World Health Organization

DEVELOPING AN APPROACH FOR USING HEALTH TECHNOLOGY ASSESSMENTS IN REIMBURSEMENT SYSTEMS FOR MEDICAL PRODUCTS

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WHO/EMP/PAU/2015.5

Executive summary

A two day meeting was held to discuss the use of health technology assessment (HTA) in low and middle income countries (LMIC), including aspects of its use in relation to medicine and health technologies, pricing policies and reimbursement decisions. The meeting brought together experts in HTA and pharmaceutical economics from academia; WHO regional advisors from Europe (EURO), Africa (AFRO), Eastern Mediterranean (EMRO) and the Americas (PAHO), as well as representatives from LMIC that have started using elements of HTA, or are working towards doing so. (Annex 1). In addition, the meeting discussed possible follow-up actions, including a proposed larger consultation to be held late in 2015.

A key discussion point was to identify the future role for WHO in supporting the development of HTA, particularly given the WHA resolution from 2014 (67.23) on the topic that called on WHO to develop global guidance on methods and processes for health intervention and technology assessment in support of universal health coverage.

As has been well described in extant literature, currently HTA is used as a tool in many high income countries as part of a process of selecting pharmaceuticals, clinical procedures and medical devices for reimbursement, budgeting, and insurance programs as well as public health interventions. A wide variety of different organizations and structures have been set up in order to use aspects of HTA, ranging from large institutions to small advisory committees and secretariats in ministries of health. Common elements in advanced systems are staff or personnel with capacity to critically appraise clinical and economic evidence, availability of data on cost and resource utilization, integration in some way with decision-making processes about budgeting, benefit packages, or reimbursement lists. In some countries, pricing of pharmaceuticals or technologies is explicitly linked to HTA (most often narrowed down to economic evaluations), but in combination with other policies such as reference pricing, generic substitution, and control of supply chain mark-ups.

Meeting participants discussed some of the current work of the WHO relating to aspects of HTA. This includes the work on health financing, guidance on cost-effectiveness of interventions and the selection of essential medicines and devices. Results of a large WHO survey of countries with respect to their reported use of and capacity for HTA were presented. Participants from Morocco, South Africa, Indonesia, Slovenia and Jordan, shared their experiences. A broad overview of European work on pricing and reimbursement was presented. Representatives from the WHO regional offices, AFRO, EMRO, EURO and PAHO, presented the regional activities and status of HTA. Some academic perspectives on models of using HTA, education and training program needs, and how to localize the use of HTA in different health care systems were also presented.

Based on the discussion, the priority areas of work for WHO were proposed as:

- Coordinating the many activities in relation to HTA that are currently being undertaken by different agencies for LMIC to ensure that countries get the support that they need and to avoid duplication of effort or conflicting messages;
- Consolidating the existing guidance from WHO, with that in development by other groups, by providing a 'clearing house' for resources, networks, training programs and capacity development;
- Defining the roles and components of HTA holistically for countries so that scientific and organizational components are understood and used appropriately and consistently;
- Promoting that the roles of HTA are understood in the context of other aspects of health system decision making and that HTA is not seen as a 'magic bullet' solution to priority setting, financing and decision-making needs of countries moving towards universal health coverage;
- Promoting that the use of HTA is appropriately linked to other policy tools for managing resources efficiently, especially with regard to pricing and reimbursement policies;
- Setting standards for technical tools used in HTA, such as economic models, to ensure that they are fit for purpose especially when used in LMIC settings
- Clarify the role of the so-called WHO 'cost-effectiveness threshold';
- Supporting countries to define sources of local data for evaluation, and for use in priority setting, managing expenditure and finances in the context of developing universal health coverage.
- Supporting countries in using assessment reports from existing HTA systems
- Developing guidance for countries that are moving towards systems for using HTA, such as a set of possible approaches (laws, regulations, functions, processes, policies to establish and update over time) based on national health care, financing systems, institutional organization and other aspects at a given time.

The objectives for the proposed follow-up consultation are:

- To ensure that the approach under development is consistent with a broader group of stakeholders' views, including a larger sample of countries, HTA agencies, civil society and academic institutions
- To create a platform for coordinating activities with other partners
- To develop drafts of pathways to using HTA over the next 3 months, based on a sample of existing country case studies of successful development and implementation of HTA
- To communicate and obtain feedback on initial approaches for WHO guidance, including the use of the cost-effectiveness threshold
- To develop methods for defining local data sources for use in priority setting and the needs for capacity for analysing and using these data for decision-making
- To launch a `clearing house` of information on capacity development and methodological guidance
- To establish a process for setting the quality standard of technical tools.

The participants in this first meeting have agreed to work as the initial Reference Group for this work.

