center’s activities such as: 3.1 The joint-cooperation project with the Ministry of Public Health to buy AZT drugs for infected mothers 3.2 The project to subsidize milk and educational fees for children born of mothers on the AZT-project list. 4. Supporting joint activities aimed at helping AIDS-infected people, such as Wednesday’s Friends Club, by giving them advice and facilitating contacts with similar networks locally and abroad. 5. Conducting social research</td>
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<tr>
<td>Medical Molecular Biology Research Unit (BIOTEC)</td>
<td>The Medical Biotechnology Research Unit (MBU) was established in 1994 as the result of collaborative effort between the National Center for Genetic Engineering and Biotechnology (BIOTEC) and the Faculty of Medicine, Siriraj Hospital, Mahidol University. The objective of the unit is to maintain expertise in medical biotechnology research, with emphasis on dengue virus and dengue hemorrhagic fever as well as human genetic research. The unit consists of three affiliated laboratories located at the Faculty of Medicine Siriraj Hospital (Mahidol University), Department of Microbiology, Faculty of Medicine, and Department of Clinical Immunology, Faculty of Associated Medical Sciences (Chiang Mai University) [28]. The unit maintains its focus of research on dengue virus and dengue hemorrhagic fever, human genetic diseases, and basic immunology. Their research activities include: 1. Dengue research • Pathogenesis of dengue hemorrhagic fever (DHF) and dengue shock syndrome (DSS) • The use and application of dengue infectious cDNA clones to study the molecular biology of dengue virus and generation of dengue vaccine candidates</td>
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### BOX 3. DESCRIPTION OF UNITS/INSTITUTIONS INVITED TO THE CONSULTATIVE MEETING FOR RESEARCHERS AND ACADEMICIANS

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<tr>
<th>UNIT/INSTITUTION</th>
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<tr>
<td>Medical Molecular Biology Research Unit (BIOTEC)</td>
<td>- Development and application of dengue diagnostic technology including the application of new technologies and knowledge for better diagnosis and prevention of dengue virus infection</td>
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<td>2. Genetics/genomics of prevalent diseases</td>
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<td>- The application of genetic and genomic technologies to study a group of prevalent diseases in Thailand</td>
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<tr>
<td></td>
<td>- Development of technology for molecular diagnosis.</td>
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<td>BIOTEC is the national focal point for the ASEAN Sub-Committee on Biotechnology and the UNESCO Regional Network for Microbiology and Microbial Biotechnology in Southeast Asia.</td>
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<tr>
<td>Health Systems Research Institute (HSRI)</td>
<td>The Health Systems Research Institute (HSRI) is an autonomous state agency established by the Health Systems Research Institute Act B.E. 2535 (1992), at about the same time as the Thailand Research Fund (TRF) and the National Science and Technology Development Agency (NSTDA). Its organizational structure and management system are designed to focus on flexibility so as to be able to respond to the goal of “better knowledge management for better health systems” [29].</td>
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<td>The vision of HSRI is “Knowledge management for equitable and sustainable health system”. Its mission statement has 3 components, namely:</td>
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<td>1. Develop knowledge and policy recommendations for reducing inequities in the health systems and improving the efficiency and sustainability of the health systems.</td>
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<td></td>
<td>2. Support and promote the utilization of knowledge in the healthy public policy process for creating equitable and sustainable health systems.</td>
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<td>3. Support the strengthening of health research systems and health systems research.</td>
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<td>One of the strengths of HSRI is its networking approach and creation of “subsidiary agencies” that are institutional mechanisms working collaboratively with allied organizations. At present, HSRI has seven subsidiary agencies called “affiliated institutions” as follows:</td>
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<tr>
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<td>1. Central Office for Healthcare Information (CHI)</td>
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<td></td>
<td>2. Medical Audit (MA) Development Office</td>
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<tr>
<td></td>
<td>3. Institute for Development of Human Research Protection (IHRP)</td>
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<tr>
<td></td>
<td>4. Health Insurance System Research Office (HISRO)</td>
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<td></td>
<td>5. Institute of Health Promotion for People with Disability (IHPPD)</td>
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<td></td>
<td>7. Thai CaseMix Centre(TCMC)</td>
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The last meeting was conducted among representatives of local pharmaceutical organizations and companies like the Pharmaceutical Research and Manufacturer's Association, the Government Pharmaceutical Organization and Siam Bioscience Co. Ltd. The Faculty of Pharmaceutical Sciences, Chulalongkorn University was also invited since they work very closely with the pharmaceutical industry. A description of the units/institutions whose head/representatives were invited to attend the meeting with the local pharmaceutical organizations and companies is presented in Box 4.

**BOX 4. DESCRIPTION OF UNITS/INSTITUTIONS INVITED TO THE CONSULTATIVE MEETING FOR THE PHARMACEUTICAL INDUSTRY**

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<tr>
<th>UNIT/INSTITUTION</th>
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| **Drug Control Division, Food and Drug Administration** | The Drug Control Division is one of the 6 Divisions under the Health Product Control Division Group of the Food and Drug Administration (FDA). It is responsible for four main aspects of drug regulation [30]:
  
a. Pre-marketing control (including licensing and registration)
  b. Post-marketing monitoring and surveillance
  c. Consumer education and dissemination of information
  d. Promotion of technological development and research for export.

  The Division’s role in the area of pre-marketing control covers new drugs, generic drugs, veterinary drugs, biological products, traditional and herbal medicines and advertisement control. The Division carries out its mission in consultation and cooperation with experts in science, medicine, pharmacy, public health consumers, manufacturers, importers, distributors and retailers of drugs. It also works closely with several other organizations like universities, industries, health care professional groups, consumer groups, other relevant agencies and foreign governments in drug development and review processes. |
| **Medical Device Control Division, Food and Drug Administration** | The Medical Device Control Division of the Thai FDA has main duties and responsibilities of controlling the manufacture, import, sale and advertisement of medical devices available to consumers. Other activities include pre and post-marketing control, pre and post-advertisement control, standard development, and development of laws and regulations. It also works with the Bureau of Import and Export Control of the Thai FDA to control the import and export of medical devices in Thailand. To undertake its mission, the Division is subdivided further into 4 sections namely General Administration; System Development, Pre-marketing Control; and Post-marketing Control [31]. |
| **Pharmaceutical Research and Manufacturer's Association (PReMA)** | PReMA is a non-profit organization representing members who are research based pharmaceutical companies innovating medicines to combat the previously incurable and to improve existing treatments. PReMA is committed to promoting good health and quality of life for Thai people and to supporting the advancement of public health systems through the research and development of innovative medicines. PReMA also supports the rights of people and healthcare professionals to choose high quality medicines that best meet their needs. PReMA’s main roles, all of which align with PReMA’s value of “Innovative Medicines. Healthier Life,” are to [32]: |
### BOX 4. DESCRIPTION OF UNITS/INSTITUTIONS INVITED TO THE CONSULTATIVE MEETING FOR THE PHARMACEUTICAL INDUSTRY

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<tr>
<th>UNIT/INSTITUTION</th>
<th>DESCRIPTION/ROLES AND FUNCTIONS</th>
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| **Pharmaceutical Research and Manufacturer’s Association (PReMA)**<br>*(Continuation from previous page)* | a. Promote healthier lives through scientific advancements in research and development of high quality medicines by its members;  
b. Encourage compliance with ethical international standards;  
c. Collaborate to support patients’ timely access to innovative medicines;  
d. Educate and train related parties in public health systems; and  
e. Promote understanding of the benefits of intellectual property rights in the development of innovative medicines. |
| **Government Pharmaceutical Organization (GPO)** | The Government Pharmaceutical Organization (GPO) of Thailand is a state enterprise under Ministry of Public Health. It was founded in 1966 by merging the pharmaceutical manufacturing plant (founded in 1939) and the Pharmaceutical Department (founded in 1901) according to the GPO Act of 1966. The annual revenue of year 2009 is approx. 260m USD. The total pharmaceutical product items are more than 300 [33].  
The GPO vision is to be a leader in pharmaceutical products and medical supplies beneficial and essential to the Thai society and fairness. It has 4 missions, namely:  
a. To manufacture, sell and supply quality pharmaceutical products and medical supplies with the aim to achieve world-class standard to develop business to ensure competitiveness and self-sustainability;  
b. To maintain price level of pharmaceutical products and medical supplies necessary for Thai society to ensure people’s accessibility;  
c. To research and develop new pharmaceutical products and medical supplies to serve the need of the country. And  
d. To carry out business related pharmaceutical products and medical supplies manufacturing.  
The main responsibility of GPO is to produce medicines and pharmaceutical products to support the country’s public health. GPO was assigned to serve the national public health policy. It has a Biological Product Department which is responsible for the production of vaccines and antisera. |
| **The Faculty of Pharmaceutical Sciences, Chulalongkorn University** | The Faculty of Pharmaceutical Sciences, Chulalongkorn University was established in 1913. Its vision is to be a source of knowledge and academic resource centre, as well as a leading pharmaceutical science institution that contributes to the country’s sustainable development. It has 7 departments and offers undergraduate and graduate (masters and doctoral) level academic programs in pharmacy. It also has 6 Units offering various forms of academic and professional services as follows [34]:  
a. Chulalongkorn University Drug and Health Products Innovation Promotion Center |
b. Herbs and Natural Products Research Unit

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<tr>
<th>UNIT/INSTITUTION</th>
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| The Faculty of Pharmaceutical Sciences, Chulalongkorn University (Continuation from previous page) | c. Microbiology –Molecular Biology and Biotechnology Research Unit  
| | d. Preclinical Efficacy and Safety Assessment Unit  
| | e. Pharmaceutical Development and Technology Transfer Unit  
| | f. Cosmetics Research Unit  |
| Siam Bioscience Co. Ltd. | Siam Bioscience Co. Ltd. (SBS) was established in 2009 and is the first biopharmaceutical company in Thailand. It aspires to be in the forefront of R&D and manufacturing of biopharmaceuticals in the ASEAN. To achieve this goal, key personnel with combined work experience of over two decades in leading US and European biopharmaceutical companies have been tapped. In addition, strategic partnerships have been established with Mahidol University as the knowledge provider and Cuba Biotechnology as the technology licensor. Its mission statement covers two areas [35]:  
| | 1. Set reasonable price for own products to allow patent access and to have margin to reinvest in development of products in the pipeline; and  
| | 2. Focus on R&D of biopharmaceuticals, manufacturing and commercialization through alliance with various institutes in Thailand and licensing from reknown licensors.  
| | SBS operates in the ASEAN countries, Australia and New Zealand. |

The actual number of participants who attended each of the three Consultative Meetings conducted and the listing of institutions represented are shown in Sections 3.2.1 to 3.2.3 of this report. A couple of participants who had various designations in institutions across sectors (government research or policy-making agency, the academe and the pharmaceutical industry) attended more than one meeting. In addition, three high officials of agencies who were interviewed earlier as Key Informants were interested enough to attend the Consultative Meetings.

The Consultative Meetings were held from 26 to 28 June 2013 at the SEAMEO-Tropmed Conference Room. In each of the three meetings, the program of activities included the following:

1. Brief inputs given by the Project Team on the following:
   1.1 Overview of the project  
   1.2 Norms and standards currently used for classifying research and development activities

2. Group Discussions
   2.1 Workshop 1: Identification of R&D norms, standards and priorities currently adopted, and activities currently undertaken
   2.2 Workshop 2: What ought to be done in terms of norms, standards, priorities, and activities to be conducted, to develop and deliver health
products

3. Plenary session for the presentation and discussion of group outputs

4. Agreements

To facilitate the group discussions during the workshop sessions, guide questions with corresponding worksheets were prepared for the participants to record their inputs. These are shown in Annex 3 of the Report.

2.1.3 Key Informant Interviews

The last mode of data collection utilized for this project was the conduct of key informant interviews. This was done with the following objectives:

a. To get additional and more in-depth information on important data derived by the Project Team either during the literature review or the Consultative Meetings;

b. To get first-hand information from institutions who were invited to, but were not able to attend the Consultative Meetings; and

c. To validate some of the information derived from the literature review and the Consultative Meetings, as part of the process of triangulating the data collected

Five persons were interviewed by the Project Team as key informants. These were:

1. Dr. Rungrueng Kitphati, Director, Bureau of Emerging Infectious Diseases – He was interviewed to explain to the Project Team the organizational structure of the Ministry of Public Health and its research arms. His inputs were used in identifying the participants of the consultative meetings, and the key informants to be interviewed.

2. Dr. Yongyuth Yuthavong, former Minister of Science and Technology and Advisor to the President of the National Science and Technology Development Agency (NSTDA) – He was interviewed on the processes of setting the research agenda, identification of priorities and allocation of research funds in the country.

3. Dr. Yot Teerawatanon, Program Leader and Senior Researcher, Health Intervention and Technology Assessment Program (HITAP)

4. Dr. Inthira Yamabhai, Researcher, Health Intervention and Technology Assessment Program (HITAP)

HITAP was one of the institutions invited to attend the first Consultative Meeting, but could not send a representative at that time. Among its current research activities is an NRCT-funded project which has, as one of its objectives, the development of norms and standards for the classification of health R&D activities in Thailand. Dr. Teerawatanon and Dr. Yamabhai are the Principal Investigators of this project and they were interviewed by the Project Team to collect first-hand information about the current status of their project. A description of HITAP is presented as the last entry in Box 2.

5. Dr. Sansanee Chaiyaroj, Former Vice President for Research of Mahidol University; Executive Board Director, Office of the National Research Council of Thailand (NRCT) and Executive Board Director, Siam Bioscience Co. Ltd. Since Dr. Chaiyaroj
has the unique position of having been involved in the health R&D activities of the academe, the policy-making bodies and the pharmaceutical industry, she was interviewed to provide a comprehensive picture of the inter-relationships between these three main bodies who are the main actors in the R&D activities of the country

2.2 Data Analysis Phase

For qualitative data generated from the literature review, conduct of Consultative Meetings and key informant interviews, the following steps in data processing and management were followed:

1. Transcription of interviews and proceedings of meetings from tapes/field notes. In certain instances, this part included translation of notes and documents from Thai to English

2. Implementation of data quality control procedures -- This consisted of two main activities:

   2.1 Validation by members of the team present during each data collection activity. This included comparison of notes among project team members to ensure consistency of data collected across data collectors

   2.2 Data triangulation – this refers to the cross-verification of data collected from more than two sources, using different methodologies. In the context of this project, some of the information gathered during the group discussions in the Consultative Meetings were verified against the documents gathered during the literature review, especially the reports produced by the different research organizations. A third validation was done during the key informant interviews.

