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MaHTAS
Malaysian Health Technology Assesment Section

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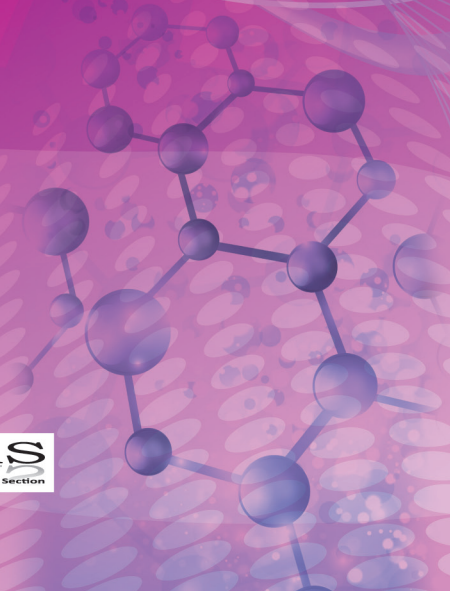
MANUAL ON HORIZON SCANNING of Health Technologies



MaHTAS
Malaysian Health Technology Assesment Section

MANUAL ON HORIZON SCANNING OF HEALTH TECHNOLOGIES

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FOREWORD

DIRECTOR GENERAL OF HEALTH MALAYSIA

Horizon scanning of new and emerging health technologies has been established in many countries to assist the decision on the uptake of new and emerging technologies. The system identifies, filters and prioritises new and emerging health technologies; assesses or predicts their impact on health, costs, society, and the healthcare system.

As Malaysia is moving towards a developed country, local innovations in healthcare will be more significant and thus, identification and prioritisation of new and emerging technologies is important to set research as well as investment priorities.

The rapid pace of health technology innovations leads to complexity of the treatment options and higher costs resulting in increasing pressure on many healthcare systems. Horizon scanning system allows proper monitoring and assessment of the new and emerging health technologies before it is being introduced into the market. This activity will inform the prioritisation of technologies for a more comprehensive health technology assessment. This is essential to ensure patient safety and at the same time support innovation.

With new innovation and emerging technologies in the upward trend, this Horizon Scanning on such technologies is pertinent for opportunistic proper planning in the introduction and diffusion of new health technologies in the Malaysian healthcare system.

It is hoped that this manual will delineate the framework of horizon scanning system in Malaysia, provide guidance on its work process and can be used as a training module or reference.

DATUK DR. NOOR HISHAM ABDULLAH
DIRECTOR GENERAL OF HEALTH MALAYSIA

1. INTRODUCTION

Health technologies are essential in delivering quality health care. Innovations of health care technologies flourishes at a rapid rate. Rapid development and premature introduction of new technologies may increase health care expenditure. Thus, selection of the potential technologies is crucial to improve patient outcomes and refine health system efficiency and should be based on scientific evidence.

Malaysian Health Technology Assessment Section (MaHTAS) was set up in August 1995 in the Ministry of Health Malaysia as it became increasingly evident that there was a need for a more effective mechanism for the selection and introduction of technologies into the healthcare system. MaHTAS was established to ensure safe, effective and cost-effective technologies are used in the Ministry of Health facilities. This is done through the conduct of Health Technology Assessment (HTA), mini-HTA (Technology Review), rapid assessment (Information Brief) and also the development and implementation of Clinical Practice Guidelines (CPG). Since its establishment, MaHTAS has produced 60 HTA reports, 284 Technology Review (TR) reports, 73 Information Brief reports and 85 CPGs (until December 2014).

Having the right evidence at the right time is an important essence in health care decision making. The early identification and monitoring of new and emerging health technologies also known as horizon scanning, early awareness and alert (EAA) systems, emerging technology assessment or early warning systems, focuses on identifying new and emerging health technologies that are likely to have significant impact on health services and/or patient care. The healthcare technologies and innovations are those that are still in the early stages of development or adoption except in the case of new applications of already diffused technologies. It is part of the regular approval processes in many countries worldwide. A survey of International Network of Agencies for Health Technology Assessment (INAHTA) members in 1998 showed that 30% of member agencies have continuing and structured horizon scanning activities then.[1]

DEFINITION OF AN EFFECTIVE HORIZON SCANNING SYSTEM

An effective horizon scanning or early warning system is a system which;

> *Identifies innovations in the field of health technology likely to have a significant impact; and disseminates information relevant to the needs of the customer which is timely, so as to enable appropriate decision making (such as resource allocation), facilitate appropriate adoption, and identify further research requirements.*[2]

DEFINITION OF HEALTH TECHNOLOGIES

Health technologies encompass all methods used by health professionals to promote health, prevent and treat disease, and improve rehabilitation and long term care. These

would include pharmaceuticals, devices, diagnostics, procedures (and technologies used as part of a procedure), programmes, settings and public health activities.[3]

EuroScan International Network defines new and emerging health technologies as technologies that are not yet adopted by the health care system. Emerging pharmaceuticals are at the phase II or III clinical trial, or pre-launch stage. Emerging medical devices are at the pre-marketing stage. New health technologies are generally in the launch, early post-markerting or early diffusion stages.[4]

INNOVATION IN HEALTH CARE

Innovation can be defined as intentional introduction and application within a role, group, or organisation, of ideas, processes, products or procedures new to the relevant unit of adoption, design to significantly benefit the individual, the group or wider society (West 1990).[5]

Healthcare innovation can be defined as the introduction of a new concept, idea, service, process, or product aimed at improving treatment, diagnosis, education, outreach, prevention and research, and with the long term goals of improving quality, safety, outcomes, efficiency and costs.[5]

Innovations of health technologies in horizon scanning system can be classified as; [4]

- A completely new technology – such as new chemical entities, new devices, new procedures
- An existing technology being used for a new patient group or new indication
- A significant incremental change to an existing technology that might have significant impact on, for instance, clinical outcomes, healthcare resources, or workforce

1.1. Purpose

The purpose of horizon scanning system is to identify health technologies that are;

- new and emerging
- represent a change in indication or use of an existing technology, or
- part of a group of developing technologies that as a whole, may have an impact, which potentially have major implications for the health system.

The aim is to provide timely advice to allow appropriate implementation and/or adoption of health technologies, and to facilitate timely budgetary planning. The system will help in decisions on undertaking primary and secondary researches. Emerging technologies identified will also be monitored when the evidence is inadequate.

1.2. Health Technology Assessment (HTA) and Horizon Scanning System

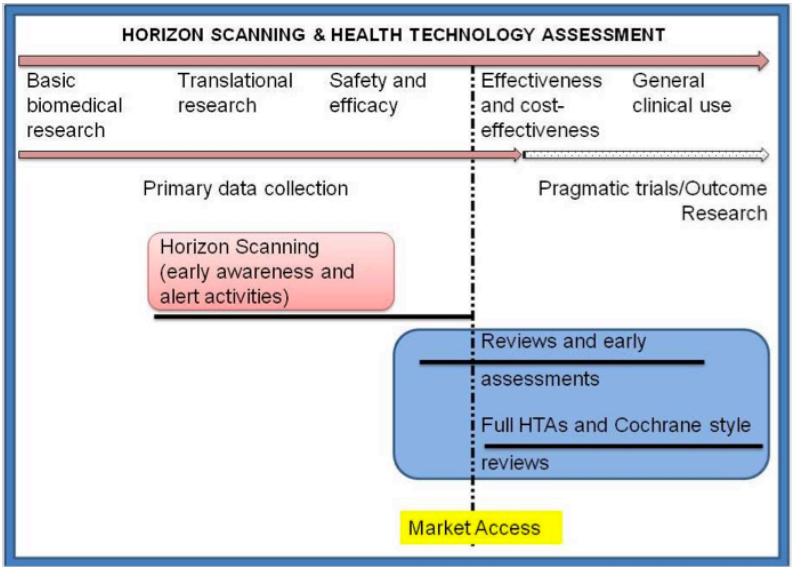

Figure 1. The continuum of HTA activities[4]

The main difference between HTA and Horizon Scanning is that the latter focuses on technologies early in the life cycle while HTA focuses on technologies that have already diffused into clinical practice. Horizon Scanning are sometimes viewed as the first stage of a comprehensive HTA process. New technologies identified through Horizon Scanning system which require further evaluation will be prioritised for HTA.

1.3. Scope

The system will cover all health technologies as below:

- Medical devices
- Diagnostics
- Biologics
- Regenerative technologies
- Procedures
- Pharmaceuticals
- Traditional and Complementary Medicine
- Public health interventions

1.4. Priority Area

The priority area will be **local innovations** and **expensive technologies**. The expensive technologies will focus on diseases with high burden and will be in line with five years' Malaysian Plan.

1.5. Time Horizon

After pre-clinical trials up to 24 months before a product is plan to be commercialised.

1.6. Who to Inform

The system will inform various stakeholders such as:

i. Policy-makers and regulators within Ministry of Health
ii. Medical Device Authority (MDA)
iii. Universities and research institutes
iv. Investment agencies such as Ministry of Science, Technology and Innovation (MOSTI), Agensi Inovasi Malaysia (AIM), Malaysian Investment Development Authority (MIDA), Malaysian Bioeconomy Development Corporation Sdn. Bhd. (Bioeconomy Corp)
v. Health care providers/practitioners
vi. Other related agencies

1.7. Potential Benefits

1. **The topics will be identified early and sent for evaluation at the right time. This will allow proper evaluation of an emerging technology** prior to adoption and widespread use, which is important to protect patients from unproven technologies which may be harmful or ineffective either clinically or economically. At the same time, this system may supports potential technologies especially local innovations.

2. **The Horizon Scanning system will alert policy-makers/health service organisations to innovations** that will change current options/decisions, change current guidance/guidelines and require further planning or commissioning activity.

3. The system will allow systematic approach in identification and evaluation of emerging health technologies.

4. Improved collaboration with agencies involved with health care technologies, to ensure safe and effective health technologies are use in the country.

2. GOVERNANCE STRUCTURE

The governance structure for horizon scanning activity is illustrated in Figure 2.