3. Drawing of conclusions – this involved the conduct of meetings among the different Team Members to discuss the findings, and reach at a consensus on the interpretation and implications of results.
3. ACTIVITIES UNDERTAKEN

3.1 Review of Related Literature

The literature reviewed for this project covers two areas:

a. Norms and standards for classification of health R&D both in health and the non-health sectors; and
b. Current status of R&D for health products at all levels, with focus on Thailand

As mentioned earlier, health products, for the purposes of this product refers to vaccines, diagnostics and medicines, based on WHA 59.24.

3.1.1 Norms and standards for classification of research and development

Norms and standards for the classification of research and development activities refer to internationally accepted definitions of R&D and its component activities. It serves as a common language which can be used by researchers in 3 important areas of work [36]:

1. Describing the research landscape;
2. Making meaningful comparisons of different aspects of research activities among different sub-groups like units within an institution (ex., departments/colleges within a university or divisions within a ministry), across sectors (ex., health, education, agriculture, etc..) or between countries; and
3. Strategic coordination of R&D activities

A concise but comprehensive review of R&D classification systems was prepared by the European Science Foundation in its Science Policy Briefing No. 43. In this paper, they identified five uses and advantages of using a common classification system which are [36]:

1. Communication
2. Identification of new opportunities
3. Comparable analysis
4. Collaboration; and
5. Efficiency

In the area of comparable analysis, the use of a common classification system for R&D is most needed for purposes of monitoring and evaluation, especially when comparing the productivity and quality of research outputs, priority areas and the allocation and flow of research funds across sectors of interest.

3.1.1.1 General Classification Systems

Several classification systems have been developed covering all areas of research. Among the original systems developed is the Frascati Manual which was originally designed for the OECD countries. This system was used as the basis of other R&D classification system
developed by countries in Asia and the Pacific like Australia and New Zealand, and Malaysia.

a. OECD Frascati Manual

One of the oldest classification system for R&D used is the OECD Frascati Manual. It was first produced in 1963, as an output of an OECD meeting with national experts on research and development statistics at Villa Falcioni in Frascati, Italy. The first edition was entitled “Proposed Standard Practice for Surveys of Research and Development”. The most recent version is the 6th edition published in 2002, with the title being modified to “Proposed Standard Practice for Surveys on Research and Experimental Development”. The document is better known as the Frascati Manual and has been used extensively worldwide, not just by OECD but by several other organizations as well [37].

The Frascati Manual deals exclusively with the measurement of human and financial resources devoted to research and experimental development, covering basic research, applied research, and experimental development. This is often referred to as R&D input data.

The Frascati Manual uses two levels in its classification system for R&D:

1. Institutional classification – refers to the characteristics of the organizations who are either performing or funding R&D; and
2. Functional distribution – refers to the nature of the R&D programs themselves

The institutional classifications used are based to the extent possible, on existing UN classifications to ensure maximum comparability with regular economic or social statistics. The main institutional classification of national R&D efforts makes use of 5 sectors: business enterprise; government; private non-profit; higher education and abroad.

The functional distributions are more detailed than the institutional classifications, since it focuses on the nature of the R&D itself. The levels of categorization include among others, the type of R&D, product field, objective, and field of science.

b. Australian and New Zealand Standard Research Classification (ANZSRC)

The Australian and New Zealand Standard Research Classification (ANZSRC) was jointly produced by the Australian Bureau of Statistics and Statistics New Zealand in 2008. [38]. ANZSRC replaces the Australian Standard Research Classification published and used in Australia since 1998 and introduces a new framework for measuring R&D activity in New Zealand. The definitions, scope and classifications of R&D used in ANZSRC generally follow the guidelines prescribed in the Frascati Manual. This is to enable international comparisons and ensure that the ANZSRC classifications can relate to those used in other countries, especially those with a stage of economic and social development similar to that of Australia and New Zealand.

ANZSRC uses three levels of classification for R&D activities:

1. Type of activity (TOA) – categorization of R&D activity according to the type of research effort namely pure basic research, strategic basic research, applied research and experimental development
2. Fields of research (FOR) – This level of classification considers the methodology used in the R&D activity being considered. The categories in this classification level include major fields of research investigated by national research institutions and organizations as well as emerging areas of study. There are 22 divisions under FOR which include, among others, the standard categories of the mathematical, physical, chemical, earth, environmental, biological, medical and health, agricultural and veterinary, and information and computing sciences, as well as specific areas like built environment and design, law and legal studies, studies in human society as well as studies in creative arts and writing. In addition to the 22 primary divisions, alternate groupings are provided to aid the understanding of research from different cultural perspectives unique to Australia and New Zealand. These alternate groupings include Aboriginal and Torres Strait Islander Studies, Maori Studies and Pacific Peoples Studies.

3. Socio-economic objective (SEO) – This refers to the purpose or outcome of the R&D as perceived by the data provider who is usually the researcher. It consists of discrete economic, social, technological or scientific domains for identifying the principal purposes of the R&D. The attributes applied to the development of the SEO classification comprise a combination of processes, products, health, education and other social and environmental aspects of particular interest. SEO divisions and groupings are categorized into 5 sectors namely defence, economic development, society, environment and expanding knowledge. The last sector covers activities without an identifiable socio-economic objective, which is usually the case of pure basic research or strategic basic research.

FOR has 3 hierarchical levels consisting of 22 divisions, 157 groups and 1238 fields. SEO makes use of 5 levels, covering 5 sectors, 17 divisions, 119 groups and 847 objectives [38].

c. Malaysian Research and Development Classification System (MRDCS)

The only Asian country which has developed its own classification system for R&D activities is Malaysia. The Malaysian Research and Development Classification System (MRDCS) was first introduced in the 1992 National Survey of Research and Development. In March 2011, the Malaysian Science and Technology Innovation Centre published the first printing of its most recent version which is already the 6th edition [39].

The MRDCS is based on the Frascati Manual, but modified to support a variety of user interests within the Malaysian R&D context. It is a two-dimensional classification system based on:

1. Field of Research (FOR) -- R&D activities are classified according to their scientific and academic disciplines. FOR covers nine divisions namely:
   a. Natural sciences
   b. Biotechnology
   c. Engineering and technology
   d. Information, computer and communication technology
   e. Medical and health sciences
   f. Agriculture and forestry
   g. Social sciences
   h. Humanities
   i. Economic, business and management

2. Socio-economic Objective (SEO) – categorization of R&D activities according to their purposes or presumed sectoral benefits as perceived by the researcher. It consists of
discrete socio-economic, social. Environmental, technological or scientific domains and reflects the profile and development priorities of the country. Six divisions are considered under SEO namely:

a. Defence and security  
b. Sustainable economic development  
c. Society  
d. Environment  
e. Advancement of knowledge  
f. Advanced experimental and applied science

MRDCS was designed primarily to enable the classification of research projects in a more consistent and structured manner. It is expected to be flexible enough to meet the needs of a variety of users, and to be applicable but not limited the following activities in the country:

a. Conducting the National Survey for Research and Development  
b. Applying for R&D funds (ex., TechnoFund; ScienceFund)  
c. Identifying and providing codes for research projects and experts in database development

### 3.1.1.2 Classification Systems for Health R&D

The development of classifications systems for health research and development has been spearheaded by various US agencies. Among these are:

a. RCDC (Research, Condition and Disease Categorization) system developed by the US National Institutes of Health (NIH)

b. MeSH (Medical Subject Headings) developed by the US National Library of Medicine

c. CSO (Common Scientific Outline) developed and used by the US National Cancer Institute

d. G Finder Survey which is funded by the Bill and Melissa Gated Foundation specifically to monitor resource flows for neglected diseases like TB, Malaria, HIV/AIDS, etc.

In 2008, the UK Clinical Research Collaboration group developed the HRSC (Health Research Classification System).

#### a. Research, Condition and Disease Categorization (RCDC)

RCDC is an electronic system that sorts NIH research investments into nearly 360 research, condition, and disease categories. The RCDC system accounts for research grants, research and development (R&D) contracts, and NIH’s own in-house research program (intramural research). It is a clear way to show how Federal research money is spent. It allows NIH to show a more transparent view of its research portfolio by providing project listings per disease, condition, or research area that will include links to abstracts for each project. [40].
The development of RCDC started in 2004 when the NIH leadership began to explore replicable, more automated ways to produce project listings and report category data. They believed it is important for the public and other Federal agencies to see and understand how much NIH spends on various types of medical research. NIH also wanted a better way to assess our entire research portfolio. At that time, each Center used its own methodology for coding research projects and associating costs to each project. These varying methods created inconsistencies across NIH. The U.S. Congress also understood the value and importance of a more transparent, consistent system. For this reason, in 2006 Congress added a requirement in the NIH Reauthorization Act to build a tool like RCDC. This mandate was prompted by two National Academy of Sciences reports recommending such a change.

The RCDC system uses a computerized process to identify grants, contracts, and intramural research projects that are relevant to specified research areas, conditions, and diseases. The system applies consistent definitions across all of the NIH’s 27 Institutes and Centers (ICs), in contrast to the previous approach in which each IC categorized the research it funded according to its own definitions. Congress mandated the system change, which has been enabled by advances in data- and text-mining computer technology. The RCDC system generates an NIH-wide report for Congress and the public on the 215 categories.

RCDC has a website (http://report.nih.gov/rcdc/) which contains more information on the categorization process, frequently asked questions, and a contact email where the general public may direct questions [41]. In addition, visitors to the RCDC web site will be able to see all of the research projects in a particular category as well as detailed information about each project, such as its funding level, title, NIH support mechanism (i.e., grant, contract, or intramural project), principal investigator(s), research institution at which it is to be conducted, NIH project identifier number, and funding IC.

b. Common Scientific Outline (CSO)

The Common Scientific Outline (CSO) system was developed by the US National Cancer Institute (NCI) in conjunction with the Department of Defence (DOD) US Army Medical Research and Materiel Command in the late 1990s. It was developed through the conduct of workshops in which scientists, panel members, applicants and programme staff categorised abstracts, and then evaluated the validity of the coding [42].

The classification system used in the CSO is organized around seven broad areas of scientific interest in cancer research:
   1. Biology
   2. Aetiology (causes of cancer)
   3. Prevention
   4. Early Detection, Diagnosis, and Prognosis
   5. Treatment
   6. Cancer Control, Survivorship, and Outcomes Research
   7. Scientific Model Systems

The CSO is complemented by a standard cancer type coding scheme. Together, these tools lay a framework to improve coordination among research organisations, making it possible to compare and contrast the research portfolios of public, non-profit, and governmental research agencies.

The CSO is now directed and managed by the International Cancer Research (ICR) Partners which was established in 2000. The Partners include two national partnerships, the
NCRI(UK) and CCRA (Canada), 8 individual funders from the U.S. including NCI/NIH and 2 other European funders, totalling 48 funding organizations worldwide. The Partners meet annually and via teleconference periodically throughout the year to share information and review the implementation of the CSO in their organizations.

c. G-Finder Survey

The G-finder survey tracts global public, private and philanthropic investments into product research and development for neglected diseases [43]. These are diseases which predominantly affect developing countries and for which products are needed to address them. However, there is inadequate commercial motivation to stimulate R&D for such products.

The survey covers R&D for 31 neglected diseases and 134 product areas including drugs, vaccines, diagnostics, microbicides and vector control products. Since there is no generally accepted definition of a neglected disease and what new products are needed, if any for these diseases, a number of steps were followed to reach a consensus position. A list of all diseases which have been classified by major health bodies or publications as a 'neglected disease' was first created. This list was then assessed by an international Advisory Committee (AC) of 17 neglected disease and R&D experts who were asked to filter it against three criteria, as follows:

1. Disease morbidity and mortality disproportionately affect people in developing countries;

2. There is no existing product to treat/prevent that disease, or a product exists but is poorly suited for developing country use; and

3. There is no commercial market to stimulate R&D by industry.

A disease will be categorized as 'neglected' for the purposes of the G-FINDER survey if it met all three criteria. Where there was disagreement between experts, their decisions were supplemented by advice from further disease and R&D experts. From the initial list used for the Year 1 survey, modifications were made in the succeeding surveys in response to feedback received, and in consultation with the Advisory Committee.

After the list neglected diseases was developed for the survey, the next task was to design the survey tool. This was done with the guidance of an international Stakeholder Network of key investors in neglected disease R&D, who later on were among the survey respondents. The Stakeholder Network comprises 30 public, philanthropic and private representatives, whose organisations stand out as the largest funders of product R&D for neglected disease R&D, or who have key significance in the field. Their input has helped ensure that the information collected in the G-FINDER survey is the most feasible, reliable and useful it can be in terms of capturing global expenditure on neglected disease product R&D.

The survey has been conducted annually since 2007, and current funding is available for the conduct of the survey until 2014. The 2012 survey was participated in by 240 organizations from high, middle and low income countries. Of these, 126 (52.5%) came from the public sector, 70 (29.2%) were private organizations and 21 (8.8%) were from the philanthropic sector. Others were from product development partnerships and other intermediary organizations.
d. Health Research Classification System (HRCS)

The Health Research Classification System (HRCS) was developed by the UK Clinical Research Collaboration (UKCRC) in 2008, with its Manual published in January 2009 [44]. It is a system for classifying and analyzing biomedical and health research funding in order to facilitate research management. It is based on the Common Scientific Outline (CSO) developed by the US National Cancer Institute.

The HRCS follows a 2-dimensional framework which are both applied for the classification of health R&D activities. These are:

1. Health categories which are used to classify the type of health or disease being studied. Twenty-one (21) categories are used which encompass all diseases, conditions and areas of health. These are shown in Table 1.