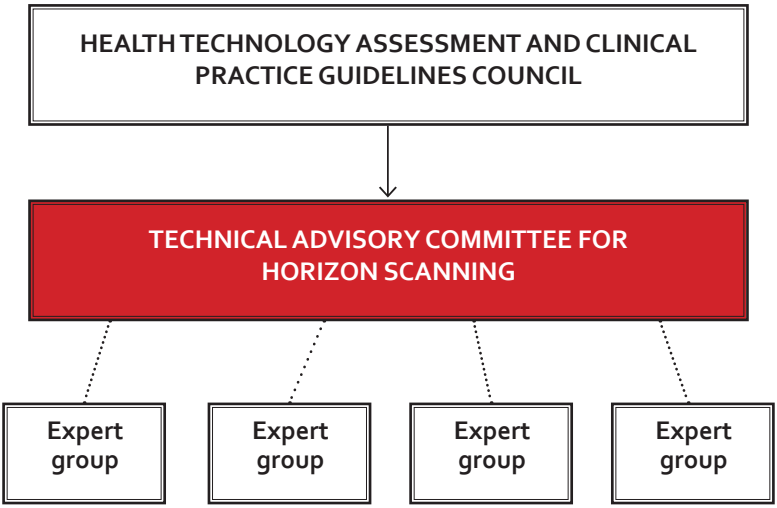

Figure 2. Governance structure of horizon scanning activity

2.1. Health Technology Assessment and Clinical Practice Guidelines Council

The Health Technology Assessment and Clinical Practice Guidelines Council is the highest authority that set the direction of horizon scanning activity and endorse horizon scanning reports. The Council is chaired by the Director General of Health and the members consisted of all the Deputy Director General of Health, the Senior Directors and Directors of relevant divisions within Ministry of Health, Deans of Medical Faculty, representative of Malaysian Medical Association, Academy of Medicine Malaysia, Association of Private Hospital Malaysia and clinicians.

2.2. Technical Advisory Committee for Horizon Scanning

The Technical Advisory Committee for Horizon Scanning (TAC HS) is comprised of policy makers, clinicians, researchers and representative from agencies involve in health care innovations. This will include Medical Device Authority, National Pharmaceutical Regulatory Agency, Engineering Division, Oral Health Division, Traditional and Complementary Medicine Division, Ministry of Science, Technology and Innovation (MOSTI), Agensi Inovasi Malaysia (AIM), Malaysian Bioeconomy Development Corporation (Bioeconomy Corp), SIRIM Berhad and Malaysian Investment Development Agency (MIDA). The Director of Medical Development Division will be the chairman of the TAC HS.

The terms of reference of the TAC HS are listed below:

1. Provide technical expertise in the development of the strategies and priorities of horizon scanning
2. Ensure the planned strategies and activities of horizon scanning are carried out effectively
3. Conduct prioritisation process of horizon scanning topics
4. Advocate horizon scanning activity to the stakeholders

2.3. Expert Group

The expert group will be formed when required to assist in assessment of certain technologies.

2.4. Euroscan International and Other International Meetings

Euroscan International Network and relevant international meetings will provide information on the latest or appropriate methods in conducting horizon scanning and may also suggest changes in format of reports.

3. METHODS

3.1. Work Process

The main stages involved in horizon scanning systems is illustrated in Figure 3.

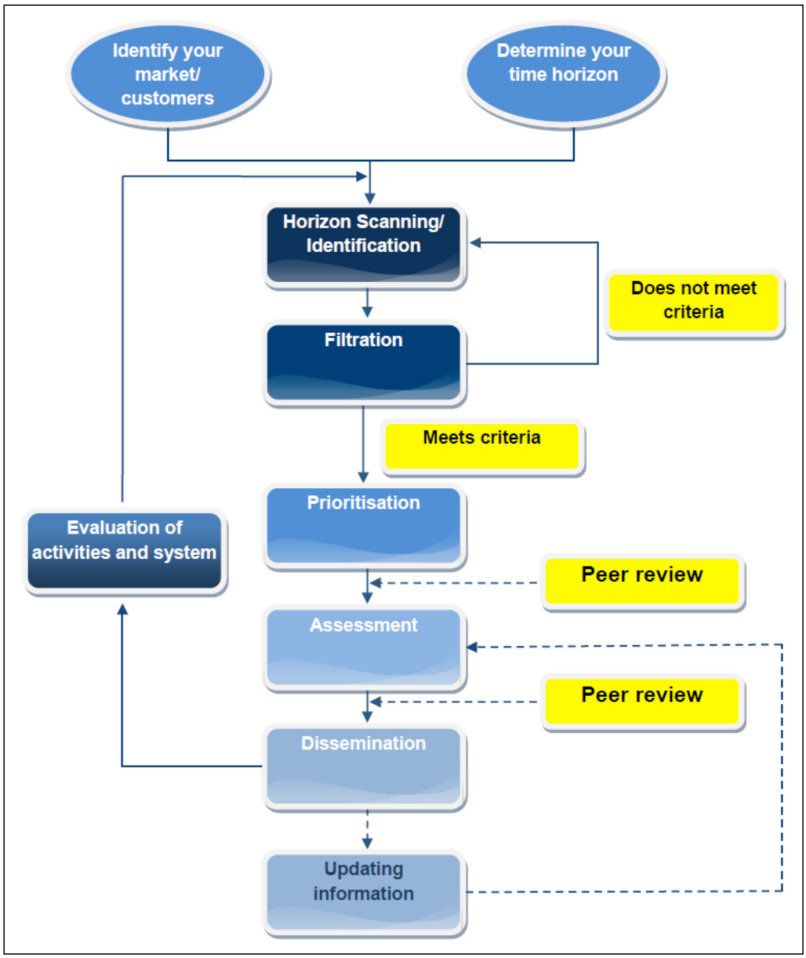

Figure 3. Main steps in horizon scanning system[4]

3.2. Identification

Identification is the first step of horizon scanning work process to **identify new and emerging health technologies** that have the **potential impact on** clinical practice and outcome, health care system, cost, burden of disease and interagency collaboration.[4]

There are two types of identification process which are;[4]

I. Proactive – looking or searching for information related to the technology. A range of sources are searched for information on new and emerging health technologies

II. Reactive – looking/waiting/viewing at information. Allow stakeholders, health professionals, consumers and/or others to inform the horizon scanning system on new and emerging health technologies

For identification, we choose the technologies with the following criteria:

- New and emerging innovative technologies
- Clinical need/burden of disease

There are three sources for identification as following:

I. Primary sources – information is obtained directly from sources closest to the technology such as commercial developers, research institutes, universities, manufacturers, clinical trial registers and patent applications

II. Secondary sources – information is obtained from sources that have used primary sources but may have edited or filtered the information such as commercial and medical media, conference proceedings and scientific journals, regulatory authorities and relevant experts

III. Tertiary sources – information is obtained from sources that have prioritised the information themselves and perhaps carried out an assessment. The sources are mainly from other Horizon Scanning organizations such as EuroScan International Network, Canadian Agency for Drug and Technologies in Health (CADTH) and National Institute for Health Research (NIHR) Horizon Scanning United Kingdom

Commercial developers

Information from commercial developers can be obtained through pipeline meeting, website, annual report, press releases and conference presentations. Pipeline meeting is elaborated in Section 6. Commercial developers may also submit information using proforma HS 01 for pharmaceutical (see Annex 1) or HS 02 for medical technologies (see Annex 2). In dealing with commercial developers, ethics as elaborated in Section 8 should be observed.

Experts

Experts in relevant fields such as clinical practice, research and public health may provide relevant information on new and emerging health technologies using proforma HS 01 for pharmaceutical or HS 02 for medical technologies. Meeting with experts is elaborated in Section 7.

How will the identification be carried out?

Proactive identification will be carried out by MaHTAS staff. The sources will include medical databases, commercial websites and media, scientific journals, clinical trial registry and patent applications. The identified technologies should be recorded using **Horizon Scanning Identification Form (HS 03)** (see Annex 3) based on the identification criteria.

As for reactive identification, the sources either commercial developers, researchers or experts will fill up the proforma (**HS 01** and **HS 02** for **pharmaceutical and medical technology,** respectively) and submit to MaHTAS.

The scanning frequency will depends on the type of sources which may ranged from daily, weekly or monthly.

3.3. Filtration

Filtration is a work process which considers technologies found at the identification stage and selects those that are relevant to horizon scanning system by application of preset criteria. It helps narrow the potential number of technologies to evaluate.[4]

Filtration can be done by using predefined criteria and filling up the Horizon Scanning Filtration form [**HS 04** (see Annex 4)]. More information on the technology can be obtained when necessary in completing the filtration form.

Filtration criteria

1. The technology is **new/emerging or innovative**:
   - Innovative technology can be an established technology with new indication of use or a significant modification of an existing technology.
   - For example, a 64-slice CT scanner compared to a 32-slice. Is this modification significant?
   - However, one should bear in mind that sometimes there will be some difficulty in determining whether the technology is truly innovative or merely an incremental development to an existing one.

2. The technology is within the **time frame:**
   - for medical technology, the time frame for assessment is within 24 months the technology is expected to be launched or marketed, and if the available time frame adequate for a horizon scanning report to be completed
   - for pharmaceuticals, the time frame is within 24 months the drug is expected to be licensed

3. The **target technologies** are:
   - Medical technologies:
     - Medical devices
     - Diagnostics

- Biologics
- Regenerative technologies
- Procedures
- Traditional and Complementary Medicine

- Pharmaceuticals
- Public health activities

4. The technology/ies is/are for diseases with high burden based on current Malaysia Plan:
   - Disease burden is the impact of a health problem as measured by financial cost, mortality, morbidity or other indicators.
   - For example, in Tenth Malaysia Plan, infectious diseases such as dengue, drug resistant tuberculosis, malaria and non communicable diseases (NCD) such as hypertension, diabetes, hypercholesterolemia, adult asthma are given priority.

How will the filtration be carried out?

Filtration process will be done in-house (MaHTAS staffs) by completing the filtration form (HS 04). The completed filtration form will be discussed internally and decision for prioritisation will be done. The framework for filtration is as in Figure 4.

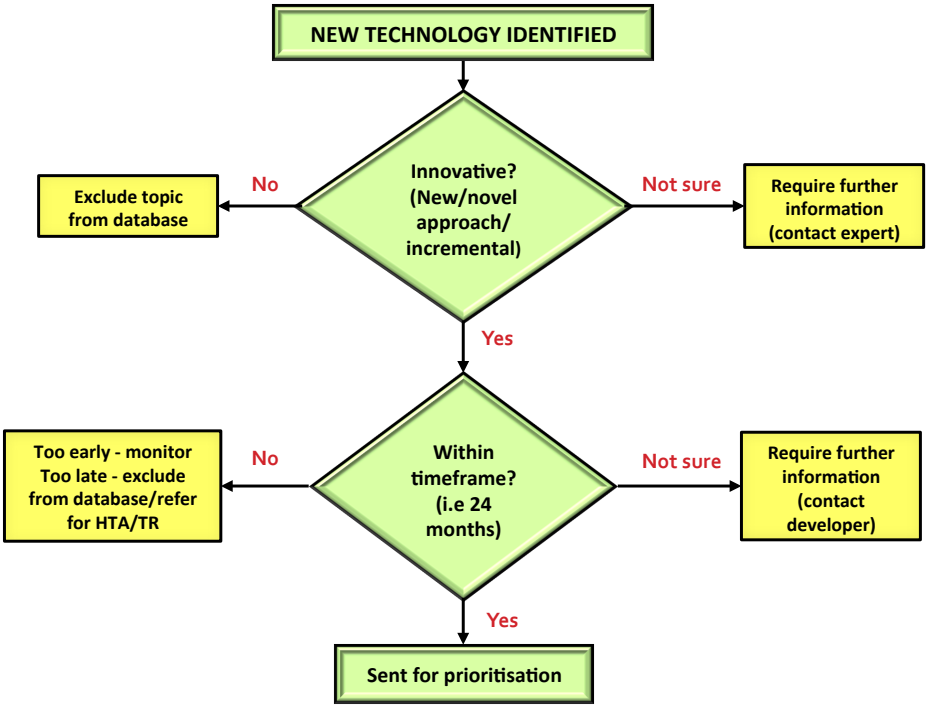

Figure 4. Filtration framework

3.4. Prioritisation

Once technologies relevant to the horizon scanning system have been filtered, the filtered technologies need to be prioritised.

Prioritisation helps to determine the filtered technologies for further assessment with an expected major clinical or financial impact and ensuring filtered technologies appropriate to the customer needs.

EuroScan recommends constructing a set of pre-defined prioritisation criteria based on stakeholder and customer requirements. Technologies must satisfy one or more of these criteria before being accepted for further assessment or evaluation. As with filtration, further information about a technology may be required to enable its prioritisation.[4]

Prioritisation criteria

These are the **pre-defined prioritisation criteria** which need to be considered:

1. **Population/end-user**
    a. Disease burden – the impact of the disease in terms of number of people affected, morbidity, mortality and other indicators
    Higher priority for diseases with higher burden
    b. Current options for patients – are there already other treatment regimen available for this specific indication or is this technology a completely new therapy? Will the technology replace the current treatment or is it an add on?
    Is the technology
        i. Novel
        ii. Incremental
        iii. New indication
    Higher priority for novel technologies and if there is no treatment regimen available

2. **Potential impacts of technology**
    a. Patients – clinical impact such as morbidity, mortality, quality of life, diagnosis
    Higher priority for technologies that may reduce morbidity, mortality, improve quality of life and diagnosis
    b. Cost – such as increase cost or savings, large capital outlay, direct and indirect costs for patients and society
    Higher priority for expensive technologies
    c. Organisation - increase or decrease utilisation of service, structural changes and staff training
    Higher priority for technologies which leads to increase use of service, needs changes in infrastructure and require training

d. Societal and/or ethical issues – *Higher priority for technologies with higher impact to the society*
e. Safety/adverse events – invasiveness of the technology and the associated adverse events
Higher priority for technologies with higher safety risk

How will prioritisation be carried out?

Prioritisation can be carried out in a number of ways depending on resources and time available, transparency of process and who is involved.

Prioritisation will be carried out by:

1. In-house (MaHTAS staff)
2. Technical Advisory Committee for Horizon Scanning (TAC HS). Further detail in Section 2.2.

Due to potential conflict of interest, prioritisation does not usually involve industry or commercial developers or clinicians and researchers who work closely with a technology.

The technologies will be prioritised by using scoring system. The TAC HS members will give scores to the filtered technologies based on the criteria above. Then, the scores for each technology will be calculated, and the technology will be prioritised according to their score rank and discussion among the TAC HS.

Prioritisation is done using prioritisation form **HS 05** as in Annex 5.

3.5. Assessment

Assessment of a technology or prediction of potential impact is an important activity that a horizon scanning system performs. This will determine the influence of the technology either it will be diffused or not in the healthcare system later. This will also depends on stakeholders' interests and needs.

Assessment of the prioritised technologies will determine whether a technology is likely to have a significant impact to the healthcare system, clinical practice, outcomes and costs.

Types of Assessments

Assessment may include:

Rapid: Taking 24 – 48 hours to complete, producing a 1 – 2 page brief overview. Rapid assessments are usually conducted in response to a specific request from stakeholder about an emerging technology. A pre-formatted template **(HS 06)** is use for rapid assessment (TechScan), see Annex 6.

2. **Brief**: A more in-depth but still brief overview taking approximately 1 – 2 weeks and around 4 – 10 pages length to produce. The assessment typically includes background of the technology, information on how it works the clinical burden of the disease, current comparator, safety and effectiveness data, costs, social, ethical, and legal concerns. See Annex 7 for brief assessment (**TechBrief**) template (**HS 07**).

3. **In-depth**: A focused assessment (but not systematic review) using a structured search strategy. Taking approximately 4 – 6 months to complete, can be longer than 40 pages. See HS 08 for in-depth assessment (**Horizon Scanning Report**) template in Annex 8.

How will the assessment be carried out?

Assessment will be carried out by MaHTAS staffs after prioritisation process.

A search strategy should be developed to ensure consistency in retrieving the relevant information. The comprehensiveness of the search will depends on the types of product i.e. rapid, brief overview or in-depth report, and the content of the final report. Sources for searching may include:

- Databases of ongoing clinical trials
- Commercial pharmaceutical databases
- Registration and licensing sites
- Relevant scientific conferences
- Bibliographical databases

See Annex 9 and Annex 10 for pharmaceutical and medical technology search record, respectively.

An assessment template as in Annex 6, 7 and 8 should be used as guidance for write up. The fields may include:

1. Technology related information
2. Patient and setting related information
3. Evidence and policy
4. Impact predictions

See Figure 5 on the flow of assessment.

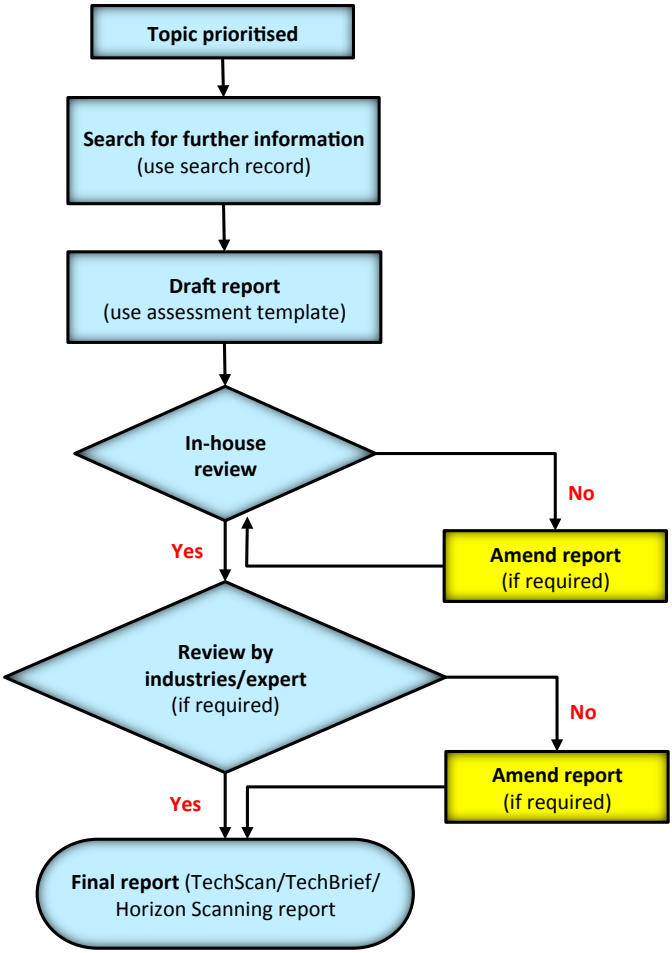

Figure 5. Flow of assessment

3.6. Methods for Predicting Potential Impacts

One of the main purpose of MaHTAS horizon scanning system is to assess or predict the future impact of a technology so that research funder may set funding priorities, investment agencies may decide on the investment priorities and decision/policy can be made on adoption/procurement of health technologies based on the assessment. It is a challenge to assess the potential impacts of a technology that is still in the development stage. This is due to lack or uncertainty of data. Various methods have been applied by horizon scanning agencies to predict the future impacts of the technologies as discussed below.

Use of experts

Input from experts in the related field is important in forming opinions about the potential for an emerging technology to work, be adopted and have a significant impact. The expert have the knowledge and experience in managing patients with specific diseases using the current available technologies. The relevant National Head of Clinical Disciplines will be contacted to get their opinion on a technology and to suggest the relevant experts to be involved in the analysis.[6]

Use of quantitative modelling

Quantitative models have been used to predict utilisation, cost and sometimes outcomes of technologies. However in horizon scanning, the concerns are; the prediction accuracy could be difficult to validate due to uncertainty in the assumptions regarding emerging technologies and quantitative modeling is generally time-consuming and expensive. On the other hand, quantitative modeling would provide valuable input to stakeholders to reduce uncertainty in their decision-making process and the intelligence and insight developed during the modeling process could be valuable for stakeholders.[6]

The accuracy of the model will depends on the availability and quality of data, and the granularity of the prediction requested. Inputs from external experts may potentially help reduce the uncertainty in the modeling process and thus improve the model's performance. These experts could be engaged at various stages in modeling, from making assumptions and defining parameters at the beginning to peer reviewing the results at the end.[6]

Various forecasting methods have been proposed. A group in Italy is currently developing a forecasting method for drug utilisation, integrating a dynamic market potential model, based on cellular automata model, with the budget impact analysis approach.[7]

Best-worst scaling

Gallego et al. used Best-Worst Scaling to explore clinicians' view on emerging technologies with respect to their expected impact on hepatocellular carcinoma outcomes in the next 5 to 10 years. Best-Worst Scaling is rooted in random theory and described as a compromise between discrete choice experiments and ranking scales. Best-Worst Scaling assumes that respondents can easily choose items that are extremes (best and worst, most and least, smallest and largest) in a set of three or more items. Balanced incomplete block design was used to construct the set. This design ensured that each task contained five technologies, each one appeared five times and as a pair to another given technology five times. From the five technologies, participants choose most first, and from the four remaining technologies, they then choose the least. The measures of priority scores can be analysed using most minus least scores, square root estimates, and conditional logistic regression analysis.[8]

3.7. Dissemination

Effective dissemination strategy is important to horizon scanning system to ensure that the information produced reach the target audience in a timely fashion.