<table>
<thead>
<tr>
<th>No.</th>
<th>Health Category</th>
<th>No.</th>
<th>Health Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Blood</td>
<td>12</td>
<td>Musculoskeletal</td>
</tr>
<tr>
<td>2</td>
<td>Cancer</td>
<td>13</td>
<td>Neurological</td>
</tr>
<tr>
<td>3</td>
<td>Cardiovascular</td>
<td>14</td>
<td>Oral and Gastrointestinal</td>
</tr>
<tr>
<td>4</td>
<td>Congenital Disorders</td>
<td>15</td>
<td>Renal and Urogenital</td>
</tr>
<tr>
<td>5</td>
<td>Ear</td>
<td>16</td>
<td>Reproductive Health and Childbirth</td>
</tr>
<tr>
<td>6</td>
<td>Eye</td>
<td>17</td>
<td>Respiratory</td>
</tr>
<tr>
<td>7</td>
<td>Infection</td>
<td>18</td>
<td>Skin</td>
</tr>
<tr>
<td>8</td>
<td>Inflammatory and Immune System</td>
<td>19</td>
<td>Stroke</td>
</tr>
<tr>
<td>9</td>
<td>Injuries and Accidents</td>
<td>20</td>
<td>Generic Health Relevance</td>
</tr>
<tr>
<td>10</td>
<td>Mental Health</td>
<td>21</td>
<td>Other</td>
</tr>
<tr>
<td>11</td>
<td>Metabolic and Endocrine</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Research activity codes which are used to classify the type of research activity being undertaken, from basic to applied. There are 48 codes which are divided into 8 major groups:
   a. Underpinning research
   b. Aetiology
   c. Prevention
   d. Detection and diagnosis
   e. Treatment development
   f. Disease management
   g. Health services

The strategic aim of coding using the HRCS is to capture the main objective of the research being conducted during the lifetime of the award, rather than the background or potential application of the research. This system is routinely used in Norway, Sweden, Singapore, Ireland and the UK. Its application in Canada is currently being tested.
3.1.2 R&D on Health Products

The CEWG recommendations and the adoption of resolutions related to these recommendations at the WHA and regional levels have stimulated a lot of actions to facilitate R&D for health products especially in developing countries. Among the most recent developments is the launching of a business plan for health products R&D by the ASEAN Network for Drugs, Diagnostics, Vaccines and Traditional Medicines Innovation (ASEAN-NDI) during a stakeholders meeting held last 5 June 2013 in the Philippines. ASEAN-NDI is a regional network of ASEAN-member countries which includes Thailand. It was established in 2009 by TDR to support R&D innovation to improve access to drugs, diagnostics, vaccines, medical devices, and traditional medicine products to address priority public health problems in the region. The ASEAN-NDI business plan covers the following [45]

- The R&D landscape in ASEAN countries, significant contributors to the burden of disease in the region and a plan of action on science and technology for development;
- a business model (vision/mission, economies of scale and scope, key stakeholders, knowledge network and innovation-driven communities of practice);
- regional innovation and science and technology priorities;
- identified country commitments and collaboration (political, human resources, capital, infrastructure and funding for R&D);
- governance and organizational structure; and
- an ASEAN NDI Innovation Fund for financial sustainability

ASEAN-NDI is the second network initiated by TDR to help increase regional and intra-country collaborations for R&D related to health products. The first one is the African Network for Drugs and Diagnostics Innovation (ANDI) which was established in 2008. Its mission is “to promote and sustain African-led health product innovation to address African public health needs through efficient use of local knowledge, assembly of research networks, and building of capacity to support economic development” [46].

In the specific case of Thailand, networking of R&D institutions for enhancing innovation is the role of the National Science and Technology Authority (NSTDA). It makes use of three models to establish such networks: clustering, public-public partnerships and public-private partnerships [47]. Its research programs cover five targeted areas, one of which is health and medicine. At present, there are three R&D programs under this target area, all of which deal with health products [48]:

1. The Newly Emerging Disease - Re-emerging Disease Program -- This program aims to create knowledge and products that can promptly solve problems related to and address newly emerging and re-emerging diseases as well as increasing research capability so that the country is self reliant and stable. Key operation plans include:

   a. Doing R&D work to create dengue vaccine prototypes to be tested in humans by 2016, focusing on improving research to create dengue serotype 2 vaccines and test tetravalent vaccines in monkeys

   b. Doing R&D work to create anti-malaria substance prototypes to be tested in small laboratory animals and focusing on research on key antigens of the P. falciparum and the P. vivax.

   c. Doing R&D work to increase capability of outbreak prediction systems, using mathematical models.
2. The Genotype Technology Program -- This program uses genotype-phenotype associations to develop predictive, preventive and personalized medicinal technologies for chronic diseases and geriatric diseases such as osteoporosis, diabetes and kidney disease. In addition, there is also R&D work that leads to pharmacogenetic test kits or testing technologies to be used to test drug allergies in Thais. The focus is on preventing severe drug allergic reactions (SJS/TENS) and allergic reactions to expensive drugs that are used for a prolonged period such as cancer drugs and antipsychotic drugs.

3. Assistive Devices and Technologies for People with Disabilities and The Elderly Program -- This program focuses on R&D work on the designing and engineering of assistive technologies, devices and equipment for protecting, monitoring, rehabilitating and improving the quality of life of people with disabilities and the Elderly. Key operation plans include:

   a. Prevention/screening, which focuses on R&D work to create devices that help solve the problem of falling and prevent falling in the Elderly. This will also help solve the problem of a shortage of geriatric care personnel.

   b. Rehabilitation which focuses on R&D work to create rehabilitation equipment for people with disabilities. The equipment produced is equivalent to exported items in terms of efficiency but is reasonably priced.

   c. Assistive technology which focuses on R&D work to create assistive equipment and technology to help increase the capabilities of people with disabilities and the Elderly so that they can make a living similar to people with no disability.

There are several areas which need strengthening in relation to R&D for health products in Thailand. A national policy on advanced health biotechnologies was developed in 2009 by the National Science and Technology Development Authority [49]. However, there are no clear implementing guidelines for the policy document which has resulted in many R&D activities being conducted outside of the scope of the National Research Council (NRC) and NSTDA. In addition, there is little communication between the relevant national bodies on which areas of advanced health biotechnologies in the country will be supported [50].

A recent research conducted to analyze the current situation and examine existing public policies related to advanced health biotechnologies in Thailand showed that the system is fragmented with multiple unaddressed gaps. Other problems identified include underfunding for research and development; lack of incentives for the private sector; no clear definitions of advanced health technologies and coverage pathways; prevalence of false advertising and misinformation; and absence of responsible bodies to actively and effectively provide appropriate information and education. In view of these findings, the following recommendations were given by the research proponents [50]:

   a. Establishment of a national policy regarding R&D for advanced health biotechnologies in Thailand, including a prioritization framework and scope;

   b. Development of a strategic plan, to be done every 5 years with an option of rolling revision if needed. The plan should be developed by a multi-sectoral team which include health professionals, scientists, policy researchers, patient groups, and the private sector.

   c. The government should develop and implement strategies to avoid monopolies by private manufacturers or providers. Starting from the R&D process,
public-private partnerships should be facilitated in an appropriate manner, avoiding over-reliance on a single group or private firm;

d. The government should allocate more resources to this field, with funding provided in a long-term collaborative way instead of the usual year-by-year basis, considering the long length of time it generally takes to develop a final advanced health biotechnologies product.

e. Setting of clear ethical standards for R&D to avoid research misconduct.

3.1.2.1 Drugs

A major development in the last two decades is the focus on drugs for neglected diseases, which affect more than 1 billion people worldwide. Since the majority of those affected are poor and living in developing countries, commercial markets that traditionally motivate pharmaceutical company investment in new product research and development are lacking. Investment in R&D for new products to prevent or treat neglected diseases increased substantially over the last two decades, primarily through public and philanthropic investment [51].

A study was done in 2011 using data from the Global Health Primer database on drugs and vaccines in development for neglected diseases which is maintained by BIO Ventures for Global Health. The study covered 348 unique organizations participating alone or in partnership with each other in the development of 374 drugs and vaccines for 23 neglected diseases. Among the study results are as follows [51]:

- The top 5 diseases in terms of the number of drugs developed/identified are: TB (49); malaria (44); leishmaniasis (20); dengue (11) and HAT (10).

- Academic/research institutions, better known for their contribution to the understanding of the basic biology of neglected diseases, represent the highest number of unique developers of drugs and vaccines. They also have the greatest breadth of disease focus, the highest number of products with participation, and are involved in every phase of development for both drugs and vaccines.

- Neglected disease product developers primarily represent developed countries.

Asia is emerging as a powerhouse of pharmaceutical R&D. The large number of patent expirations, decreasing R&D productivity and high costs of drug development are forcing big pharmaceutical companies to outsource their R&D operations to other locations. Asia is proving to be the most preferred destination to carry out their drug development activities. Availability of a vast patient population, low costs, R&D workforce and a favourable regulatory environment are the main driving forces to transform Asia into the hub of R&D activities [52].

The Chinese pharmaceutical market is one of the fastest growing in the world. It is estimated to be the fifth largest in 2010 and third largest by 2020. The country offers many advantages like economical costs and huge patient population. As compared to the West, the cost of carrying out clinical trials in China is 15% lesser for Phase I and 20 percent cheaper for Phase II/III. China also has the advantage of a cheap and educated R&D workforce [52].
India is another one of the most preferred Asian countries for R&D activities. Easy availability of patient pool, diverse disease profiles in the patient population, an estimated cost savings of 50 percent in Phase I studies and 60 percent in Phase II & III studies and well-equipped institutions with skilled professionals are the major driving forces behind this trend. The country has also become TRIPS compliant since the year 2005, which also makes its pharmaceutical industry more attractive. The drug laws are also being amended to allow same phase clinical trials as in the country of origin. In addition, India has regulations that provide fiscal incentives for R&D activities. It has the largest number of FDA approved plants after the US [52].

In the case of Thailand, the demand for pharmaceuticals made in the country is on the rise. Thailand’s pharmaceuticals market is currently valued at about 129 billion baht, with sales absorbed 78% by hospitals and 12% by drugstores. The strategic direction in the local industry is for value-added products. This includes encouragement for R&D on enhanced influenza and hepatitis C vaccines, blood pressure and anti-HIV drugs, herbal antiviral and anti-cancer treatments, and supplementary products such as for weight loss. Amid the upgrade to added value, governing agencies continue to achieve progress in GMP and WHO standards compliance, stamping out counterfeiting and unethical practices, speeding up the patent approval process, and opening the local market wider [53].

The Government Pharmaceutical Organization (GPO) which is under Thailand’s Ministry of Public Health also manufactures about 300 pharmaceutical, biological and natural products to help meet domestic and export demand. Currently, a GPO focus area is the formulation of antiviral and cardiovascular drugs, as related diseases are among the top causes of death in the country [53].

In the area of traditional medicine, there has been a recent push for the inclusion of more herbs in Thailand’s national Essential Drug List. The Minister of Public Health has recently announced that 5 to 10 herb items will be added to the country’s Essential Drug List every year. Their aim to increase the current number of 71 herbs in the list to 100 by 2015. This is in line with the national policy and program on traditional medicine of Thailand which was issued in 1993 [54].

3.1.2.2 Vaccines

Vaccines are one of the most effective and affordable tools in public health. WHO estimates that global immunization campaigns save more than 2.56 million lives every year, and protect millions more from disease and disability. Vaccines are remarkable cost-effective, with the costs of infectious diseases being a lot higher than the costs of immunization [55].

During the 65th World Health Assembly held in May 2012, the Global Vaccine Action Plan was endorsed. The Plan covers the period 2011-2020 which has been declared as the Decade of Vaccines. The vision for the Decade of Vaccines (2011–2020) is of a world in which all individuals and communities enjoy lives free from vaccine-preventable diseases [56].

The elaboration of the Global Vaccine Action Plan is guided by six basic principles, of which the sixth is innovation. This means that the full potential of immunization can only be realized through learning, continuous improvement, and innovation in research and development, as well as innovation and quality improvement across all aspects of immunization. The Plan has 5 goals, the fifth being focused on the development and introduction of new vaccines and technologies. To achieve the five goals of the Global Vaccine Action Plan, six strategic
objectives will be pursued of which the last two are related to R&D for vaccines production. These objectives and the corresponding indicators for evaluation are presented in Table 1.

<table>
<thead>
<tr>
<th>Strategic Objective</th>
<th>Key Indicators for To Monitor Progress</th>
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<tbody>
<tr>
<td>5. Immunization programmes have sustainable access to predictable funding, quality supply and innovative technologies.</td>
<td>• Percentage of routine immunization costs financed through government budget</td>
</tr>
<tr>
<td></td>
<td>• Globally installed capacity for production of universally recommended vaccines within 5 years of licensure/potential demand</td>
</tr>
<tr>
<td>6. Country, regional and global research and development innovations maximize the benefits of immunization.</td>
<td>• Proof of concept of a vaccine that shows greater or equal to 75% efficacy for HIV/AIDS, TB or malaria</td>
</tr>
<tr>
<td></td>
<td>• Initiation of Phase III trials for a first generation influenza vaccine</td>
</tr>
<tr>
<td></td>
<td>• Country R&amp;D capacity will be measured by institutional and technical capacity to manufacture vaccines and/or carry out related clinical trials and operational and organizational research</td>
</tr>
</tbody>
</table>

At the regional level, the Regional Vaccine Policy for South-East Asia Region was developed in 2003. The primary purpose of this policy is to provide a framework for decision-making on wide-ranging issues related to research, production, availability and distribution of vaccines in the Region. It has six specific objectives, of which the following are related to R&D for vaccines [57]:

- To provide a coordinated approach to establishing regional vaccine needs, including evaluation of current vaccine production capacity and suggested initiatives for determining burden of vaccine preventable diseases;

- To support and direct global and bilateral inputs to the countries in the Region, including developing a multilateral health research forum, advocating for GAVI-funded research initiatives in the Region, and facilitating public-private partnerships in vaccine development; and

- To provide guidance on establishing regional vaccine research and development (R&D) priorities in the global context and determine steps necessary to strengthen regional R&D, production, and necessary regulatory oversight capacity

Under the specific policy issue of vaccine research and development, the following policy approaches and activities were identified in the SEA Regional Vaccine Policy:

1. Given the large burden of vaccine preventable disease and the potential capacity for R&D in the Region, SEAR Member Country governments, research institutions, and manufacturers, should establish a Regional Vaccine Research Network to promote and advocate for local research as well as exchange information. This group should be formed in cooperation with global research coordination efforts such as the Developing Country Vaccine Manufacturers’ Network and the Initiative for Vaccine Research (IVR) of WHO.
2. A detailed assessment highlighting strengths and weaknesses as well as competitiveness of the existing regional manufacturing capacities should be undertaken, perhaps under the aegis of the proposed Research Network. An inventory of clinical research organizations (CRO), teams, and trial sites should be established and made available for the scientific community and manufacturers to speed up clinical and vaccine efficacy assessment in humans.

3. Public-private partnerships and additional partnerships between government and universities should be encouraged in order to facilitate vaccine R&D. Current programmes in some countries to provide soft loans to manufacturers should be expanded. At a minimum, the issues that should be considered for prioritizing regional vaccine R&D include:
   - Burden of disease particularly for the Region
   - Availability of alternative/complementary vaccines
   - Status of research globally
   - Financial viability
   - R&D capacity

4. Since large developing country manufacturers are in the SEA Region, the Regional Research Network should be empowered to address ethical guidelines and intellectual property rights issues (e.g. regarding transfer of technology) in the context of global standards. Regulatory capacity to oversee quality control in developing new vaccines in the Region should be expanded.

Thailand in particular has been quite active in the area of vaccine production. In 2011, the Cabinet approved the National Vaccine Strategy which aims to advance domestic capacity in safeguarding the country against vaccine-preventable diseases. The document identified four strategies to achieve its aims [58]:

1. Drive the implementation of the policy and strategic plan on the National Agenda on Vaccine by a central agency on vaccine;

2. Develop the capacity of the country’s personnel on vaccine to acquire sufficient knowledge and skills necessary for the mission;

3. Establish and develop the infrastructure necessary for research and development, production, and quality control of vaccine, ranging from research and development, to the use of vaccine; and

4. Support domestic research and development, and production of vaccine, including basic vaccines and vaccines needed for disease prevention and control in normal and epidemic situations.