The completed report will be disseminated via email to the relevant stakeholders. In addition, the report will be uploaded to Ministry of Health Malaysia website after being endorsed by the Health Technology Assessment and Clinical Practice Guidelines Council. The reports can also be accessed through myMaHTAS mobile application.

Other methods of dissemination may include:

I. Sharing with other health care horizon scanning programmes (e.g. EuroScan International Network)
II. Newsletter on key/significant technologies
III. Producing peer-reviewed publications or presenting in other academic venues
IV. Joining and actively participating in EuroScan activities

4. HORIZON SCANNING AND DECISION MAKING

Horizon scanning reports summarised why this new technology is important. The reports will provide sound and timely information to stakeholders for decision making process. Advanced information enables earlier and more effective decision making and planning, thus will results in faster uptake in patients who need the technologies for their treatment.

Horizon scanning will identify topics for Health Technology Assessment activity at an earlier stage so that proper evaluation can be carried out before the technology is adopted.

Technologies which are identified to have potential impact but with insufficient evidence, can be prioritised for research.

Horizon scanning of medical technologies can be used for decision on procurement, planning, programme initiation, health policy making, research, investment, and in clinical practice by various stakeholders as in Figure 6.

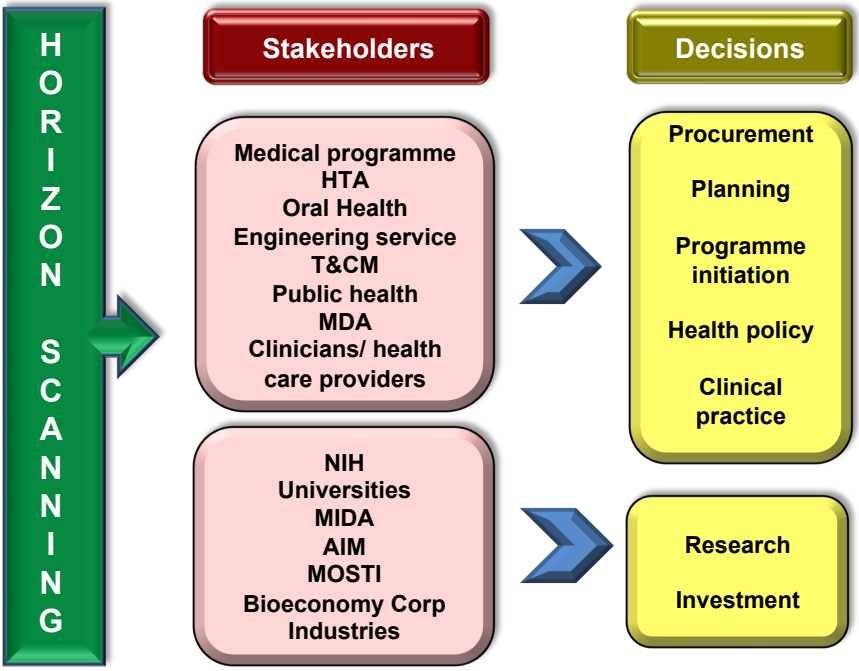

Figure 6. Horizon scanning framework for medical technology

**MaHTAS (Malaysian Health Technology Assessment Section), T&CM (Traditional & Complimentary Medicine), MDA (Medical Device Authority), NIH (National Institutes of Health), MIDA (Malaysian Investment Development Authority), AIM (Agensi Inovasi Malaysia), MOSTI (Ministry of Science, Technology & Innovation), Bioeconomy Corp (Malaysian Bioeconomy Development Corporation)*

For pharmaceuticals, the input can be used in making decision regarding drug registration before it reaches local market, drug evaluation and pharmacoeconomic evaluation as well as planning, procurement, health policy, clinical practice and investment (Figure 7).

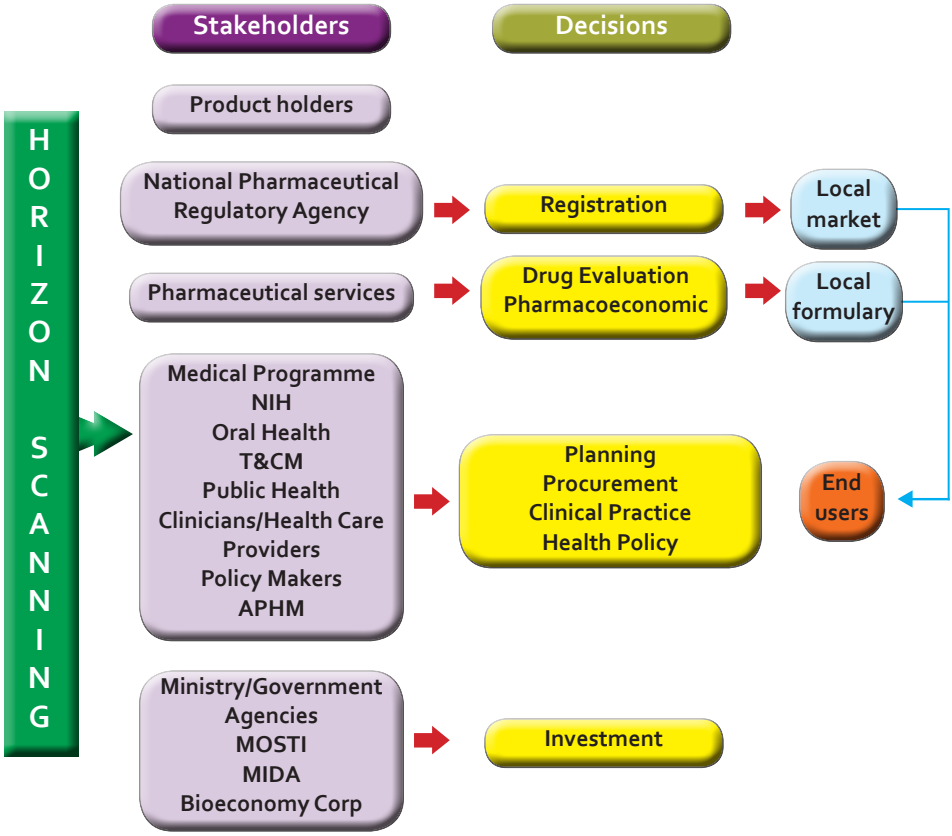

Figure 7. Horizon scanning framework for pharmaceuticals

NIH (National Institutes of Health), T&CM (Traditional & Complimentary Medicine), APHM (Association of Private Hospitals of Malaysia), MOSTI (Ministry of Science, Technology & Innovation), MIDA (Malaysian Investment Development Authority), Bioeconomy Corporation (Malaysian Bioeconomy Development Corporation)

5. EVALUATION OF HORIZON SCANNING METHODS AND SYSTEM

Evaluation is an important component in any horizon scanning system to ensure its effectiveness and efficiency so that further development and improvement can be carried out. A horizon scanning program can be evaluated in terms of its structure,

process and outcomes.[6]

The main outcome of horizon scanning system is the ability to predict the potential impacts of certain technologies. However it is quite challenging to design and conduct rigorous studies for this type of assessment. Simpson et al. conducted a study to assess the accuracy of forecasting using standard diagnostic assessment tools where the sensitivity, specificity and predictive values of the United Kingdom National Horizon Scanning Centre's prediction methods were estimated with reference to an imperfect gold standard, that is expert opinion of impact 3 to 5 years after prediction.[9] Such evaluation may be conducted at least five years after the system has been established.

A periodical survey may also be conducted to ask the stakeholders on the impact of the horizon scanning reports on their decision making.

The direct outputs of the horizon scanning system such as the number and type of assessment, the quality and acceptability of the report and the accessability can be evaluated periodically. A periodical survey or feedback mechanism can be developed to assess the quality and acceptability of the report whereas the accessability can be evaluated based on number of request of the report and number of downloads from the website.

The structural aspect that can be evaluated includes funding, governance and mandate, place in policy making process, independence from commercial, political or other influence, staffing and facilities.[4]

The process that can be evaluated includes timely identification of topics, application of explicit and agreed identification criteria, application of explicit agreed filtration and/or prioritisation criteria, application of agreed investigation and reporting methods e.g. timeliness, quality sources, use of experts, peer review and timely updating of information systems such as licensing plans, expert contact details and output from system.[6] The evaluation of the structures and processes may be conducted through internal or external audit process.

6. ENGAGEMENT WITH COMMERCIAL DEVELOPERS

Basic information about a technology can usually be found on company websites, in commercial databases and through general internet searches. However, to obtain detailed information about a technology such as development status, regulatory or marketing plans, unpublished or ongoing studies and pricing information, it is usually necessary to contact the developer directly.[4]

Some of the technologies which are within the pipeline or still in the research stage will not be available publicly. Thus, the engagement with industries such as pharmaceutical companies, medical device companies and manufacturers of diagnostic tests is essential. However, it is recognised that working with these

industries can be problematic due to differing purposes and conflicts of interest.

Three mechanisms are used for engagement process, via:

a) proforma send by industries/agencies/research institutes
b) pipeline meeting with industries
c) routine company contact

MaHTAS Horizon Scanning Unit recommends Guidelines on Interaction with Industries (see Annex 11) to be observed by the members while interacting with industries. This guideline aims to protect the interest of both parties, in order to cultivate positive contacts and to ensure that interaction happens on terms acceptable to both parties.

MaHTAS Horizon Scanning Unit has prepared Confidentiality Statement (see Annex 12) to be given to the industries in gaining their trust to provide the information needed as well as protecting their confidentiality.

6.1. Pipeline Meeting

The pipeline meeting is a platform to exchange information between MaHTAS and commercial developers especially to discuss technologies which are yet to enter the market and to gain additional information and constructive advice from the industries regarding their pipeline products.

The pipeline meeting is usually conducted with key innovator companies which are identified and prioritised based on their research & development (R&D) budget, complexity/size of known pipeline, timing and success of previous meetings and existing relationships.

The meeting which is conducted either through face to face, video conference, tele-conference or email exchange, gives opportunity for exchange information as below:

- The role and function of MaHTAS Horizon Scanning Unit and other relevant agencies
- Development stage, patient indications and regulatory plans/timelines for all company products
- Identify other products that were not previously identified through scanning or prior company contacts
- Remove discontinued/obsolete products

Information and advice obtained from the pipeline meeting will be excerpted to produce Horizon Scanning report. Furthermore, pipeline meeting may also be used to present report on specific technologies produced by the company and seek their insight and opinion.

The frequency of the pipeline meeting will depends on the size of the companies' pipeline products and agreement between the companies and MaHTAS.

6.2. Routine Company Contact

Routine established company contact can be done by email. For non established company, the contact details can be retrieved from website, publications, licensing information, telephone call or contacting CEO directly to request information;

- on individual products identified through routine scanning or prior company contacts
- to support initial filtration, prioritisation or later preparation of full briefing outputs
- on development stage, patient indications and regulatory plans/timelines
- on updates of technologies already being tracked
- for filtration, prioritisation and output for writing

Routine company contact will also provide opportunity to the companies to comment on draft outputs, correct factual errors and identify commercially confidential information.

7. ENGAGEMENT WITH EXPERTS

Experts play an important role in horizon scanning system. Experts is one of the source of information for emerging technologies. They may also be consulted to get additional information prior to filtration process especially to verify the innovativeness of a particular technology within their specialty area and to get more information about current management of the diseases.

Input from experts is important to assist in predicting the potential impacts of a particular technology during the assessment process. However, it is important to bear in mind, expert opinion should not substitute comprehensive, proactive searches of other sources of information.[6]

Engagement with experts can be done through these mechanism:

a. Proforma submitted by experts
b. Periodic meeting with experts to get input on emerging technologies or prioritised area via various medium such as face to face, videoconference, teleconference and email exchange

Potential conflict of interest is an important factor to consider in selecting expert informant.[6] The identified experts will be appointed as expert panel for a specific technology being analysed and will have to declare their conflict of interest by completing the Declaration of Competing Interest form (see Annex 13). A database of experts who are willing to be involved with horizon scanning activity will be kept.

8. CODE OF PRACTICE AND CONFIDENTIALITY STATEMENT

Engagement with commercial developers requires careful management and transparent processes understood by both parties at the outset. MaHTAS has delineated the code of practice in dealing with industries in Guidelines on Interaction with Industries (see Annex 11). This guidelines has to be observed by all MaHTAS members to avoid conflict of interest and in maintaining integrity. All horizon analysts will have to declare their conflict of interest by completing the Declaration of Competing Interest form (see Annex 13).

Some of the information received by MaHTAS Horizon Scanning Unit may be confidential. Explicit statements about how the commercial in confidence information is identified and managed, the purpose of sharing confidential information and with whom the information will be shared is declared in the Confidentiality Statement (see Annex 12).

Confidential information will be kept in confidential files in a locked and barred metal cabinet as outlined in Guidelines and Procedure on Classification and Reclassification issued by the Office of the Chief Government Security Officer. Only appointed officers are allowed to handle confidential information.

GLOSSARY

Medical Devices

'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

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

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

Note: Products which may be considered to be medical devices in some jurisdictions but not in others include disinfection substances, aids for persons with disabilities, devices incorporating animal and/or human tissues, devices for in-vitro fertilization or assisted reproduction technologies. (http://www.who.int/medical_devices/definitions/en/)

Diagnostics

A diagnostic includes any technologies either an equipment or technique used in medical diagnosis.

Biologics

Biologics are medications targeted to specific genotypes or protein receptors. Biologics include hormones, growth factors, interferons, interleukins, polypeptides, monoclonal antibodies and vaccines.[10]

Clinical Procedures

Clinical Procedures is defined as any practice of a health practitioner that involves a combination of special skills or abilities and may require drugs, devices or both.[11]

Surgical procedures refer to all invasive therapies performed as in-patient surgery, where in-patient surgery is defined as a surgical operation or procedure which is performed with an overnight stay in an in-patient institution.

(International Classification of Disease (ICD) 9-CM and case mix)

Regenerative Technologies

Regenerative technologies refer to technologies used in regenerative medicine in replacing or regenerating human cells, tissue or organs to restore or establish normal function.[12]

Pharmaceuticals

A pharmaceutical is a drug or medicine that is prepared or dispensed in pharmacies and used in medical treatment.

Traditional and Complementary Medicine

Traditional medicine

Traditional medicine is the sum total of the knowledges, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.

Complementary/alternative medicine (CAM)

The terms "complementary medicine" or "alternative medicine" are used interchangeably with traditional medicine in some countries. They refer to a broad set of health care practices that are not part of that country's own tradition and are not integrated into the dominant health care system.
(http://www.who.int/medicines/areas/traditional/definitions/en/)[13]

Public Health Interventions

Public Health Intervention is defined as a set of actions which may include policy, regulatory initiatives, single strategy projects or multicomponent programmes intended to promote or protect health or prevent ill health in communities or populations.[14]

Commercial Developers

A commercial developer of a health technology/technologies is defined as an individual, a group of people or a company that develops, manufactures, markets or distributes a health technology/technologies.

ANNEXES

MaHTAS
Malaysian Health Technology Assessment Section

PHARMACEUTICAL INFORMATION PROFORMA

Instruction notes:

1. *This form is intended to be used for pharmaceutical only.*
2. *For other medical technologies, please use form HS 02 (Medical Technologies Information Proforma)*
3. *Please fill in the form as complete as possible*

Date:		**Name:**	
Company name:		**Position in company:**	
Address:		**Email:**	
		Telephone:	

Technology description		**Confidential Information Tick (√) where applicable**
Technology/product name		
Generic/ active pharmaceutical ingredient name		
Patient group/ indication including stage of disease and targeted patient-sub-groups (*e.g.: advanced or metastatic disease in women with HER-2 positive breast cancer*)		
Place in the treatment pathway (*e.g.: first or second line*)		
Brief description of the technology		

Is it a new drug?		
Intended use of technology (*e.g.: prevention, treatment*)		
Route of administration (*e.g.: oral or intravenous*)		
Treatment schedule &/ or combination (*e.g.: once a day, 28 days cycle*)		
Is the new technology planned to be additional to current therapy or used as a substitute?		
Is the technology already available for a different patient group?		
Who are the commercial developers &/or distributors?		

Stage of development, availability, and licensing and launch plans		**Confidential Information Tick (√) where applicable**
Does the technology have the marketing authorization in a different patient group/s		
When do you anticipate submitting a local marketing authorization application?		
Is your product a designated orphan drug in any countries? Please state		

Is your product available, licensed or launched in other countries? If not, do you have any marketing plans in other countries?		

Current alternatives		**Confidential Information Tick (√) where applicable**
What are the current treatment or management options for the patient group?		
What advantages does the new technology have over current options? (*e.g.: fewer adverse effects, shorter length of stay etc*)		

Costs		**Confidential Information Tick (√) where applicable**
What is the cost per treatment or per unit of administration &/or estimated cost over a specific time period.		
Are the additional cost related to your product? (*e.g.: days in hospital, monitoring tests*)		
What is the cost of current treatment or other management options for this patient?		

Clinical need, burden of disease		**Confidential Information Tick (√) where applicable**
What is the burden of disease in Malaysia? (*e.g.: morbidity, service use & quality of life*)		
Estimated potential uptake of the technology amongst the relevant patient group or healthcare professionals.		

Research evidence		**Confidential Information Tick (√) where applicable**
<u>Published clinical trials</u> *Please list references, and attach copies of relevant publications and abstracts from publications or conferences that are not readily available on the internet.*		
• trial number/name		
• location		
• trial funders, sponsors		
• study design		
• inclusion and exclusion criteria		
• treatment arms		
• length of follow up		
• primary and secondary endpoints		

• numbers of patients in trial		
• start date		
• date of full patient accrual		
• date of interim analysis		
• date of final analysis or publication		
• results		
Unpublished completed clinical trials *Please give details of the following, &/or attach copies of protocols, press releases and abstracts*		
• trial number/name		
• location		
• trial funders, sponsors		
• study design		
• inclusion and exclusion criteria		
• treatment arms		
• length of follow up		
• primary and second-ary endpoints		
• numbers of patients in trial		
• start date		
• date of full patient accrual		
• date of interim analysis		
• date of final analysis or publication		
• results		

Ongoing clinical trials *Please give details of the following attaching copies of protocols, press releases and abstracts.*		
• trial number/name		
• location		
• trial funders, sponsors		
• study design		
• inclusion and exclusion criteria		
• treatment arms		
• length of follow up		
• primary and secondary endpoints		
• planned patients number		
• start date		
• anticipated date of full patient accrual		
• date of interim analysis		
• expected date of final analysis or publication		
• expected results		

What is the potential or intended impact of the technology (speculative)?

Please tick at the relevant boxes.

Patients		
☐Reduced morbidity	☐Reduced mortality or increased survival	☐Improved quality of life for patients or carers
☐Other, please specify		
Services		
☐Increased use e.g. length of stay, out-patient visits	☐ Service re-organization required	☐ Staff or training needs
☐Decreased use e.g. shorter length of stay, reduced referrals	☐Services – other, please specify	
Costs		
☐Increased unit cost compared to alternative	☐Increased – more patients coming for treatment	☐ Increased – capital investment needed
☐New costs, please specify	☐Savings, please specify	☐Other, please specify

Please email/fax this Proforma to:
Malaysian Health Technology Assessment Section (MaHTAS)
Fax: 03 - 8883 1230
Email: horizonscanningunit.cptk@moh.gov.my
Tel: 03 - 8883 1229

MaHTAS
Malaysian Health Technology Assessment Section

MEDICAL TECHNOLOGIES INFORMATION PROFORMA

*Please use this proforma for medical devices, regenerative technologies, biologics, intervention/procedures, diagnostics, traditional and complementary medicines.

Date:		**Name:**	
Company name:		**Position in company:**	
Address:		**Email:**	
		Telephone:	

Technology description		**Confidential Information Tick (√) where applicable**
Name of the device/ product Please list any brand name/s, synonyms		
Who are the commercial developer/s &/or distributors (if different)?		
Patient group &/or indication *Please include stage of disease and targeted patient sub-groups (including sex, age-range etc)*		
Brief description of the device (2 paragraphs) *i.e. what it is and how it works*		
What is the intended use of the device? *e.g. prevention, treatment, rehabilitation*		
What is innovative about the device?		

What advantages does the device have over current options? *e.g. ease of use compared to current options, non or less invasive, fewer adverse effects, shorter length of stay in hospital, fewer infections*		
Is the device already available for a different patient group?		
Stage of development, availability and launching plans		**Confidential Information Tick (√) where applicable**
Date of CE mark/ FDA/TGA approval / equivalent		
If not yet CE marked or FDA/TGA/equivalent approved, when is this anticipated? *e.g. Q3 2014*		
Date of actual or planned launches:		
Malaysia – research use		
Malaysia – clinical use: private		
Malaysia – clinical use: government facilities		
Is it available or launch in other countries?		