The National Vaccine Strategy includes recommendations for human resources, infrastructure development, and domestic production of vaccines for ten diseases—dengue, diphtheria, tetanus, pertussis, mumps, measles, encephalitis, polio, hepatitis B, and tuberculosis. At present, Thailand produces only two out of 11 vaccine antigens routinely provided under the EPI. [58]

In 2011, the National Vaccine Institute of Thailand was established. [16]. Its goal is to strengthen the country’s preparedness against deadly diseases and reduce the high cost of imported vaccines.
Among the on-going R&D activities in Thailand related to vaccine production are [59]:

- BIO-NET Asia, a Thailand-based vaccine-focused biotech company has been working closely with NSTDA and with scientists in South Africa in pediatric vaccine development. Together they have successfully developed a 5-in-1 or ‘cocktail’ vaccine covering diphtheria, tetanus, pertussis, hepatitis B and meningitis in one shot. This vaccine is due for release within the next 5 years.

- BIO-NET Asia is also conducting research on a vaccine against Bordetella pertussis which causes whooping cough, and against Haemophilus influenzae type b (Hib) which is a pathogen that can cause meningitis and severe pneumonia. It is estimated that despite recommendations from the World Health Organization, three fourth of children worldwide are not yet immunized against Hib disease. One reason behind the insufficient vaccination program is the high cost of Hib vaccine; BIO-NET is working on the development of a low cost vaccine using high yield fermentation and conjugation technologies.

- The dengue program at NSTDA is one of the most advanced research collaborations in Thailand involving medical experts from a number of research institutes. A patent resulting from the collaboration was recently licensed to BIONET-ASIA for further development into a dengue vaccine. The 300 million THB investment is expected to lead to a locally produced dengue vaccine which will be available to the public in 5-8 years. This new vaccine will act as a preventive measure against the resurgence of epidemic dengue fever along Thailand’s borders.

- An ongoing study for the development of an HIV/AIDS vaccine has been conducted by the US National Institutes of Health, the US Military HIV Research Program and the Thailand Ministry of Public Health. The study, often referred to as the RV144 Thai vaccine trial was started in 2009 and involves 16,000 volunteers, 47 health centers and 8 clinical sites. It has shown very promising results which have been recently published in international journals like the Lancet and the New England Journal of Medicine [60].

- In 2009 the Thai Royal government decided to invest approximately USD $45 million to build an influenza vaccine plant. The plant is now under construction with the aim of producing two million doses of inactivated influenza vaccine by 2014. The plant's production can be expanded to ten million doses of influenza vaccine in the future [58].

3.1.2.3 Diagnostics and Medical Devices

The WHO Aide-Memoir for National Medical Device Administrations defines a medical device as an instrument, apparatus or machine used to prevent, diagnose or treat disease. It also serves to detect, measure, restore or modify the structure or function of the body for a given health purpose. It can range from a simple wooden tongue depressor or a stethoscope to the most sophisticated implants or medical imaging devices [61].

Thailand’s medical device market was worth more than $850m in 2012, and is set to expand at 7.5% annually over the next several years [62]. The responsibility for protecting consumer health by ensuring the quality, safety and efficacy of medical devices in the country is under
the responsibility of the Medical Device Control Division of Thailand’s Food and Drug Administration.

NSTDA has been actively supporting R&D activities for medical devices and related products. The following are examples of such health products which have been developed in the country:

a. A new device called G-breath has been developed by Dr. Srung Smanmoo, a researcher at the National Center Genetic Engineering and Biotechnology (BIOTEC), the National Science and Technology Development Agency (NSTDA), which detects ketones and other chemical markers such as acetone, ethanol, carbon dioxide and methyl nitrate in the breath of diabetic patients. Though the device is still at the prototype stage, it shows very promising signs of becoming an alternative to traditional invasive blood tests and could lead to a reduction in the number of cases of DKA [63]

b. Dental CT (DentiScan) is the first Thai-made prototype of computerized X-ray machine for dental treatment. It is a product of a collaboration between MTEC (National Metal and Materials Technology Center) and NECTEC (National Electronics and Computer Technology Center) for their hardware and software development, respectively. The machine has gone through a clinical trial in mid 2011 with more than 170 volunteers. It has obtained the Radiation Control Certification from Department of Medical Science, Ministry of Public Health, and has been certified by the Electrical and Electronic Product Testing Center (PTEC) of Thailand for its safety. Currently there are two machines built in this collaboration. A black color cone beam was projected on a flat panel detector installed on the opposite site of the X-ray tube. The equipment rotates around the patient head to collect the raw data from all angles. These data are then processed to derive a cross-cutting 3D image using image translation software. It helps eliminate problems of image distortion found from regular 2D X-ray machine. The 3D image helps dentists diagnose problems with teeth, jaws and facial bones more precisely. It also facilitates better analysis and effective planning for dental surgery such as removal of wisdom tooth, root canal treatment, mouth, jaw and facial surgery. In addition, imported CT scans are found to generate higher radiation, bulkier in size and costlier than the one made in Thailand [64].

c. The National Nanotechnology Center (NANOTEC), National Science and Technology Development Agency (NSTDA) has developed NNET NANO, a highly effective insecticidal bed-net. The mosquito bed-net is coated by a synthetic pyrethroid derivative, Deltamethrin, which is known for safe to human and all mammals. Deltamethrin is also approved by WHO and has been used worldwide. Moreover, NNET NANO was developed as a multifunction mosquito bed-net having various special properties i.e. anti-bacterial, anti-UV, and water repellent, which improve the shelf-life of the insecticidal effect. NNET NANO is suitable for daily use or during the flood which has normally infested by mosquitoes. [65]

d. NSTDA under its medical and public health clusters has been supporting Thai researchers to invent and develop medical diagnosis kits. Examples of such diagnostic kits which have already been developed are the following [66]:

- **Simple Test Kit for Alpha Thalassemia Carrier Screening** – The classification of alpha thalassemia carrier patients is not easy, so the medical profession needs the invention and development of a test kit that is rapid, cost-
effective, and helps avoid complicated patient diagnosis and classification procedures. Acknowledging this need, a research team from the Biomedical Technology Research Unit of the Faculty of Associated Medical Sciences, Chiang Mai University, has studied and developed a simple test kit which uses a solution or an antibody which is distinct to haemoglobin Bart's found in an alpha thalassemia carrier’s blood to detect the haemoglobin. This test kit uses only 3 minutes to perform a single test. It is convenient to use, inexpensive and is 99% accurate. Now the invention has been passed on to private companies for commercial manufacturing.

• **White Blood Cell Count Solution for General Automatic Blood Cell Counters** -- The method of counting CD4 cells is used to identify a patient's HIV/AIDS immune status which helps to predict the severity of their illness and determine the amount of anti-viral medication to be given to the patient. Currently, this is done using a flow cytometry machine, which is an expensive and complicated practice and is available only at certain hospitals. Acknowledging the need, a research team from the Faculty of Associated Medical Sciences, Chiang Mai University, has developed a new invention for white blood cell testing. The CD4 white blood cell test kit uses a solution to test a patient’s blood sample. The testing procedure no longer requires a flow cytometry machine, but requires only an automatic blood cell analyzer which is normally used in every hospital. The test kit gives accurate test results. It takes only one hour to perform each test and it is inexpensive. Now the invention has been passed on to private companies for commercial manufacturing.

• **Conjugate Solution for Rabies Diagnosis** -- Researchers from Queen Saovabha Memorial Institute of the Thai Red Cross Society have studied the procedures of conjugate solution preparation for rabies diagnosis. The viral disease is severe and invariably fatal and it has caused the loss of over 60,000 people’s lives each year. The standard procedure used to diagnose an animal with the disease is called the immuno-fluorescent detection technique. Labeling the conjugate solution with a fluorochrome, the areas of the brain where there are rabies viruses will illuminate under a fluorescent microscope once it is dyed in the solution. The sensitivity and the specification ability of detection depend mostly on the quality of the conjugate solution.

Researchers from Queen Saovabha Memorial Institute of the Thai Red Cross Society have studied the procedures of conjugate solution preparation from rabbits stimulated by rabies' nucleoproteins by separating the globulin protein from the serum and labeling it with a label with fluorescein isothiocyanate. The solution has been tested by five Rabies Autopsy Units in Thailand and all have confirmed the same results as those tested by the samples dyed in commercial solutions attained from outside the country. Currently, a private company is allowed to use the rights of this research to manufacture and distribute the invention for commercial purposes domestically and in foreign countries.

• **Bio-Sensor Bird Flu Diagnosis Kit** -- One of the successful bird flu preventive invention research and development projects that NSTDA has given its support to is the ‘Development of the Bio-Sensor Principle Bird Flu Diagnosis Kit’ which is effective and 100 times more accurate than the current method. Testing is easy and the results can be attained in 15 minutes. Also, it can be used to test animals that have not shown any symptoms.

The new bird flu diagnosis kit is an extension of research on the monoclonal
antibody which is used to diagnose several kinds of flu by developing the antibody into an H5 bird flu test kit. One test kit includes a testing stripe and a set of H5 bird flu interception solution. Researchers have found that a bio-sensor test kit takes only 15 minutes to test a sample while its accuracy is higher than currently-used immuno-chromatography, which takes more time and the result analysis can be done with the naked eye. Moreover, such tests require a greater amount of bird flu virus sample in order to perform an accurate diagnosis, so it is more appropriate to perform such diagnoses on animals with visible bird flu symptoms. The Bio-sensor test kit, on the other hand, can identify that an animal has bird flu even though the sample taken from it contains 100 times smaller amount of the bird flu virus, which also favors early infection diagnosis.

Now, this new bio-sensor principle bird flu diagnosis kit has a patent pending and later it will be registered with international organizations. The invention will be passed on to Innova Biotechnology Co., Ltd. who will manufacture and distribute the test kits under the names of INNOVA Platinum® H5 Biosensor and AIV Biosensor, the latter is used to detect the H5 and avian influenza A (AIV). These test kits will be the world’s first bio-sensor bird flu diagnosis kits.

- **Thai Red Blood Cells Test Kit** -- Testing for a reaction between the antigen and the antibody of red blood cells is the basic test in the blood bank laboratory. The development of the Gel Test technique will help to avoid errors that occur from identifying results using a sample-shaking technique of test tubes. The results can also be re-read anytime by anyone.

Researchers from Khon Kaen University successfully developed the “Test Kit for Antigen-Antibody’s Reaction on Red Blood Cells” by producing three different Microtube Gel Tests: Neutral Gel, Antiglobulin Gel and Specific Gel, which can be used to test for the reaction between the antibody and the antigen on the surface of red blood cells as effectively as using test tubes. Additionally, the test kits come in the forms of microtube and microstrip gel test, which can test 1-12 samples at a time. The microstrip can be assembled into a microplate to use with an 8 or 12 channel pipette for convenient use. It saves time and money, uses fewer staff, and helps decrease the number of errors.

The test kit is appropriate for daily use, especially in huge laboratories that have to handle many samples each day. The trial kits have also been used at the central blood bank of Srinagarind Hospital, Khon Kaen province and received satisfactory feedback. The research team has already filed for the product’s patent.

- **Integrated Influenza Test Kit** -- The collected data since the spread of the new swine flu 2009 show that the A H1N1 influenza virus that caused the spread has resisted drug action and is now unresponsive to treatment. Consequently, Thailand needs to prepare diagnosis procedures to be able to identify the breed of the virus in a patient and inspect the cause of any unresponsive treatment in order to help doctors decide which type of medication is the most appropriate for each patient to regain control on the spread.

Researchers from the Faculty of Medicine, Ramathibodi Hospital, Mahidol University, have developed a new “All-in-One” integrated influenza test kit to be used with the pyrosequencer machine. The same procedure is recommended by the World Health Organisation (WHO) for testing the unresponsiveness of amantadine and oseltamivir and allows doctors to perform tests on several samples at once. Helping doctors identify the activation time of amantadine and
oseltamivir, and the time taken until the virus becomes unresponsive to medication, it can identify whether a patient is infected by H5N1 bird flu, seasonal influenza H1N1, the new swine flu 2009, or H1N12009 within 4-6 hours after receiving a sample. Performing a test costs around Bht. 500 (excluding management and instrument expenses), which is about the same price as a real-time PCR kit. This invention is now available for actual use at Ramathibodi Hospital and is ready to be passed on to the laboratories concerned.

3.2 Consultative Meetings

Part of the methodology for this project was the conduct of a series of Consultative Meetings among three groups of stakeholders in the country’s research and development activities. These are the:

a. health policy makers and planners;
b. researchers and academicians; and the
c. pharmaceutical industry

The objectives of these meetings were presented earlier in Section 2.1.2 of this report. In each of these meetings, two presentations were made by members of the Project Team on the following topics:

a. Overview of the project, to provide the participants a better understanding of the background, rationale and objectives of the project in general and of the Consultative Meetings in particular; and

b. Norms and standards currently used for classifying research and development activities, to provide the participants with a brief overview of current practices in the health and non-health sectors in this area

A copy of these presentations are presented in Annex 1a and 1b of this report. The results of these Consultative Meetings are presented in the following sections.

3.2.1 Meeting with Health Policy Makers and Planners

The meeting with policy makers and planners was held at the SEAMEO-Tropmed Conference Room on 26 June 2013. It was attended by 24 participants who were the Directors, high-level officials and representatives of the following research and research-related institutions and organizations in Thailand:

a. Ministry of Public Health (MoPH)
   - Food and Drug Administration
   - Department of Medical Sciences
   - International Health Policy Program
   - Bureau of Vaccine Policy Development, National Vaccine Institute
   - Health Systems Research Institute
   - Department of Disease Control
     - Bureau of Emerging Infectious Diseases
     - Bureau of Non-Communicable Disease
     - Bureau of Knowledge Management

b. National Science and Technology Development Agency (NSTDA)
c. National Science Technology and Innovation Policy Office
d. Thailand Center of Excellence for Life Sciences (TCELS)
e. Pharmaceutical Research and Manufacturers Association

The meeting was also attended by Dr. Monisha Sidhar, Regional Adviser for Intellectual Property Trade and Health of WHO-SEARO, who provided additional inputs to the participants on the background and importance of their active participation in the meeting. The complete list of participants for the meeting of health policy makers and planners is presented in Annex 2a.