Research evidence		**Confidential Information Tick (√) where applicable**
Published clinical trials Please list references of relevant publications and abstracts from conferences		

Unpublished completed clinical trial Please provide brief details &/or web links/ trial names/codes for any unpublished completed trials		
Ongoing clinical trials Please provide brief details by attaching copies of protocols, press releases, web links		

Possible impact	
Likely impact of this technology in terms of **patient benefits** (please quantify where possible), *e.g. increased effectiveness in meeting outcomes, safety etc*	
Likely impact of this technology in terms of **system benefits** to the health service (please quantify which possible), *e.g. price, net cost savings, training needs etc.*	

Please email/fax this Proforma to:
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Email: horizonscanningunit.cptk@moh.gov.my
Tel: 03 - 8883 1229

Annex 3
HS 03

MaHTAS
Malaysian Health Technology Assessment Section

HORIZON SCANNING IDENTIFICATION FORM

Date/Week:	
Source:	

Technology Identified:

Source	Name of Technology	IDENTIFICATION CRITERIA			
		Indication/Diseases*	Innovation		
			Novel	Incremental	New indication

*Priority for high burden diseases according to national priority (ie: Diabetes, Hypertension, IHD, dengue, TB, cancer, emerging diseases)

By,

_____

MaHTAS
Malaysian Health Technology Assessment Section

HORIZON SCANNING FILTRATION FORM **No. :** ☐

Technology name: ☐

Innovation:

☐ New

☐ Old with novel approach (*existing technology being used for a new indication/patient group*)

☐ Incremental (*significant innovation of an existing technology*)

☐ Other: _____

Type of technology:

☐ Medical device
☐ Biologic
☐ Diagnostic
☐ Intervention/procedure
☐ Regenerative technology
☐ Pharmaceutical
☐ Traditional & Complementary Medicine

Manufacturer/developer/company:

☐

Time to availability: (*expected to be launched within 24 months)*

- **Stage of diffusion:**

☐ Available but not fully diffused

☐ In clinical trials (phase: _____)

☐ Pre-registration (_____)

☐ Licensed (_____)

☐ Other, *please specify* (_____)

- **CE marking/US FDA approval and equivalent:** (*please mark whichever applicable*)

CE marking	☐	Yes (Date:	)	☐ No
US FDA approval	☐	Yes (Date:	)	☐ No
TGA	☐	Yes (Date:	)	☐ No
Others: *(Please state)*	☐	Yes (Date:	)	☐ No

- **Launching plan:**

Patient group/indication: *(including stage of disease and targeted patient sub-groups, if any)*

Brief description of the technology *(i.e. what is it and how it works):*

Source of information:

☐ MaHTAS team: _____

☐ Company: _____

☐ Expert informants: _____

References:

Prioritisation: ☐ Yes ☐ No

Notes:

MaHTAS
Malaysian Health Technology Assessment Section

HORIZON SCANNING PRIORITISATION FORM

Date	
No.	
Category (Pharmaceutical /Other medical technologies)	

Technology ID		
Technology Name		
Technology Indication		
Company		
Innovativeness (Please tick (√) where appropriate	Novel - completely new	
	Incremental - incremental improvement of the existing technology	
	New indication - new indication of an existing technology	

Technology description

Please score on a scale of 1 to 10 [score 1-3 (low priority), score 4-7 (moderate priority), score 8-10 (high priority)], for each of the sub-criteria below. The total score is 70.

Criteria	Sub-criteria	Explanation	Score
Population/end-user	Disease burden	The impact of the disease in terms of number of people affected, morbidity, mortality and other indicators. **(Higher priority for diseases with higher burden)**	
	Current options for patients	Are there already other treatment regimen available for this specific indication or is this technology is a completely new therapy? Will the technology replace the current treatment or is it an add on? **(Higher priority for novel technologies and if there is no treatment regimen available)**	
Potential impact of technology	Patient	Clinical impact such as morbidity, mortality, quality of life, diagnosis. Comparison with current treatment **(Higher priority for technologies that may reduce morbidity, mortality, improve quality of life and diagnosis)**	
	Cost	Such as increase cost or savings, large capital outlay, direct and indirect costs for patients and society **(Higher priority for expensive technologies)**	
	Service/ organisation	Increase or decrease utilisation of service, structural changes and staff training **(Higher priority for technologies which leads to increase use of service, needs changes in infrastructure and required training)**	
	Societal or ethical	Societal reaction or acceptability towards the technology , ethical issues that may surface **(Higher priority for technologies with higher impact to the society or ethics)**	
	Safety/adverse events	Invasiveness of the technology and the associated adverse events **(Higher priority for technologies with higher safety risk)**	
Total score			

Decision: Prioritised ☐
Not prioritised ☐

Note: _____

Horizon Scanning

Report No. : 000/Year

SUMMARY

- Briefly on:
  - The technology (what is it, how it works)
  - Related (patient group), disease burden.
  - The developer.
  - Current stage of development.
  - Photo of the technology (if available)

POTENTIAL IMPACT

- Clinical – mortality, morbidity, quality of life, diagnosis
- Cost
- Organisational - services , infrastructure, human resources

EVIDENCE

- Studies done on the technology (published papers / abstracts / unpublished paper / ongoing studies / conference paper presentation)

REFERENCES

- Information form – e.g. from company, time-limited internet search
- Vancouver method

Disclosure: The author of this report has no competing interest in this subject and the preparation of this report is totally funded by the Ministry of Health, Malaysia.

Disclaimer: TechScan report is prepared based on information available at the time of research and a limited literature. It is not a definitive statement on the safety, effectiveness or cost-effectiveness of the health technology covered. Additionally, other relevant scientific findings may have been reported since completion of this report.

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Web: http://www.moh.gov.my

TITLE

INTRODUCTION

- Briefly on the technology and the related disease.

THE TECHNOLOGY

- Photo of the technology (if available
- What is it (the technology)?
- Type of technology.
- How does it work / mechanism of action?
- What is the expected outcome?
- Who is the developer?
- In what the current stage of development?
- What is the regulatory status/ approval status?

- *Pharmaceutical
- What is it (the technology)?
- What is its place in the treatment pathway (eg first line, second line)
- What class of drug or pharmacological action of this product?
- Is it a new class of drug for the patient group?
- What other indication is the product licensed for?
- - What is the route of administration? (eg oral, subcutaneous, intravenous (short or infusion)?
- - What are the treatment schedule and/or combination (eg once a day, twice a day, day 1-5 in a 28 day cycle)?

PATIENT GROUP AND INDICATION

- Intended to be used in which group of patient?
- What is the clinical need and burden of the disease?

CURRENT PRACTICE

- What is the current practice/ existing technology for the disease/patient group?
- Compare existing technology with advantages/benefits of the new technology.

SAFETY AND EFFICACY

- Evidence on safety and efficacy

ESTIMATED COST

- Estimate the cost of the technology
- If cost not available report cost of similar technology

OTHER ISSUES

- Organisational
- Ethical

POTENTIAL IMPACT

- Clinical – mortality, morbidity, quality of life, diagnosis
- Costs

- Organisation – health services, infrastructure, human resources
- Social, ethical, legal concerns

REFERENCES

- Information from eg company, time- limited internet search
- Vancouver method

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Report No. : 000/2015

TITLE

INTRODUCTION

Objectives
Clinical Need and Burden of Disease
Current Clinical Practice

METHOD

Search Strategy
Inclusion Criteria
Contacting developers
Clinical Expert and Patient Consultation

RESULTS

No of technologies identified

OVERVIEW OF FINDINGS

Technology 1

Technology 2

Technology 3

DISCUSSION AND CONCLUSION

REFERENCES

Disclosure: The author of this report has no competing interest in this subject and the preparation of this report is totally funded by the Ministry of Health, Malaysia.

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Web: http://www.moh.gov.my

MaHTAS
Malaysian Health Technology Assessment Section

PHARMACEUTICAL – SEARCH RECORD

ID/No.	
Date search record started	
Date output allocated to author	

Technology ID	
Technology Name	
Technology Indication	
Company	

Commercial Developer Contact

Contact Name	
No. Tel	
Email	
Received additional document / information	

Annex 9
HS 09

1. Technology

Technology description, stage of development, press release etc	Date	Search criteria[a]	Notes[c]	N/A (tick √)
Company Websites Technology name (inc codes, etc), background, latest trial info etc				
Google Consider using advanced search (limit to search to last year if appropriate)				
Drug-specific				
Pharmaprojects Drug name				
Adis http://bi.adisinsight.com Drug name				
Electronic medicines compendium (eMC) Licensed drugs http://www.medicines.org.uk				
Tertiary Sources & Other HTA Agencies				
The Cochrane Library Systematic reviews, clinical trials, publications http://www.thecochranelibrary.com/view/0/index.html				
Centre for Reviews and Dissemination – database HTA http://www.crd.york.ac.uk/crdweb				
EuroScan http://www.euroscan.org.uk Require membership login				
CADTH http://www.cadth.ca				

[a]E.g Technology name, disease name, years/quarters, terms, etc
[b]E.g File name, hits, search results

2. GOVERNMENT PRIORITY AREA & RELEVANT GUIDANCE

	Date	Search criteria	Notes	N/A (tick √)
Department of Health National Services Frameworks and Health and Social Care topics http://www.nhs.uk/nhsengland/NSF/pages/Nationalserviceframeworks.aspx				
National Commissioning Group http://www.specialisedservices.nhs.uk/index.php/key-documents/ - NCG policies and publications e.g. annual report also lists regionally commissioned designated services set				
Relevant guidance				
NHS Evidence Health information sources – guidance http://www.evidence.nhs.uk/				
Scottish Intercollegiate Guidelines Network http://www.sign.ac.uk/ Do not rely on search engine – use the Guidelines button on left hand side				

3. CLINICAL BACKGROUND & PATIENT GROUP SIZE

Also useful for patient group size; mortality; and current treatments/tests (see also Section 4 below)	Date	Search criteria	Notes	N/A (tick √)
NIHR HSC briefings Previous and in preparation (see tech. db; progress list or topic allocations list on J drive)				
NICE guidance – technology appraisals, clinical guidelines and interventional procedure guidance; NICE Pathways; NICE Quality Standards Published, in development and proposed (scoping documents) http://www.nice.org.uk NB also consider any associated guidance on implementation, e.g. costing report, which may contain additional information on the likely patient group size in order to inform an economic model				
TRIP www.tripdatabase.com				