The participants were divided into two groups for the group discussions. The following are the important results of the group discussions conducted by the policy makers and planners:

1. Various offices have their own basis of classifying their R&D activities, which are based on any of the following:
   a. Local/Institutional policies issued by their respective Boards of Directors or Research Committees
   b. Policies issued by national research and research-related bodies/organizations like the National Research Council, National Vaccine Committee, or the Science Innovation and Technology Office (STI)
   c. International classification schemes like the WHO 6 Building Blocks for health systems and the ISO standards

2. The policy makers and planners were in agreement that there is a need for Thailand to develop its own norms and standards for the classification of health R&D activities. They further recommended that the development of a unified set of norms and standards for Thailand can be done by undergoing the following process:
   a. Review the existing international and national norms and standards for R&D classification currently used;
   b. Convene a working group which will conduct a series of fora and meetings to assess the need for a unified set to be used by researchers and research institutions in the whole country and prepare a draft of the norms and standards; and
   c. Conduct a series of consultations with various stakeholders to refine and finalize the unified norms and standards for R&D classification to be used in Thailand.

3. Dr. Yongyuth, former Minister of Science and Technology who participated in the meetings suggested that Thailand can start by using a simple and basic classification system using only 4 categories of research activities:
   a. Clinical
   b. Epidemiologic
   c. Biomedical; and
   d. Public Health

The use of a simple classification scheme can first be tested, and additional categories can be added with time.
4. The current priority areas for health R&D and the corresponding activities/projects currently undertaken in line with these priority areas identified by the policy makers and planners are as follows:

<table>
<thead>
<tr>
<th>PRIORITY AREAS</th>
<th>ACTIVITIES/PROJECT UNDERTAKEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine development for the following diseases:</td>
<td>Dengue and JE vaccine development (pre-clinical phase)</td>
</tr>
<tr>
<td>• Dengue</td>
<td></td>
</tr>
<tr>
<td>• Japanese encephalitis</td>
<td></td>
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<tr>
<td>Development of diagnostic kits for vector-borne diseases</td>
<td>Diagnostic rapid test for malaria</td>
</tr>
<tr>
<td>Development of medical devices</td>
<td>Medical robotics</td>
</tr>
<tr>
<td>Health risk assessment (covering 8 areas);</td>
<td>Genetic risks</td>
</tr>
<tr>
<td>Wellness and health</td>
<td>Cell and gene therapy</td>
</tr>
<tr>
<td>Public health surveillance</td>
<td>Surveillance for disease mutation</td>
</tr>
<tr>
<td>• Emerging and re-emerging diseases</td>
<td>Anti-microbial resistance</td>
</tr>
<tr>
<td>• Food safety</td>
<td></td>
</tr>
<tr>
<td>Orphan product development</td>
<td></td>
</tr>
</tbody>
</table>

5. Several basis for identification of current priorities were identified including the country strategy, MOPH policy and strategy, technology roadmap, vision and mission of their respective organizations, as well as the burden of disease.

6. The policy makers and planners recommended the following priorities for R&D on health products and the corresponding projects to be implemented to develop and deliver these priority health products:

<table>
<thead>
<tr>
<th>RECOMMENDED PRIORITIES FOR R&amp;D ON HEALTH PRODUCTS</th>
<th>RECOMMENDED PROJECTS/ACTIVITIES TO BE IMPLEMENTED TO DEVELOP/DELIVER HEALTH PRODUCTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccines</td>
<td>Vaccine development for the following diseases:</td>
</tr>
<tr>
<td></td>
<td>• Dengue</td>
</tr>
<tr>
<td></td>
<td>• HPV</td>
</tr>
<tr>
<td></td>
<td>• HIV (licensing agreement); GMP plant; clinical trial III</td>
</tr>
<tr>
<td></td>
<td>• Malaria</td>
</tr>
<tr>
<td></td>
<td>• Japanese encephalitis</td>
</tr>
<tr>
<td></td>
<td>• Leptospirosis</td>
</tr>
<tr>
<td></td>
<td>• Influenza</td>
</tr>
<tr>
<td>Diagnostic kits/Rapid tests</td>
<td>Pharmacogenomics; Naverapine</td>
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<tr>
<td></td>
<td>Screening kits for cancer</td>
</tr>
<tr>
<td></td>
<td>Markers for NCDs</td>
</tr>
<tr>
<td></td>
<td>Markers for diseases indigenous to Thailand</td>
</tr>
<tr>
<td>Orphan and neglected diseases</td>
<td>DHFR, malaria</td>
</tr>
<tr>
<td></td>
<td>Dengue vaccine</td>
</tr>
<tr>
<td>Biological products</td>
<td>Growth hormone</td>
</tr>
<tr>
<td></td>
<td>Monoclonal antibody; cancer</td>
</tr>
<tr>
<td>Regenerative medicine/therapeutics (cell and</td>
<td>Clinical research on thalassemia</td>
</tr>
<tr>
<td>gene therapy)</td>
<td>Stem cell</td>
</tr>
</tbody>
</table>
3.2.2 Meeting with Researchers and Academicians

The second of the series of Consultative Meetings was attended by researchers and academicians. It was held on 27 June 2013 at the SEAMEO-Tropmed Conference Room. The meeting had 18 participants who were the Heads and representatives of the following institutions:

a. Mahidol University
   - The Mahidol Oxford Tropical Medicine Research Unit (MORU)
   - Mahidol Vivax Research Center, Faculty of Tropical Medicine
   - Dept. of Tropical Nutrition and Food Science
   - Center of Excellence for Antibody Research, Faculty of Tropical Medicine
   - Dept. of Tropical Hygiene, Faculty of Tropical Medicine
   - Dept. of Biotechnology, Faculty of Science
   - Dept. of Pharmacology, Faculty of Science
   - Faculty of Pharmacy
   - Division of Instruments, Office for Research and Development, Faculty of Medicine, Siriraj Hospital

b. Chulabhorn Research Institute
   - Laboratory of Pharmacology
   - Laboratory of Immunology
   - Laboratory of Natural Products

c. Armed Forces Research Institute of Medical Sciences (AFRIMS)

d. Thai Red Cross AIDS Research Centre
   - HIV-NAT Medical Department
   - CRA Department

e. Medical Molecular Biology Research Unit (BIOTEC)
f. Health Technology Systems, Health Systems Research Institute
g. Office of the National Research Council of Thailand

The highlights of the group discussions among the researchers and academicians were as follows:

1. As in the case of the policy makers and planners, each institution, unit or department within a university follow their own system of classifying their research and development activities. These are usually based on policies set by their respective faculty or research committees. In the case of the Mahidol Oxford Tropical Medicine Research Unit (MORU), they use the Integrated Research Information System (IRIS) to classify R&D activities according to funding sources, department, type of activity and students. MORU is a collaborative project between Mahidol University, Oxford University and Wellcome Trust which was established in 1979. Hence their system of classifying their R&D activities is based on the information system used within their own network which is IRIS.

   In the case of national research and research-related institutions represented in the meeting, they cited the policies of the National Economics and Social Development Board (NESDB) as basis of the norms and standards they are currently using.

2. A very important input shared during the meeting by the Executive Board Director of the Office of the National Research Council of Thailand, is a recommendation given by the Health Intervention and Technology Assessment Program (HiTAP) for Thailand to use a modified version of the Health Research Classification System
(HRCS) developed by UK as basis for the classification of its health R&D activities. She got this information during a very recent meeting she attended. HiTAP recommended the use of 9 major categories of research activities namely:

a. Underpinning research  
b. Aetiology  
c. Prevention of diseases and conditions, and promotion of well-being  
d. Detection, screening and diagnosis  
e. Development of treatments and therapeutic interventions  
f. Evaluation of treatments and therapeutic interventions  
g. Management of diseases and conditions  
h. Health and social care services research  
i. Health policy and systems research  

Of the 9 research categories recommended by HiTAP, the first 8 are the major categories used in the HRSC. The ninth category is an additional category suggested by HiTAP to meet the specific needs of Thailand.

3 Several current priority areas in health were identified by the participants covering the following:

• Drugs  
• Diagnostics  
• Pathophysiology  
• Mathematical models  
• Pharmacology  
• Vaccine development and production  
• Vector control  
• Clinical management  
• Social science  
• Cancer research  
• Nutrition  
• Natural products  
• Environmental science; environmental toxicology (ex., heavy metals in the industrial areas)  
• Viral research  

4 The identification of current priority areas in health are based on the plans, strategies and priority areas identified by the respective institutions, like the strategic plan and research policy of the universities. For example, in the case of Mahidol University, the University identified the following 12 priority areas in awarding grants for goal-oriented research and for collaborative research projects:

a. Post genomic medicine  
b. Tissue engineering  
c. Bio-engineering  
d. Stem cell research  
e. Systems biology  
f. Aging  
g. Food security  
h. Material science and engineering  
i. Nanotechnology and nanoscience  
j. Research to seek measures to control and prevent major diseases and unhealthy conditions in Thailand both at present and in the future (ex., accidents, heart and blood vessel diseases, cancer, infections, drug addiction)
k. Research to prevent/diminish problems related to global warming; and
l. Environment and water resource management

In the case of AFRIMS which is the research arm of the military, among their priority areas are infectious diseases important to the military like dengue and leptospirosis, as well as surveillance of HIV infection in the borders of Thailand with Myanmar and Cambodia.

5 In terms of sources of research funds, the academicians and researchers have several options:
   a. Internal sources – Possible internal sources of research funds are:
      • University research funds granted to faculty members who are interested to conduct research within the priority areas identified by the University
      • Funds coming from national institutions like the National Research Council of Thailand (NRST), the National Science and Technology Development Authority (NSTDA), Thailand Research Fund (TRF) and the Health Systems Research Institute (HSRI). Each of these institutions have their own priority areas for research and their own criteria for granting research funds. For example, TRF is focused on capacity building and gives research grants to senior scholars who are required to involve and develop new researchers in the process of conducting their research.

   b. External sources – this refers to funding from international organizations which fund health R&D activities like WHO, the Gates Foundation, USAID, and others. For these types of R&D activities, the researchers generally pursue their individual research interests irrespective of the national priorities or the priorities set by their institutions.

6 The following are the recommendations of the researchers and academicians for priority areas for R&D on health products, and corresponding projects and activities to be implemented for the development and delivery of such products:

<table>
<thead>
<tr>
<th>RECOMMENDED PRIORITIES FOR R&amp;D ON HEALTH PRODUCTS</th>
<th>RECOMMENDED PROJECTS/ACTIVITIES TO BE IMPLEMENTED TO DEVELOP/DELIVER HEALTH PRODUCTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis</td>
<td>Development of diagnostic kits for infectious diseases, NCD, genetic screening, etc.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Drug development using natural and chemical products</td>
</tr>
<tr>
<td>Vaccines</td>
<td>Vaccine development for Infectious diseases and cancer</td>
</tr>
<tr>
<td>Devices</td>
<td>Development of life support and safety devices</td>
</tr>
<tr>
<td>Control and prevention program</td>
<td>Conduct of public engagement campaign</td>
</tr>
</tbody>
</table>

In addition to the above, the following are also recommended for inclusion among the priority areas for health R&D in Thailand:

   a. Infectious diseases such as malaria, TB, dengue, and liver fluke
   b. Non-communicable diseases
   c. Nutrition and food safety
   d. Maternal and child health and aging
   e. Environmental health
   f. Health systems research
3.2.3 Meeting with the Pharmaceutical Industry

The last meeting was conducted among representatives of the pharmaceutical industry and related institutions. It was held on 28 June 2013, also at the SEAMEO-Tropmed Conference Hall. It was attended by 8 participants coming from the following institutions:

- Food and Drug Administration
  - Medical Device Control Division
  - Drug Control Division
- Pharmaceutical Research and Manufacturer’s Association
- The Government Pharmaceutical Organization
  - Biological Product Department
  - Sales and Marketing Department
- Faculty of Pharmaceutical Sciences, Chulalongkorn University
- Faculty of Science, Mahidol University

Because of the small number of participants, they were no longer divided into groups. In addition, the meeting was conducted only for half a day since it was faster to generate consensus on the same issues discussed during the first two meetings.

Important agreements reached during the meeting among representatives of the pharmaceutical industry and related institutions were as follows:

1. They agree that Thailand must develop its own norms and standards for the classification of its health research and development activities. In particular, they are amenable to adopting the classifications used by the HRSC system under the category on pharmaceuticals, as follows:

<table>
<thead>
<tr>
<th>5. Development of treatments and therapeutic Interventions</th>
<th>Discovery and development of therapeutic interventions and testing in model systems and preclinical settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1 Pharmaceuticals</td>
<td>- Identification and development of pharmaceutical small molecules, therapeutic vaccines, antibodies and hormones including:</td>
</tr>
<tr>
<td></td>
<td>- pharmacogenetics, prediction of genetic variation and responses to drugs</td>
</tr>
<tr>
<td></td>
<td>- drug screening and development of delivery systems</td>
</tr>
<tr>
<td></td>
<td>- Mechanism of action including side effects and drug resistance</td>
</tr>
<tr>
<td>6. Evaluation of treatments and therapeutic Interventions</td>
<td>Testing and evaluation of therapeutic interventions in clinical, community or applied settings</td>
</tr>
<tr>
<td>6.1 Pharmaceuticals</td>
<td>- Small scale settings and pilot studies</td>
</tr>
<tr>
<td></td>
<td>- Phase I, II, III and IV trials</td>
</tr>
<tr>
<td></td>
<td>- assessing sensitivity, efficacy, specificity, relapse, survival, therapeutic value, pharmacokinetics, reproducibility and safety</td>
</tr>
<tr>
<td></td>
<td>- studies monitoring response, outcome,</td>
</tr>
</tbody>
</table>
7. The current R&D priorities of the pharmaceutical industry are in 3 areas as follows:
   a. Vaccine development
      • Dengue vaccine
      • Flu vaccine – In relation to this, they also mentioned the need for planning
        for the flu pandemic, as an issue of national security
   b. Drugs
      • Biosimilar/Biobetters/Biosuperior
      • Anti-malarial drugs
      • Orphan drugs (ex., for melioidosis)
   c. Quality assurance for medicinal products
      • Substandard drugs
      • Counterfeits

8. Among the current activities undertaken in relation to the above priorities are the:
   • establishment of a clinical research network (i.e., MedResNet)
   • promotion of good clinical practice (GCP)

9. Future activities to be conducted to develop and deliver health products for Thailand
   are as follows:
   a. Conduct of a survey to assess the current status of the pharmaceutical industry
   b. Capacity building activities (Human resources, especially preclinical research
      personal GLP, early-later stage development, translational research, regulatory
      bodies)
   c. Management of R&D value chain
   d. Strengthen Intellectual Properties
   e. Provision of Infrastructure for R&D (translational research)

3.3 Key Informant Interviews

The key informant interviews had 5 participants who were selected either based on their
current or past designations or on the activities they are currently undertaking in relation to
health R&D in Thailand. The names of the 5 key informants interviewed for this project and
their designations were listed earlier in Section 2.3 of this report.

Three sets of important information were derived from the key informant interviews:
   a. Identification of agencies/institutions and names of persons within these institutions
      who should be invited to the Consultative meetings;
   b. Roles and inter-relationships among various national research organizations in
      agenda-setting, identification of priorities and allocation of research funds
   c. Status of the project to determine norms and standards for the classification of health
      R&D activities in Thailand, conducted by HiTAP
3.3.1 Role of National Research Agencies in Agenda Setting, Prioritization and Fund Allocation

Based on the information provided by the key informants, the research institution involved with the main task of setting the research agenda for the country is the National Research Council of Thailand (NRCT). However, it is not the only one in the country since there are several other institutions which are supported by law, which also set their own research agenda and identify their own research priorities. These other institutions include, among others, the National Science Technology and Development Authority (NSTDA), the National Science Technology and Innovation Office, the Thai Research Fund (TRF) and the Health Systems Research Institute (HSRI). This results in lack of coordination and overlapping of some functions. According to one key informant, “It is a system with too many agencies involved which are not connected to one another”.

About a quarter (25%) of the total research funds for the country is allocated to health research. Of the budget for health research, about two-thirds goes to Health Systems Research Institute while the rest goes to the Thai Research Fund and the academe. A major thrust of Thai Research Fund is capacity building. TRF allocates 2.5M baht of its budget for research grants for Senior Scholars who are identified based on their tract record for research. One of the requirements of the research grant for Senior Scholars is for them to develop and involve young researchers in the conduct of their research.

Among the academic institutions, the largest budget goes to Mahidol University. According to one of the key informants, one of the issues related to the allocation of government research funds to the universities is under-utilization especially among smaller universities who do not have the faculty who are capable of conducting good quality research projects.

3.3.2 Norms and Standards for the Classification of R&D Activities in Thailand

During the second Consultative Meeting, one of the participants mentioned about a current project to develop norms and standards for the classification of R&D activities in Thailand. This project is conducted by the Health Intervention Technology Assessment Program (HiTAP) of the Ministry of Health. To determine the current status of this project, the Project Team interviewed two of its Principal Investigators as key informants.

The task of developing norms and standards for the classification of health R&D activities in Thailand is part of a bigger project looking at health systems, polices and governance. It is funded by the NRCT and is scheduled to be completed in July 2013. It was included as one of the project objectives since they recognize the absence of a unified classification system for R&D in Thailand, and the resulting problems especially in terms of monitoring and evaluating R&D activities.

After reviewing several existing classification systems, the project proponents decided to recommend the use of the Health Research Classification System (HRCS) developed in the UK with some modifications. They decided that it is more advantageous to adopt this existing system instead of developing an entirely new one for Thailand, because of the following reasons:

1. It has already been extensively tested and shown that it can be used retrospectively. Based on the UK experience, they were able to classify 90% of their research activities based on this system.
2. It is a simple system which can be easily understood even by a non-specialist. In addition, the research categories under this system are neither too few nor too many.

The project proponents are recommending that Thailand should adopt the 8 research activity codes used in the HRCS. These were listed earlier in Section 3.2.2 of this report. In addition to the use of the 8 HRCS research activity codes, they are recommending the addition of a ninth category on health policy and systems research which will have the following sub-areas:

1. Research to study the potential and the appropriate roles of the agencies involved in the distribution of power;

2. Research to develop good governance in the management and use of the limited resources of the national, provincial and local levels;

3. Education to integrate the collaboration of several professionals to fix problems cause by the interaction between human, animals, and the environment;

4. Research to develop a national policy;

5. Research for development and methods for monitoring and evaluation of public or health policy;

6. Research to improve health systems in order to reduce the disparity between the benefits;

7. Research and policy development in the rational use of technology by integrating various sectors;

8. Research for the development of health workforce management system for a sufficient number; and

9. Research for the development of rules and standards in order to support research and development of health care products, especially product that use bio-technology to produce products or provide services

The recommendations of the HiTAP project on the norms and standards for classifying R&D activities in Thailand were presented in a meeting to the NRCT Board. Several questions were raised during the meeting especially in relation to the uni-dimensionality of the proposed categories. In addition, researchers who field of specialization are in the basic health/medical sciences felt that the proposed categories were not adequate to reflect their research activities. Further discussions are needed to resolve the issues raised by NRCT before the recommended classification system will be accepted and implemented in the country.

An additional information derived during the interviews conducted is that a similar project, investigating a classification system for R&D activities in the country is also being conducted by faculty members in Chiang Mai University.
4. SUMMARY AND DISCUSSION OF RESULTS

4.1 Norms and Standards for the Classification of Health R&D Activities

This study has shown that there are several existing norms and standards for classifying R&D activities, both health-specific as well as covering all research areas. However, researchers in Thailand are not currently using a unified system of classification. One important output of the Consultative Meetings conducted for this project is a consensus reached among all three groups of R&D stakeholders – health policy makers and planners, researchers and academicians, and the pharmaceutical industry – that there is a need for the country to use a uniform system of classifying health R&D activities. They do not have to start from zero since initial research has already been conducted on the development of such a classification system, with the researchers recommending the use of a modified version of the HRCS developed in the UK.

4.1.1 Development of Norms and Standards

The process of developing norms and standards for classifying R&D activities is a very tedious one involving the different stakeholders from the very wide variety of specialized sub-areas within health and medicine. The crucial points in the development of such a classification system are the identification of people involved in determining the various classification categories to be used, and the process of consensus-building among several key players in such an activity.

The identification of resource persons who will be asked to participate in determining the classification categories to be used is very crucial since people may have different concepts of relevant categories depending on their roles (i.e., whether a practicing researcher, a research manager, a funding agency or a user of research results and products) and their area of expertise and research application (i.e., whether basic or applied science, laboratory or field, etc.) In the case of Thailand, the people who were doing the initial project of classifying R&D activities were health economists doing health systems research hence when the initial recommendations were presented to NSTDA, those who work in the basic health sciences and in the laboratories could not relate and felt left-out in the initial categories recommended. It is very important for the group of resource persons to be heterogeneous, with the various sub-areas within health and medicine represented, to ensure that the resulting categories are exhaustive.

The process of building consensus for the final classification categories to be used can be a long and tedious one, involving several revisions and iterations of the initial list. Since not all resource persons who will be asked to determine the classification categories can be expected to come from one place, the use of consensus-building methods like the Delphi technique can be applied [67].

In the process of finalizing the categories for classification of R&D activities, it must always be borne in mind that the resulting system must be simple to use, relevant to the country’s needs, consistent even after modifications are made with time, standardized, multidimensional and flexible. In addition, it must be robust enough to be applicable even when there are differences in operational processes among research institutions and sectors. Inter-operability in the presence of different research information systems being used can be an issue which should be addressed [36].
4.1.2 Health R&D Observatory

Although the concept of a health R&D observatory was not tackled in the Consultative Meetings and in the Key Informant Interviews conducted for this project, its establishment is one of the key recommendations in WHA65.22 [11], SEA/RC65/R3 [1] and WHA66.22 [6]. As such its establishment at the national, regional and global levels have to be discussed. In addition, this is one area for immediate application of norms and standards for the classification for R&D activities.

The importance of the role of a Health R&D Observatory cannot be overemphasized. At the global level, a Global Health R&D Observatory will need to operate as the hub in a network of national and/or regional observatories, and either establish common or harmonize existing standards so that information can be aggregated, compared, analyzed, and utilized to inform policy. It should also work in close collaboration with other organizations that currently gather data on science and technology indicators (e.g. UNESCO, OECD, etc), and other agencies working on innovation indicators such as WIPO. It should collect, distil, and analyze different types of data, including inputs (ex., investments, number of researchers), activities (ex., projects, clinical trials), outputs (ex., publications, inventions) outcomes (ex., new products) and impacts (health impact) [68].

There are existing R&D databases within research institutions in the country which can be used as part of the national R&D observatory. The issues to be addressed in establishing a national R&D observatory include the goals and objectives of the observatory, the management/organizational structure, the types of data to be collected and the methods for data collection, data quality control mechanisms, effective data dissemination and utilization processes to be adopted, including the transformation of information into policy. Another very important issue to be addressed is the role of the national health R&D laboratory at the regional and global levels.

4.2. Priorities for Health Products

The priority setting process in this country study started with the identification of relevant stakeholders for health R&D in the country. The stakeholders consisted of policy makers and technical people who develop the policies that provide the direction for health R&D of the country; the research institutions and the academe that implements research projects, and the pharmaceutical group that are involved also in research and manufacturing of health products.

The study made sure that these stakeholders in health R&D of the country participated in the series of meetings organized and/or were interviewed. This is to ensure that the findings will reflect the collective thinking of the different stakeholders in defining the priorities for health products. The review of related literature in the country also validated and complemented the findings during the meetings and the interviews.

The priority setting process for health R&D during the consultative meetings was implemented through the conduct of small group discussions. In the small group discussions participants reviewed the current research areas in health R&D as well as the existing policies that guided the research activities. Then the discussion proceeded to the identification of priority areas for health products’ R&D.

The bases for the prioritization utilized by the different groups are national R&D policies, health policy plans of the country, research and academic institutions’ missions, goals and research agenda as well as the burden of disease/priority health needs of the country.
The table below summarizes the priority areas as identified by the three groups of stakeholders and by the literature review.

Table 2: Priority Areas/Projects for Health Products R&D

<table>
<thead>
<tr>
<th>Priority Areas/Projects</th>
<th>Policy makers</th>
<th>Researchers</th>
<th>Pharmaceutical group</th>
<th>Literature review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine Development (Dengue)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>“Ophan” product development (Meliodosis)</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Diagnostics/Screening kits (For infectious, diseases, NCD &amp; cancer markers)</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug development using natural products/medicinal herbs</td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

4.2.1. Vaccine Development

The different groups of stakeholders were in agreement in the inclusion of vaccine development as one of the priority areas for health R&D of the country. Thailand has accelerated its efforts towards vaccine development and production. It has elevated the Office of the National Vaccine into an Institute in 2011 under the Department of Disease Control of the Ministry of Public Health [16]. A National Vaccine Strategy was approved by the Cabinet in 2011. The strategy aims to advance domestic capacity in safeguarding the country against vaccine-preventable diseases. The plan includes recommendations for human resources, infrastructure development and domestic production of vaccines for ten diseases- dengue, diphtheria, tetanus, pertussis, mumps, measles, encephalitis, polio, hepatitis B and tuberculosis. At the moment, the country produces only two out of the 11 vaccine antigens scheduled in EPI. This national vaccine strategy aims not only for the country to be self-reliant but also to meet the regional needs. Furthermore, in 2009, the government decided to invest approximately USD 45 million to build an influenza vaccine plant [69]. In addition, a facility known as the National Biopharmaceutical Facility (NBF) is existing which aims to be the center of technology transfer for vaccine production which will ensure that the country will meet international standards [70].

Thailand is also a provider of clinical trials. There are several reasons why the country is an important clinical- trials provider. The country offers faster patient enrollment, lower dropout rates, and higher patient concentration per trial site in addition to a less expensive workforce [71].

Public-private partnership (PPP) plays an important role in accelerating the country's capacity for vaccine development. This is embodied in the national Vaccine Strategy. Two notable PPPs in vaccine development are:

1. Collaboration of NSTDA with BIO-NET Asia which is a vaccine focused biotech company
2. Joint venture between the Thai government and Sanofi Pasteur (GPO_Merieux) that is manufacturing innovative vaccines that meet regional needs [72].
4.2.2. Orphan Drugs

The area of orphan drugs is another priority research area identified by the different groups of stakeholders. An orphan drug as defined by Wikipedia is a pharmaceutical agent that has been developed specifically to treat a rare medical condition, the condition itself being referred to as an orphan disease [73]. Thus, investing in the development and manufacture of an orphan drug is not profitable. In 1983, the US enacted what is known as the Orphan Drug Act which aimed to provide incentives to manufacturers for them to invest in the development and manufacture of these types of drugs. This was followed by similar acts in 1991 in Singapore, 1993 in Japan, 1997 in Australia, and in 2000 in the European Union.

An economic analysis of orphan versus non-orphan drugs done by Thomas Reuters Life Sciences consultants showed that although orphan drugs are targeting a smaller population, the high cost of treatment and the incentives provided by the Orphan Drugs Act such as tax break, extended exclusivity, and shorter clinical trials have made top orphan drugs as equally profitable and viable as non-orphan one. In addition, orphan drugs can command higher prices [74]. FiercePharma’s 2013 Orphan Drug Report reveals that orphan drugs are now showing a greater return on investment than products aimed at larger patient pools [75].

In Thailand, an interview with the then Managing Director of GPO, Witit Artavatkun reveals that GPO is “looking more and more at orphan drugs”. And that the GPO profit submitted to the Finance Ministry are used for public goods such as the production of medicines to respond to emergency situations, e.g. influenza pandemics and to produce orphan drugs needed by the country [76]. The orphan disease of Thailand identified in the consultative meetings with policy makers and pharmaceutical group is melioidosis.

4.2.3 Diagnostics/Screening Kits

Inexpensive and specific diagnostic kits are needed both for infectious diseases and NCDs for purposes of improving clinical management, surveillance and outbreak investigations. The use of these diagnostic kits can result to reduced morbidity and mortality. Thus, diagnostic/screening kits have been identified as a priority research area in this study.

There are several commercially available diagnostic kits/tests but the performance of these kits/tests has not been adequately evaluated. For example, a number of rapid, POC tests for dengue are commercially available in developing countries. Several studies have shown that the majority of rapid tests for dengue are neither sensitive nor specific enough for use in cases where short turnaround times are critical. Further, faulty POC devices and the inappropriate use of these devices present risks to patients and health-care workers through the generation of incorrect results. Unfortunately, some companies are not familiar with the required diagnostic product specifications that would address clinical and public health needs in resource-poor settings [77].

In Thailand, in addition to the commercially available diagnostic kits, universities and research institutions are also involved in the development of diagnostic kits. Moreover, NSTDA provides support to researchers to invent and develop medical diagnostic kits. Examples of these kits are cited in Section 3.1.2.1 of this report.
4.2.4. Natural Products/Medicinal Drugs

Drug development using natural products/medicinal herbs was identified as a priority area by the researchers and by the pharmaceutical group. However, the non-inclusion of this priority area in the group of policy makers does not mean that it is not considered as such. The rational given for the exclusion of this area during the meeting with policy makers is that this is a broad area of concern that needs to be discussed separately.

Its inclusion in the priority areas for health R&D in this study underscores the fact that the Thai government attaches greater importance to traditional medicine and indigenous herbs. This can be seen in the following policy statements of the government gathered from the literature review.