Map of medicine Clinical pathways of care http://app.mapofmedicine.com/mom/1/index.html Require membership login				
UK HTA programme Reports and projects http://www.ncchta.org/				
Orphanet EU info on rare diseases http://www.orpha.net/consor/cgi-bin/home.php?Lng=GB				
Specifically for patient group size and mortality data: Make sure you have the correct ICD code(s) e.g. for HES/mortality data – if in doubt ask				
Clinical Evidence (book or electronic access) http://www.clinicalevidence.bmj.com/ceweb/servlet/LoginServlet Require membership login				
Hospital Episode Statistics (need ICD or OPCS code) Codes: http://www.who.int/classifications/apps/icd/icd10online/ HES data: http://www.hesonline.nhs.uk/				
Mortality data (need ICD 10 code) Series DR available at: http://www.statistics.gov.uk/hub/releasecalendar/index.html?newquery=*&uday=0&umonth=0&uyear=0&title=Mortality+Statistics%3A+Deaths+registered+in+England+and+Wales+%28Series+DR%29&pagetype=calendar-entry&lday=&lmonth=&lyear=or				
The Association of Public Health Observatories Useful information on a number of conditions, including prevalence models for Cancer, CVD, CKD, COPD, CHD, Dementia, Diabetes, Hypertension, Mental Illness, Stroke (NB not all up to date) http://www.apho.org.uk/default.aspx http://www.apho.org.uk/resource/view.aspx?RID=48308				

NHS Indicator Portal A wide-ranging collection of over 1,000 indicators designed to provide a comprehensive overview of population health at a national, regional and local level. Also: GP Practice data, Local Basket of Inequalities Indicators, NHS Outcomes Framework, Summary Hospital-level Mortality Data. https://indicators.ic.nhs.uk/webview/				
Additional sources used by author (optional): Remember to reference clearly in the briefing				

4. REGULATION & LICENSING

Reports on same technology that is licensed for another indication	Date	Search criteria	Notes	N/A (tick √)
EMEA EudraPharm Database of authorised products (inc MedTech) in EU www.eudrapharm.eu				
EMEA Details of orphan drug status http://www.emea.europa.eu/htms/human/orphans/intro.htm				
FDA http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm Search FDA drugs database and whole website, sometimes get extra information this way.				
FDA orphan drug list Details of orphan drug application http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm				

5. EFFICACY & SAFETY

Clinical trials - ongoing; completed and published (e.g. abstract, journal article etc.)	Date	Search criteria	Notes	N/A (tick √)
ClinicalTrials.gov http://www.clinicaltrials.gov				
WHO International Clinical Trials Registry http://www.who.int/trialsearch/Default.aspx				

EU Clinical Trials Register https://www.clinicaltrialsregister.eu/				
Current Controlled Trials Un-tick National Institutes of Health http://www.controlled-trials.com/mrct/				
UKCRN Portfolio Database http://public.ukcrn.org.uk/search/				
PROSPERO http://www.crd.york.ac.uk/PROSPERO/ International open-access database of ongoing systematic reviews hosted by CRD, University of York				
Primary research: Epidemiology and number of trials published				
PubMed, Medline & Medline in Progress, & EMBASE* http://www.elibrary.bham.ac.uk/ - Require membership login Click on 'find resource' then enter name of database i.e. Medline, Embase or Pubmed Or access PubMed separately using: http://europepmc.org/				

*Instructions for Medline searching:
Mark searches as human (don't limit to English as there may be English abstracts for foreign language papers)
Search all disease names using MeSH (exploded) and KEYWORDS and technology names KEYWORDS as appropriate
Combine results using OR and select all subheadings (If there are lots of hits – reduce to more recent publications)
Limit to clinical trials by selecting appropriate terms for clinical trials of interest
Combine searches of disease and drug name using AND
You won't be able to use MESH headings or limit to clinical trials in 'Medline in Progress'.

You won't be able to limit to clinical trials in EMBASE

6. COST

	Date	Search criteria	Notes	N/A (tick √)
BNF & BNF for Children Paper copy in G27 and website: http://www.bnf.org/ (need to register for own login) Or Drug Tariff http://www.ppa.org.uk/ppa/edt_intro.htm				
NHS Reference Costs (Healthcare Resource Groups - HRGs) - Need to be used in conjunction with the OPCS/ICD codes. HRGs are standard groupings of clinically similar treatments which use common levels of healthcare resource: http://www.ic.nhs.uk/services/the-casemix-service/new-to-thisservice/healthcare-resource-groups-4-hrg4				

7. SPECIFIC DISEASE AREAS

Scientific meeting abstracts and patient groups; for other disease areas not listed below, attempt to identify & search the most relevant conference, association etc.

	Date	Search criteria	Notes	N/A (tick √)
CANCER				
ASCO (American Society for Clinical Oncology) http://www.asco.org				
ESMO (European Society for Medical Oncology) http://www.esmo.org				

	Date	Search criteria	Notes	N/A (tick √)
CANCER				
European Organisation for Research and Treatment of Cancer http://www.eortc.be/ - go to 'protocols database'				
National Cancer Institute http://www.cancer.gov/clinicaltrials				
Southwest Oncology Group - SWOG http://swog.org				

Eastern Cooperative Oncology Group - ECOG http://ecog.dfci.harvard.edu - go to "active protocols"				
National Surgical Adjuvant Breast and Bowel Project - NSABP http://www.nsabp.pitt.edu				
San Antonio Breast Cancer Symposium http://www.sabcs.org				
Cancer Research UK Cancer information, stats and trials http://info.cancerresearchuk.org/cancerstats/?a=5441				
CancerBackup (Now on Macmillan cancer support website) http://www.macmillan.org.uk/Home.aspx				
Leukaemia Research http://www.lrf.org.uk/				
National Cancer Intelligence Network lead national registries http://www.ncin.org.uk/collecting_and_using_data/leadregistries.aspx				
Welsh Cancer Intelligence & Surveillance Unit http://www.wales.nhs.uk/sites3/home.cfm?orgid=242				
CARDIOLOGY & CARDIOVASCULAR DISEASE				
Cardiology Trials http://www.cardiosource.com				
British Heart Foundation Statistics http://www.heartstats.org				
Stroke trials http://www.strokecenter.org/trials/				
American College of Cardiology www.acc.org - search latest conference on left and/or "cardiosource"				

	Date	Search criteria	Notes	N/A (tick √)
CANCER				
Medscape – Cardiology www.medscape.com/cardiologyhome - search "medscape" and/or "drug reference"				
European Society of Cardiology Annual Congress http://www.escardio.org				
DIABETES				
Diabetes UK http://www.diabetes.org.uk/				
American Diabetes Association http://www.diabetes.org				
Yorkshire and Humber public health observatory http://www.yhpho.org.uk (check for current diabetes model)				
Diabetes Data Directory Access to different datasets & links http://yhpho.york.ac.uk/diabetesdd/introddd.asp				
OTHER SPECIALTIES				
American Society of Hematology (ASH) http://www.hematology.org//				
European Hematology Association (EHA) www.ehaweb.org				
Association of Rheumatology Health Professionals (ACR/ARHP) www.rheumatology.org/arhp/index.asp				
European League Against Rheumatism (EULAR) http://www.eular.org				
American Association for the Study of liver Diseases (AASLD) www.aasld.org				
European Association for the Study of Liver Diseases (EASL) www.easl.ch Abstracts not on web - published in Journal of Hepatology				

OPTIONAL SOURCES

Clinical background & epidemiology:	Date	Search criteria	Notes	N/A (tick √)
Merck Manual http://www.merck.com/pubs/mmanual_home/contents.htm				
Health Care Needs Assessment Series http://www.hcna.bham.ac.uk/chapters.shtml				
Clinical background & epidemiology:	**Date**	**Search criteria**	**Notes**	**N/A (tick √)**
ASERNIP and ASERNIP-S NETS Surgical procedures only http://www.surgeons.org/Content/NavigationMenu/Research/ASERNIPS/default.htm				
Evaluation and Review of NICE Implementation Evidence (ERNIE) http://www.nice.org.uk/usingguidance/evaluationandreviewofniceimplementationevidenceernie/evaluation_and_review_of_nice_implementation_evidence_ernie.jsp				
Google http://www.google.co.uk/				
GOOGLE – SCHOLAR http://scholar.google.com/ Specific article – authors last name then keywords in quotation marks				
NHS Evidence http://www.evidence.nhs.uk/				
NHS Choices http://www.nhs.uk/Pages/HomePage.aspx				
Patient UK http://www.patient.co.uk				
National Cancer Intelligence Network Useful links to other relevant cancer –related websites www.cancer.nhs.uk/index.htm				

The Association of Public Health Observatories Useful information on public health topics. http://www.apho.org.uk/default.aspx				
Labtests online Information on disease area and currently available tests http://www.labtestsonline.org/				
Census data Key statistics tables - see list of tables on left, e.g. KS01. Put the table you want into the search box http://www.statistics.gov.uk/census2001/table_list_ks.asp				
Community Health Profiles (click on profile for England on left) http://www.communityhealthprofiles.info/				
Health Protection Agency Infectious disease (topics A-Z) http://www.hpa.org.uk/				
Clinical background & epidemiology:	**Date**	**Search criteria**	**Notes**	**N/A (tick √)**
eMedicine (need to register for free access) US data www.emedicine.com				
National Screening Programmes http://www.screening.nhs.uk/				
Patient group size & mortality data:				
Compendium of Population Health Indicators NHS Information Centre – a wide range of information on individual conditions, primary care, secondary care, Public Health and inequalities https://indicators.ic.nhs.uk/webview/				
Quality Outcomes Framework GP data http://www.ic.nhs.uk/statistics-and-data-collections/supportinginformation/audits-and-performance/the-quality-and-outcomesframework/qof-2007/08/data-tables				

Prescribing data - England Primary and secondary care prescribing J:\HS-HORIZON\data and databases\Prescription data and costs http://www.ic.nhs.uk/statistics-and-data-collections/primarycare/prescriptions				
Health Statistics - Wales http://new.wales.gov.uk/topics/statistics/theme/health/?lang=en				
Welsh Prescribing data Applies to community prescribing only http://www.wales.nhs.uk/sites3/page.cfm?orgid=428&pid=13533				
Patient groups: *For rare diseases where more information is still needed* *If used as source, reference clearly in briefing*				
Contact a Family http://www.cafamily.org.uk				
National Organisation for Rare Disorders http://www.rarediseases.org				
UK & International HTA & drug info:				
ECRI http://www.ecri.org - click on 'members' Username: xxxxx Password: xxxxx				

Clinical background & epidemiology:	**Date**	**Search criteria**	**Notes**	**N/A (tick √)**
OPCS Chemotherapy regimes J:\HS-HORIZON\data and databases\ICD and OPCS codes\OPCS46 chemo reg List and HCD list subpack Contains information on high cost drugs for cancer and chemotherapeutic regimes.				
UK Database of Uncertainties about the Effects of Treatments (DUETs) http://www.library.nhs.uk/duets/ Site maintained by NHS Evidence				

CADTH, Canada (Diabetes Library) http://www.cadth.ca/index.php/en/diabetes				
Australia and New Zealand Horizon Scanning Network (ANZHSN) Devices and diagnostics http://www.horizonscanning.gov.au/internet/horizon/publishing.nsf/Content/technologies-assessed-lp-2				
The Institute of Cancer Research http://www.icr.ac.uk/research/				
Licensing				
Scottish Medicines Consortium http://www.scottishmedicines.org/ - go to medicines or work programme				
Costs				
NHS Reference Costs (Healthcare Resource Groups - HRGs) - Need to be used in conjunction with the OPCS/ICD codes. HRGs are standard groupings of clinically similar treatments which use common levels of healthcare resource: J:\HS-HORIZON\data and databases\HRG_3.5 (HRG codes) - OLD or http://www.ic.nhs.uk/services/the-casemix-service/new-to-thisservice/healthcare-resource-groups-4-hrg4 and **J:\HS-HORIZON\data and databases\Reference costs & Tariff (costs)**				

Annex 9
HS 09

Any additional sources used by author (optional): *Remember to reference clearly in the briefing*	**Date**	**Search criteria**	**Notes**	**N/A (tick √)**

MaHTAS
Malaysian Health Technology Assessment Section

MEDICAL TECHNOLOGY – SEARCH RECORD

ID/No.	
Date search record started	
Date output allocated to author	

Technology ID	
Technology Name	
Technology Indication	
Company	

Commercial Developer Contact

Contact Name	
No. Tel	
Email	
Received additional document / information	

Annex 10
HS 10

1. Technology

	Date	Search criteria	Notes	N/A (tick √)
Company Websites Technology name (inc codes, etc), background, latest trial info etc				
Google Consider using advanced search (limit to search to last year if appropriate)				
Tertiary Sources & Other HTA Agencies				
ASERNIP and ASERNIP-S NETS Surgical procedures only http://www.surgeons.org/racs/research-and-audit/asernip-s/asernip-s-procedures				
TRIP www.tripdatabase.com				
ECRI http://www.ecri.org Require membership login				
EuroScan http://www.euroscan.org.uk Require membership login				
CADTH http://www.cadth.ca				
HealthPACT – Formerly Australia and New Zealand Horizon Scanning Network (ANZHSN) Devices and diagnostics assessed after 2011 http://www.health.qld.gov.au/healthpact/html/tech-evaluated.asp Devices and diagnostics assessed before 2011 http://www.horizonscanning.gov.au/internet/horizon/publishing.nsf/Content/technologies-assessed-lp-2				
NETSCC www.netscc.ac.uk				

Testing Sources & Other HTA Agencies	Date	Search criteria	Notes	N/A (tick √)
NICE guidance Under 'find guidance' go to 'guidance by type' and search: Technology appraisals, clinical guidance, interventional procedures guidance, medical technologies guidance, diagnostic guidance – look at published, in development and proposed etc				

2. EVIDENCE

Clinical trials – ongoing; completed and published (e.g abstract, journal article, etc)	Date	Search criteria	Notes	N/A (tick √)
ClinicalTrials.gov http://www.clinicaltrials.gov				
WHO International Clinical Trials Registry http://www.who.int/trialsearch/Default.aspx				
Current Controlled Trials Un-tick National Institutes of Health http://www.controlled-trials.com/mrct				
PROSPERO http://www.crd.york.ac.uk/PROSPERO International open-access database of ongoing systematic reviews hosted by CRD, University of York				
EU Clinical Trials Register http://www.clinicaltrialsregister.eu				
The Cochrane Library http://www.cochrane.org – select the blue Cochrane Library button				
The Institute of Cancer Research (if a cancer topic) http://www.icr.ac.uk/research/research_divisions/Clinical_Studies/clinical_trials/index.shtml				
UKCRN Portfolio Database (if a cancer topic) http://public.ukcrn.org.uk/search				

Clinical trials – ongoing; completed and published (e.g abstract, journal article, etc)	Date	Search criteria	Notes	N/A (tick √)
PubMed, Medline & Medline in Progress, & EMBASE http://www.elibrary.bham.ac.uk – Require membership login **OR** **PubMed only** http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=PubMed				
GOOGLE SCHOLAR http://scholar.google.com/				

MINISTRY OF HEALTH MALAYSIA

GUIDELINES ON INTERACTION WITH INDUSTRIES

1. MaHTAS Horizon Scanning Unit should in all respects remain entirely independent from industry, should act impartially and should not be influenced by social or business relations. Gifts and hospitality from industry should not be accepted.
2. Where there is a potential for a private interest to be relevant to the business of Horizon Scanning systems the relevant interests should be declared and recorded in the individual Horizon Scanning member's register. The register should be kept up to date, and available for scrutiny.
3. When somebody is providing information to the MaHTAS Horizon Scanning Unit, the information should be transparent and contain specific conflict of interest (CoI) declaration.
4. MaHTAS Horizon Scanning Unit recognises that some information supplied by industry is considered as 'commercial in confidence'. Confidential information received from industry will be handled according to the written policy for maintaining confidentiality.
5. MaHTAS Horizon Scanning Unit will maintain a neutral approach towards industry on the identification and prioritisation of technologies and to any assessment of impact undertaken.
6. The information provided by MaHTAS Horizon Scanning Unit in our assessment of impact should reflect accurately and critically (as from any other source) any information that has been provided by industry, should make reference to the source, and should not endorse any particular product or company.
7. Any assessments of technologies that contain information provided by industry and not generally available could be sent to the relevant industry contact for comment before publication. MaHTAS Horizon Scanning Unit will decide how to handle any comments returned.
8. The assessments of impact produced by MaHTAS Horizon Scanning Unit remain the responsibility of the MaHTAS Horizon Scanning Unit itself, and we have the full authority to decide how they will be published and distributed.

Adapted from EuroScan International Network, A Toolkit for the Identification and Assessment of New and Emerging Health Technologies, October 2014

MINISTRY OF HEALTH MALAYSIA

CONFIDENTIALITY STATEMENT

The MaHTAS Horizon Scanning Unit, Ministry of Health Malaysia is funded by the Ministry of Health Malaysia (MOH) to provide key MOH policy-makers, research funders and research institutes with advance notice of health technologies and interventions that are likely to have a significant impact on the public health services in Malaysia.

Information held by the MaHTAS Horizon Scanning Unit is used to provide advice to national policy-makers responsible for evaluating and appraising new technologies and planning or supporting their introduction into the public health services.

The advice provided by the MaHTAS Horizon Scanning Unit may be in the form of verbal briefings, electronic updates, and/or written briefings. The information provided by the MaHTAS Horizon Scanning Unit may contain confidential and/or commercially sensitive information ("Confidential Information"); this may be shared with: MOH policy-makers, research institutes within MOH, Malaysian Investment Development Authority, Medical Device Authority, National Innovation Agency Malaysia, Malaysian Bioeconomy Development Corporation Sdn. Bhd., Ministry of Science, Technology and Innovation who may wish to contact the technology developer(s) for additional information about products in development.

1. The MaHTAS Horizon Scanning Unit acknowledges that information may be disclosed to it which is Confidential Information.

2. The MaHTAS Horizon Scanning Unit undertakes to:
   a. keep all Confidential Information strictly confidential;
   b. not use any Confidential Information for any purpose other than participating in the MaHTAS Horizon Scanning Unit's processes;
   c. restrict access to any Confidential Information to only those persons that need to know such information;
   d. not disclose any Confidential Information to any third party other than for the purposes outlined in the text above, and where the third party is fully aware of the Confidential Information and agrees to be bound by these undertakings.

3. The undertakings set out in paragraph 2 above shall not apply to the use or disclosure of information which:
    a. at or after the time of disclosure or acquisition is in the public domain;or
    b. was lawfully in a third party's possession prior to its disclosure by the MaHTAS Horizon Scanning Unit; or
    c. is required by a court or government agency, provided that the third party notifies the MaHTAS Horizon Scanning Unit in advance of such disclosure; or
    d. is approved for release by prior authorisation from the technology developer(s).

DECLARATION OF COMPETING INTEREST

Horizon Scanning of emerging health technologies is the systematic identification of new and emerging health technologies that have the potential to impact on health, health services, and/or society; and which might be considered for health technology assessment. The methods used can also identify health technologies that are becoming obsolete.

Horizon Scanning reports are important for decision making process. Thus it is important to ensure that the processes are done in a systematic and transparent method. Potential conflict of interest may occur among the heath technology assessors including analysts, expert panels, or other experts involved in reviewing the evidence and predicting the potential impact of the technology . A conflict of interest may be in any form such as financial or other interest that conflicts with one's contributions in an assessment group because it could impair that person's objectivity or could create an unfair advantage.

All the authors and expert panels appointed to assist in assessment of emerging health technologies and the Technical Advisory Committee for Horizon Scanning (TAC HS) members are required to complete a declaration of competing interest detailing the sources of funding, and other possible conflicts of interest. An explicit statement regarding the above is made in the horizon scanning reports.

DECLARATION OF COMPETING INTEREST*

1. Have you in the **last three years** accepted the following from any pharmaceutical and medical device industries that may in any way gain or lose financially from the results of your work (in relation to this health technology):

- A fee for speaking?
- Fund support for research?
- Funding fo r publication?
- Consultancies?

If so, please declare the occasion or event and the organization that provided you with financial support.

Organization	Event

2. Have you, during **last three years,** been employed by an organization that may in any way gain or lose financially from the results or conclusion of this assessment or systematic review?

If so, please declare the organization and the nature of your relationship with that organization.

Organization	Event

3. Do you have any competing financial interest such as investments or directorships? If so specify.

Organization	Interest

4. Do you belong to a political party, special interest group or hold deep personal or religious convictions that may have affected what you have written/contributed and that readers should be aware of when reading your paper?

Organization/personal beliefs that could be perceived as influencing your work.

5. List the source(s) of funding for the assessment of this/these emerging technology/technologies.

_____

_____

_____

Signature : .....

Name : .....

Work place : .....

.....

Title of HTA/TR/HS/CPG that you have contributed : .....

.....

.....

Date : .....

I understand that this declaration will be retained by the MaHTAS Administrator and made available on inspection at the MaHTAS, Ministry of Health Malaysia.

** The Ministry of Health Malaysia requires all the authors, expert panels and the TAC members to fill in this form.*

REFERENCES

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(Android and iOS application)

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