(i) The National List of Essential Drugs (NLED) of Thailand includes herbal drugs and hospital formulary to promote national self-reliance [78]

(ii) The National Drug Policy (NDP) also states as one of its objectives”

“the development of the domestic drug industry, biological products and medicinal herbs for self-reliance” [79]

An interview with the Public Health Minister Wittaya Buranasiri also underscores the importance placed on medicinal herbs by the Thai government when he said that [54]:

“5-10 herb items would be added to the list of essential drugs each year, from 2012-2015”

One of the health development strategies identified in the 11th National Health Development Plan of the country is: “Strategy to strengthen partners for health promotion and self-reliance with Thai wisdom.” In this strategy, it is mandated to promote healthy life styles using Thai wisdom with safety and acceptable qualities, develop systems for learning and knowledge management for Thai traditional indigenous and alternative medicine to be of acceptable standards, promote more use of appropriate technology in Thai traditional medicine for diagnostic and therapeutic purposes, and promote research and development for self-reliance in health [80].

Thailand is rich in natural resources and natural herbs thus there’s a lot of opportunities for development of drugs from natural products. This direction is also seen as a means of increasing self-reliance and reducing dependence on western medicine and medical expenditures.

4.3. Health R&D Projects

One of the objectives of the study is to identify projects/activities to be implemented to develop/deliver the health products within the prioritized areas for health R&D.

4.3.1. Dengue Vaccine Development

The need for a dengue vaccine has been articulated by all groups of stakeholders during the consultative meetings. The literature review undertaken also highlights the importance of developing a vaccine for dengue since this is a public health problem not only in Thailand, but also in about 100 countries where this disease is endemic.
Dengue, a mosquito-borne flavivirus disease, is a leading cause of morbidity and mortality in the tropics and sub-tropics. As many as 50-100 million new infections are estimated to occur annually in more than 100 endemic countries [81]. The disease is caused by four closely related viruses, the Dengue viruses 1-4. At the moment, there are no specific dengue therapeutics and prevention is currently limited to vector control measures. A dengue vaccine would therefore represent a major advancement in the control of the disease.

This urgent need for the development of a dengue vaccine satisfies one of the seven core principles of a new global framework for R&D which is being health needs driven. This was articulated in the “Multi-stakeholder Technical Meeting on Implementation Options Recommended by WHO CEWG on R&D: Financing and Coordination organized at the Rockefeller Foundation Bellagio Center, 16-19 October 2012 [68].

The urgency of engaging in dengue vaccine development is manifested in the following WHO resolutions:

- The 55th World Health Assembly Resolution specifically: “REQUEST the Director General to ….. “to mobilize financial resources to be spent on vector control and research into vaccines.” [82]
- The Southeast Asia Regional Resolution (SEA/RC61/R5) on Dengue Prevention and Control wherein the Regional Director was requested to “to facilitate the acceleration of dengue vaccine research and development;” [83]

At the country level, several policies are in place to provide impetus and support to dengue vaccine development. The National Vaccine Strategy approved by the Cabinet in 2011 includes domestic production of vaccines for 10 diseases including dengue. The NSTDA key operation plans include:

“Doing R&D work to create dengue vaccine prototypes to be tested in humans by 2016, focusing on improving research to create dengue serotype 2 vaccines and test tetravalent vaccines in monkeys.” [84]

There are now several existing efforts on dengue vaccine development in Thailand. The research projects on dengue vaccines in the country range from basic research to clinical settings. A number of research institutions and the academe are involved in these efforts. One of the most notable effort is the joint venture between the Ministry of Public Health, Mahidol University and Sanofi Pasteur Thailand. Results of the phase IIb study of CYD-TDV in Thailand has been published September 2012 [85].

Although dengue vaccine development has been identified as a priority research project in this country study, the results will not be able to identify specifically what stage of the vaccine development cycle should the research project focus on. It should be decided by the working group/collaborating groups that will be established specifically for this purpose taking into consideration the current state of activities related to dengue research in the country.

4.3.2. Orphan drugs/diseases- Melioidosis

Within the scope of orphan diseases in the country, the stakeholders identified melioidosis to be the focus of the priority research project. Melioidosis, an infectious disease caused by a gram-negative bacteria found in soil and water, is endemic in Southeast Asia, particularly
Thailand, and northern Australia. Northeast Thailand has the highest incidence of melioidosis recorded in the world (21.3 cases per 100,000 persons per year). In this part of Thailand, 80% of children are positive for antibodies against *B. pseudomallei* by the age of 4. Melioidosis mode of transmission is not through person-to-person but is a result of an environmental encounter. Thus, it has implications for travel and occupation [86].

Without access to appropriate antibiotics, the septicemia form of melioidosis has a mortality rate that exceeds 90%. Treatment of melioidosis is a challenge especially in resource-poor settings, since the cost of optimal Phase 1 and 2 therapy imposes severe restraints and is a likely contributor to unsuccessful clinical outcomes [87].

A number of research efforts on melioidosis are currently being undertaken by several universities in the country in collaboration with international partner organizations and the Ministry of Public Health. On epidemiology, diagnosis, treatment and prevention. As a suggested priority research project, it is still not clear where the focus of the project will be.

### 4.3.3. Diagnostics/Screening Kits and Natural Products/Medicinal Drugs

The different groups of stakeholders who participated in the meetings and interviews identified diagnostic/screening kits and natural products as priority areas for research. However, there was no agreement on specific projects to undertake within the scope of diagnostics and natural products. For diagnostics, several suggestions were given such as: (i) screening kits for cancers; (ii) markers for NCDs and indigenous diseases in Thailand; (iii) genetic screening.
5. CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

The following conclusions are drawn from the findings of the literature review, results of the consultative meetings, and from the information derived from key informant interviews.

- There are several existing national institutions/bodies that are involved in developing policies at the national level related to research and development of science, technology and innovation in general with the primary objective/goal of improving the state of the art of science and technology in the country. At the same time, there are also policy making bodies/institutions primarily focused on research and development efforts on health. These are in addition to a number of departments in the Ministry of Public Health which also develop policy guidelines for health research in the country. However, it was gathered from the different data collection activities utilized in this study that, a weak coordination mechanism exist between and among these different bodies. It appears that there is no single body that provides the policy direction for health research.

- There is no single body that identifies the priority areas for health research for the entire country. Priority areas of current research efforts are based on the policies and plans of specific institutions. In addition, availability of internal and external funding sources, opportunities for collaborative researches, as well as interests and expertise of the researchers influence decisions for type and area of research. However, it was also noted that several of the areas covered in the current research efforts are relevant to the health needs of the country.

- It was established that there is a strong focus on clinical trials than the other stages of health research for drugs/medicines and vaccines in the country.

- There is no single/common system of norms and standards for the classification of health research and development that is mandated to be utilized by research institutions and researchers in the country.

- It was established that there are initial efforts towards the development of a common system of norms and standards for classification of health research in the country. The use of a modified version of the Health Research Classification System (HRCS) developed in the UK was recommended for use in Thailand in a current study done in the country, with the preliminary results having been recently presented to the policy-making bodies of health research. Another study on the classification of health R&D activities is also being done in one of the universities.

- Results of this country study showed that there was a consensus among all three groups of stakeholders (policy-making bodies, researchers and academicians, pharmaceutical groups) that a common system of norms and standards for the classification of health research and development activities be developed and utilized for Thailand.
The priority areas for medical products identified by the three groups of stakeholders who participated in the Consultative Meetings include:

- Vaccine development
- Orphan product development
- Diagnostic/screening kits
- Drug development using natural products/medicinal herbs

Dengue vaccine was identified to be health R&D project for vaccine development while meliododis will be the focus of the project on orphan drug/diseases.

The stakeholders was not able to identify specific projects on diagnostic/screening kits but have suggested to work on (i) screening kits for cancer; (ii) markers for NCDs and indigenous diseases in Thailand.

On drug development using natural products no specific project was also identified. Although there was an agreement to undertake a project in this area.

There is also a consensus that more efforts should be exerted on translational research so that medical products can be made more accessible and appropriate to the population in need.

5.2 Recommendations

Given the current R&D activities and priorities on health of Thailand, the following projects are suggested in order to develop and deliver health products.

1. Development/Adoption of a common norm and standard for classification of health research and development activities that can be used by everyone involved in these activities.

- The National Research Council of Thailand can lead the efforts on this initiative. The process should be participated by all groups of stakeholders i.e. policy makers from the different institutions, researchers and academicians and the pharmaceutical group.

- As suggested, a review of the existing ones can be the starting point of the process to come up with a system of norms and standards that will suit the needs and context of the country. The initial work of HiTAP and Chiang Mai University on norms and standards can be the starting point of the activity. Since the development of norms and standards requires a lot of in-depth and detailed discussions among various sectors within health, it is suggested that this activity be considered as a separate project focused only on this area, rather than just a rider activity such as the current one.

- The following steps can be followed in the development of norms and standards:
  a. Identification of resource persons who will be asked to participate in determining the categories for the classification of health R&D activities to be used in Thailand. The initial decision to be made by this group will include the:

     - Number and types of dimensions to be used in the classification system
     - Areas/categories and sub-areas/sub-categories within each dimension
b. Consensus-building among resource persons on the dimension, categories and sub-categories to be used

c. Pre-testing of initial set of categories developed at two levels:
   ➢ Retrospective application of the recommended classification system, using an existing health R&D database
   ➢ Current application of the recommended classification system, through the conduct of a survey among researchers, and asking them to use the recommended classification system to their current R&D activities

d. Modification of initial draft of the classification system, based on the pre-testing results. This will involve the following steps:
   ➢ Informing the resource persons on the results of the pre-testing
   ➢ Asking them to modify the initial categories recommended based on the results of the pre-test
   ➢ Consensus building on the modified version of the recommended classification system
   ➢ Finalization of the modified version of the recommended classification system

e. Preparation of a User’s Guide for the newly developed classification system

f. Conduct of awareness building and training activities on the use of the newly developed classification system, to ensure its utilization by the different stakeholders

g. Application of the classification system for a couple of years as a pilot-testing phase, closely monitoring problems encountered

h. Evaluation of the newly developed system

• The system that will be developed should be simple so that it will be user friendly, exhaustive to include all health R&D activities in the country, and flexible enough so as not to restrict its users.

• Complementary to the development of a system of norms and standards, efforts should also be exerted to strengthen protection of intellectual property rights.

2. Global, Regional and National Health R&D Observatory

• Conduct of a series of Consultative Meetings among different health R&D stakeholders to discuss the role of a health R&D observatory at the national, regional and global levels, including the most effective mechanism for its establishment, management, monitoring and evaluation

• The merits, acceptability and feasibility of the idea of the global health R&D Observatory acting merely as a Coordinator of a network of regional and national observatories with national level observatories taking a more major role covering different areas of health R&D must be explored. This is a deviation from the usual set-up wherein countries merely act as data providers to a global observatory based somewhere else, say in Geneva. This approach will result in countries having a greater sense of ownership of the data and in so doing, greatly improve
data quality. It also offers more opportunities for capability building on data processing, analysis and utilization at the country level.

3. Collaborative Project on Dengue Vaccine Development

- Efforts of existing institutions/bodies involved in dengue vaccine development should be consolidated.

- Mapping of the strengths and current work on dengue vaccine development of each institution should be undertaken to identify the gaps, the focus of the collaborative project, as well as the possible roles and contributions of each institution to the collaborative project.

- A higher body/national body should lead this collaborative effort and a technical body composed of representatives of the participating institutions should be established.

- A national meeting of research institutions involved in dengue research will be organized on the first week of September 2013 in Bangkok. One of the objectives is to recommend research priorities on dengue. Dengue vaccine development can be discussed in this meeting.

4. Collaborative project on Melioidosis

The institutions currently working on melioidosis can organize and develop the proposal for a collaborative project on melioidosis, taking into consideration the current efforts of the different institutions on the subject, as well as the expertise and resources available in each institution.

A project organizational structure should be established to delineate clearly the roles and responsibility of the institutions to be involved.

5. Projects on diagnostics/screening kits and drug development using natural products/medicinal herbs

- More detailed discussions should precede the development of the project proposals for these two priority areas. Interested institutions should work together to come up with more detailed plan.

6. If possible, WHO should facilitate sourcing of funds for projects on the priority areas since products on these priority areas can also meet the needs of the region.

7. Knowledge gained and products of these projects can be shared throughout the region to ensure equitable access of the needy population.
ANNEXES
ANNE 1a
PRESENTATION ON THE OVERVIEW OF THE PROJECT

Slide 1

Overview of the Project

Country Study: R & D On Health
Consultative Meeting

Slide 2

56th WHA 2003

- WHO Secretariat presented an information document on intellectual property, innovation, and public health which noted:
  - “A significant proportion of the world’s population, especially in developing countries, has yet to derive much benefit from innovations that are commonplace elsewhere.…”
  - Document focused on the need to look at mechanisms for stimulating innovation and the relationship with intellectual property and public health.
- WHA adopted a Resolution which asked the DG to establish “an appropriate time limited body to collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries.”

Slide 3

- Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH)
  - established in early 2004
  - Its report published in 2006
  - Central recommendation:
    “WHO to develop a Global Plan of Action to secure enhanced and sustainable funding for developing and making accessible products to address diseases that disproportionately affect developing countries”
59th WHA 2006

• Agreed to establish an
  “...Intergovernmental Working group to draw up a global strategy and plan of action in order to provide a medium term framework based on the recommendations of the Commission...”


61st WHA 2008

• Adopted the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI)

• with 8 elements and action points for governments international organizations and other stakeholders

• 7th element:

  Promoting sustainable financing mechanisms

7th element of the GSPA-PHI

• Key action:

  “establish a results-oriented and time limited expert working groups under the auspices of WHO and linking up with other relevant groups to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of financing to stimulate R&D related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases”
Expert Working Group

- EWG on R&D: Coordination and Financing
- Established in November 2008
- Composed of 24 members
- Met several times in 2009
- Submitted a summary of its report in January 2010 to the Executive Board
- Submitted a final report to the 63rd WHA 2010

Consultative Expert Working Group

- Established by the WHA 2010 by Resolution WHA 63.28
- Task: “deepening the analysis and taking forward the work done by the previous Expert Working Group (EWG) on R&D: Coordination and Financing”

Report of the CEWG on R&D: Financing & Coordination

- Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination
- April 2012
**Slide 10**

Resolution WHA 65.22

- requested:
  - Regional Committees to discuss at their 2012 meetings the report of the CEWG
- WHO Regional Committee for South-East Asia
  - Convened a regional technical discussion of the CEWG’s report (7 September 2012, Indonesia)
  - Resolution (SEA/RC65/R3)

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**Slide 11**

Resolution WHA65.22

- requested the Director-General to hold an open-ended meeting of Member States
  - Organized 26-28 November 2012, Geneva
  - Representatives from 81 member States
  - Chaired by Dr. Viroj Tangcharoensathien
  - Endorsed the strategic work plan

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**Slide 12**

Resolution (SEA/RC65/R3)

- Country studies
- Regional meeting on July 25-26 2013
- SEAMEO TROPMED Network to undertake Thailand Country Study
TOR of the project

- Suggest methodologies to develop norms and standards for classification of health R&D needs of developing countries based on systematically collected and collated information. For this purpose, it would be necessary to examine:
  - Current norms and standards for classification of health R&D in developed and developing countries
  - Classification of health R&D by health and non-health sectors
  - Based on the above suggest possible methodologies for norms and standards for classification of health R&D needs of developing countries

TOR (2) ...

- Identify priorities for R&D for health products based on public health needs of developing countries
- Identify projects in order to develop and deliver health products.
- Participate in the regional meeting in July 2013 and present their findings to the meeting

Methodologies

- Consultative Meetings
  - Policy making bodies
  - Researchers
  - Pharmaceuticals
- Interviews
- Literature Review
Slide 16

Policy-making Bodies

- Participants:
  - MOPH (FDA, CDC, IPP, HSRI, NVI, HS, KM)
  - NSTDA
  - NSTI Policy Office
  - TCELS
  - Phar. Research Manufacturers

- Consensus on Norms & Standards for classification
- Priority Health Issues/ projects on R&D

Slide 17

Research Organizations

- Armed Forces Research Institute of Medical Science
- BIOTEC
- Chulabhorn Research Institute
- Health System Research Institute
- Office of the National Research Council
- Thai Red Cross Research Centre
- Mahidol University
  - Faculties of Pharmacy, Science, Tropical Medicine

Slide 18

- Research policies
- Different Funding Sources
- Basis of Prioritization
- Identified priority areas
- Norms and Standards for classification
  - Consensus- need to have
  - Report of Prof. Yoth- HITAP
Slide 19

Objectives of the Meeting

• List current R&D activities (medicine and drugs; diagnostics; vaccines; in relation to the country’s public health needs;
• Identify norms and standards for classification of health R&D utilized by the different organizations;
• Identify priorities for R&D for health products based on country’s public health needs; and
• Identify projects in order to deliver and/or deliver health products.

Slide 20

Mechanics

• Brief inputs
• Workshops- small group discussions
• Guide questions
• Plenary presentation and discussions of outputs
• Agreements

Slide 21

Health products

• Include:
  - vaccines,
  - diagnostics,
  - Medicines
• based on resolution WHA 59.24
ANNEX 1b.
PRESENTATION ON NORMS AND STANDARDS
CURRENTLY USED FOR CLASSIFYING R&D ACTIVITIES

Slide 1

NORMS AND STANDARDS
CURRENTLY USED FOR CLASSIFYING
RESEARCH AND DEVELOPMENT
ACTIVITIES

Ophelia M. Mendoza
Consultant

Slide 2

QUESTIONS WE WOULD LIKE TO ANSWER
• What do we mean by norms and standards for the classification of health research and development (R&D) activities?
• Why is it important to develop norms and standards for classifying health R&D activities?
• What are examples of norms and standards currently used for classifying health R&D activities?
• What are the important characteristics of successful research classification systems?
• What are some of the issues met in the development of a unified set of norms and standards for classifying R&D activities?

Slide 3

What do we mean by norms and standards for the classification of health research and development (R&D) activities?
• They are internationally accepted definitions of research and development, and the classification of its component activities
• It serves as a “common language” to be used in:
  o describing the research landscape
  o making meaningful comparisons of R&D activities among different sub-groups
  o Strategic coordination of R&D activities
Why is it important to develop norms and standards for classifying health R&D activities?

1. Communication
2. Identification of new opportunities
3. Comparable analysis
4. Collaboration
5. Efficiency

What are examples of norms and standards currently used for classifying R&D activities?

ALL R&D AREAS
1. OECD Frascati Manual
2. Australian and New Zealand Standard Research Classification (ANZSRC)
3. DFG Classification System (Germany)
4. Malaysian Research and Development Classification System (MRDCS)

What are examples of norms and standards currently used for classifying R&D activities?

HEALTH-SPECIFIC
1. RCDC System (Research, Condition and Disease Categorization - US NIH)
2. MeSH (Medical Subject Headings – US National Library of Medicine)
3. CSO (Common Scientific Outline – US National Cancer Institute)
4. G-Finder Survey (specifically for neglected diseases like TB, malaria, etc. – George Foundation for International Health)
5. HRCS (Health Research Classification System – UK Clinical Research Collaboration)
Example 1:
Malaysian Research and Development Classification System (MRDCS)

- Based on the OECD Frascati Manual, but modified to support a variety of user interests within the Malaysian R&D context
- Uses two classification systems based on
  1. Field of research (FOR)
  2. Socio-economic Objective (SEO)

MRDCS: 9 Divisions under Field of Research

1. Natural Sciences
2. Biotechnology
3. Engineering and Technology
4. Information, Computer and Communication Technology
5. Medical and Health Sciences
6. Agriculture and Forestry
7. Social Sciences
8. Humanities
9. Economics, Business and Management

28 Health Categories Under the Division of Medical and Health Sciences

1. Immunology
2. Medical Biochemistry and Clinical Chemistry
3. Medical Microbiology
4. Pharmacology
5. Physiology
6. Neurosciences
7. Clinical Medicine
8. Public Health
9. Dentistry
10. Nursing
11. Nursing Education
12. Nursing Management
13. Health Care System
14. Other Health and Social Sciences
15. Medical, Dental, and Allied Health Professions
16. Biomedical Sciences
17. Complementary/Ancient Medicine
18. Sports Science
19. Pharmacy
20. Speech and Language Pathology
21. Audiology
22. Medical Diagnostic Imaging
23. Radiotherapy
24. Anatomy
25. Anatomy
26. Other medical and health sciences
10 Groups Under the Pharmaceutical Industry Category

1. Botanical pesticides
2. Drug pricing
3. Halal labelling
4. Human pharmaceutical products (including blood products, diagnostic, therapeutic agents, vaccine and halal products)
5. Labelling and safety
6. Law and ethics
7. Licensing
8. Natural products
9. Nutraceuticals
10. Personal care products and cosmetics

MRDCS: 6 Divisions under Socio-Economic Objective

1. Defence and security
2. Sustainable economic development
3. Society
4. Environment
5. Advancement of knowledge
6. Advanced experimental and applied science

Example 2: Health Research and Development Classification System (HRCS)

- Published in 2008
- Based on the Common Scientific Outline (CSO) developed by the US National Cancer Institute
- The system provides a broad overview of the center of gravity of a set of research awards by assigning codes to capture the main objective(s) of a particular study
- System is routinely used in Norway, Sweden, Singapore, Ireland and the UK
Two-dimensional framework of HRCS

1. 21 health categories used to classify the type of health or diseases being studied. The categories encompass all diseases, conditions and areas of health
2. 8 groups of research activity codes with 48 categories, used to classify the types of research being undertaken, from basic to applied

8 Research Activity Codes Used in HRCS

1. Underpinning research (normal biological development and functioning, psychological and socioeconomic processes, methodologies and measurements, etc.)
2. Aetiology (biological and endogenous factors, factors related to physical environment, psychological, social and economic factors, etc.)
3. Prevention of disease and conditions and promotion of well-being
4. Detection, screening and diagnostics
5. Development of treatments and therapeutic interventions
6. Evaluation of treatments and therapeutic interventions
7. Management of disease and conditions
8. Health and social care services research

Categories of Pharmaceuticals Covered Under Research Activity #5 Used in HRCS

5. Development of treatments and therapeutic interventions

5.1 Pharmaceuticals

- Discovery and development of therapeutic interventions and testing in model systems and preclinical settings
- Identification and development of pharmaceutical small molecules, therapeutic vaccines, antibodies and hormones including:
  - Drug screening and development of delivery systems
  - Mechanisms of action including side effects and drug resistance
  - Pharmacometrics, prediction of genetic variations and responses to drugs
  - Testing in vitro and in vivo model systems
Slide 16

Categories of Pharmaceuticals Covered Under Research Activity #6 Used in HRCS

4. Evaluation of treatments and therapeutic interventions
   Testing and evaluation of therapeutic interventions in clinical, community or applied settings

4.1. Pharmaceuticals
   Clinical evaluation and application of pharmaceuticals, small molecules, therapeutic vaccines, antibodies and hormones in humans including:
   - Small scale settings and pilot studies
   - Investigating, assessing sensitivity, efficacy, specificity, relapse, survival, therapeutic value
   - Pharmacokinetics, reproducibility and safety
   - Studies monitoring response, outcome, drug resistance and side effects

Slide 17

Key characteristics of successful research classification systems

1. Simple
2. Relevant
3. Consistent
4. Standardized
5. Multi-dimensional
6. Flexible

Slide 18

Issues in the development of a unified set of norms and standards for classifying R&D activities

1. No single ideal classification
2. Differences in operational processes
3. Overlaps between scientific areas and/or interdisciplinary research
4. Various research information systems in use
5. Resource requirements for the maintenance of the system
6. Quality assurance and control
ANNEX 2a
Consultative Meeting Among Health Policy Makers and Planners
26 June 2013
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Consultative Meeting Among Researchers and Academicians

27 June 2013
SEAMEO TROPMED Network Office, Bangkok, Thailand

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Consultative Meeting Among Representatives of the Pharmaceutical Industry
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ANNEX 3a
GUIDE QUESTIONS: GROUP WORK 1

IDENTIFICATION OF R&D NORMS, STANDARDS, AND PRIORITIES CURRENTLY ADOPTED AND ACTIVITIES CURRENTLY UNDERTAKEN

1. NORMS, STANDARDS AND POLICIES CURRENTLY USED IN CLASSIFYING R AND D ACTIVITIES

1.1 What is the specific role of your agency in health R&D?

1.2 Are there existing norms, standards and policies which you are currently using in classifying the health research and development activities which you are undertaking?

1.3 If YES: (Please record answers in Worksheet 1.1a)
   1.3.1 What are these norms, standards and policies currently used?
   1.3.2 How were these existing norms, standards and policies developed?
   1.3.3 In what way do these existing norms, standards and policies affect your R and D activities?
     • Do they act as facilitating or inhibiting factors?
     • How?
   1.3.4 How do you classify your current R and D activities based on these norms, standards and policies?

1.4 If NO: (Please record answers in Worksheet 1.1b)
   1.4.1 How do you classify your R and D activities?
   1.4.2 What is the basis of your current practice of classifying R and D activities?
   1.4.3 Are you affected by the absence of existing norms, standards and policies in classifying R and D activities?
     • If yes, how?
     • If no, why not?

(Please records answers to questions 1.4, 1.5 and 1.6 in Worksheet 1. 2)

1.5 How do you prioritize your R and D activities?
1.6 What is the basis for such prioritization?
1.7 Who defines
   a. priority areas for R&D?
   b. priority areas for funding?
1.8 What activities are you currently undertaking in line with these priorities

**WORKSHEET 1.1a. NORMS, STANDARDS AND POLICIES CURRENTLY USED IN CLASSIFYING R&D ACTIVITIES**

<table>
<thead>
<tr>
<th>Name and role of agency in health R&amp;D</th>
<th>Norms, standards and policies currently used in classifying R&amp;D activities</th>
<th>Basis of norms, standards and policies currently used (Who developed? How was it developed?)</th>
<th>Effects of norms, standards and policies currently used on R&amp;D activities</th>
<th>How current R&amp;D activities are classified based on existing norms standards and policies</th>
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<td>Positive Effects</td>
<td>Negative Effects</td>
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**WORKSHEET 1.1b. MODE OF CLASSIFYING R&D ACTIVITIES FOR THOSE WITHOUT NORMS AND STANDARDS**

<table>
<thead>
<tr>
<th>Name and role of agency in health R&amp;D</th>
<th>How R &amp; D activities currently undertaken are classified (Please indicate name of institution/sector in parenthesis)</th>
<th>Basis of mode of classification of R &amp; D activities currently used</th>
<th>Effect of absence of existing norms and standards for classifying R and D activities</th>
<th>If affected, how?</th>
<th>If not affected. Why not?</th>
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</table>
## WORKSHEET 1.2: IDENTIFICATION OF CURRENT R&D PRIORITY AREAS AND ACTIVITIES UNDERTAKEN

<table>
<thead>
<tr>
<th>Current priority areas for health R&amp;D activities (Please indicate name of institution/sector in parenthesis)</th>
<th>Basis for identification of current priority areas</th>
<th>In your institution/sector, who defines:</th>
<th>Activities/projects currently undertaken in line with current priority areas health for R&amp;D</th>
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<tr>
<td></td>
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<td>Priority areas for health R&amp;D?</td>
<td>Priority areas for funding?</td>
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</table>
ANNEX 3b
GUIDE QUESTIONS: WORKSHOP 2
WHAT OUGHT TO BE DONE IN TERMS OF NORMS, STANDARDS, PRIORITIES AND ACTIVITIES TO BE CONDUCTED TO DEVELOP AND DELIVER HEALTH PRODUCTS

1. DEVELOPMENT OF A UNIFIED SET OF NORMS AND STANDARDS FOR THE CLASSIFICATION OF THAILAND’S R&D ACTIVITIES

1.1 What are the advantages and disadvantages of developing a unified set of norms and standards for the classification of Thailand’s R&D activities?

1.2 Given all things taken altogether, should Thailand adopt a unified set of norms and standards for the classification of the country’s R&D activities?

1.3 If YES to question 1.2, how should the Thailand proceed in developing a unified set of norms and standards for the classification of the country’s R&D?

WORKSHEET 2.1
DEVELOPMENT OF A UNIFIED SET OF NORMS AND STANDARDS FOR THE CLASSIFICATION OF THAILAND’S R&D ACTIVITIES

<table>
<thead>
<tr>
<th>Advantages of adopting a unified set of norms and standards for the classification of Thailand’s R&amp;D activities</th>
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<th>Disadvantages of adopting a unified set of norms and standards for the classification of Thailand’s R&amp;D activities</th>
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<th>Process/steps to be followed in developing a unified set of norms and standards for the classification of Thailand’s R&amp;D activities</th>
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2. SETTING OF PRIORITIES FOR R&D ON HEALTH PRODUCTS AND IDENTIFICATION OF PROJECTS TO DEVELOP AND DELIVER PRIORITY HEALTH PRODUCTS

2.1 What should be Thailand’s priorities for R&D on health products?

2.2 What is the basis for setting these as Thailand’s priority areas for R&D on health products?

2.3 What projects/activities should be implemented to develop and deliver the priority health products which you have identified?

WORKSHEET 2.2
SETTING OF PRIORITIES FOR R&D ON HEALTH PRODUCTS AND IDENTIFICATION OF PROJECTS TO DEVELOP AND DELIVER PRIORITY HEALTH PRODUCTS

<table>
<thead>
<tr>
<th>Priority No.</th>
<th>PRIORITY AREA FOR R&amp;D ON HEALTH PRODUCTS</th>
<th>BASIS FOR SELECTION OF PRIORITY AREA</th>
<th>PROJECTS/ACTIVITIES TO BE IMPLEMENTED</th>
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