This meeting was organized with the financial contribution of the European Commission through the EU/ACP/WHO Renewed Partnership on Pharmaceutical Policies . The outcome of the HTA consultations will provide guidance to the 15 African ACP countries part of this project and more particularly those establishing reimbursement systems.

Background

The resolution on Health Intervention and Technology Assessment in Support of Universal Health Coverage (WHA67.23, 2014) called on the World Health Organization (WHO) to develop global guidance on methods and processes for Health Technology Assessment (HTA). HTA is described WHO Executive Board EB134/30 as:

> *'…..is the systematic evaluation of properties, effects and/or impacts of health technologies and interventions. It covers both the direct, intended consequences of technologies and interventions and their indirect, unintended consequences. The approach is used to inform policy and decision-making in health care, especially on how best to allocate limited funds to health interventions and technologies. The assessment is conducted by interdisciplinary groups using explicit analytical frameworks, drawing on clinical, epidemiological, health economic and other information and methodologies. It may be applied to interventions, such as including a new medicine into a reimbursement scheme, rolling-out broad public health programmes (such as immunization or screening for cancer), priority setting in health care, identifying health interventions that produce the greatest health gain and offer value for money, setting prices for medicines and other technologies based on their cost–effectiveness, and formulating clinical guidelines.'*

Recent requests from countries to WHO also reinforce the need for guidance and support for structures and systems to establish HTA processes and policy frameworks. Countries also are in need of tools to develop benefits packages for insurance programmes and require capacity to undertake the technical aspects of HTA. Existing guidance from WHO being used as a starting point include:

- the WHO Model List of Essential Medicines[1];
- WHO clinical treatment and policy guidelines[2];
- benefits package and health financing strategies;
- selected national health strategic plans and or national medicines policies; and
- WHO-CHOICE.

Some upper-middle and high-income countries, have developed guidance documents that are intended to contribute to facilitate decisions made in different areas, including:

- provision of new services;
- reimbursement of technologies in insurance processes;
- pricing of medicines and technologies (and its associated budget impact);

[1] www.who.int/medicines/publications/essentialmedicines/en/
[2] www.who.int/medicines/areas/quality_safety/quality_assurance/guidelines/en/

- geolocation of sites of provision of new services and technologies;
- associated health system investments to provide the new services and technologies that are to be provided or reimbursed; and
- de-commissioning/dis-investment of superseded technologies.

In the context of several projects managed by EMP/PAU[3] aimed at improving access to medicines and health technologies, a number of countries have requested support for developing 'road maps' for initiating and enhancing HTA-informed reimbursement systems for medicines, health interventions and technologies. Within WHO, there have been initial activities to map current HTA activities carried out internally, as well as mapping of the international organisations undertaking HTA activities. Some of the WHO Regional Offices have established regional networks of interested Member States as well as working with existing well-established networks, such as EUnetHTA. Key international professional associations including HTAi, INAHTA and EuroScan also have official links with WHO.

Currently, some independent technical support is being provided to selected countries by established HTA agencies, including NICE (UK), through its consultancy arm, NICE International and HiTAP (Thailand). The Bill and Melinda Gates Foundation is funding some of this work. In addition, there are many academic institutions contributing evidence and capacity strengthening for decision making, for example, the London School of Economics, Harvard Medical School and Mahidol University.

Meeting objectives

In line with resolution WHA 67.23, WHO aims to establish a coordinating and convening role for these many different activities and stakeholders, to ensure that the requirements of the WHA resolution are carried out effectively and efficiently and that the needs of Member States are met. In view of this, the objectives of this initial consultation were:

- developing (or collating if they already exist) a series of country case studies that describe the development of HTA, pricing and reimbursement systems, and highlight what has or has not worked in different contexts
- developing a 'roadmap' for countries to use as a guide for establishing HTA in systems of decision-making
- taking an inventory of existing WHO publications that are potentially useful to guide countries

[3] EU/ACP/WHO Renewed Partnership to strengthen pharmaceutical systems and improve access to quality-assured medicines in 15 African ACP countries: www.who.int/medicines/areas/coordination/en/
Medicines Transparency Alliance http://www.who.int/medicines/areas/coordination/meta/en/

- identifying and defining options for capacity development required for initiating HTA in decision-making; and
- discussing and exploring country needs for WHO technical collaboration in HTA

Summary of presentations

Brief update of the work of the WHO

Any global activities or program of work on HTA must be set in the context of global work on priority setting and health financing, and similarly in countries, HTA needs to be set in the context of the health system. Therefore, an overview of the work on health financing being undertaken by the WHO was provided. Health financing is a key factor in countries' efforts to progress towards universal health coverage. The WHO provides technical and policy advisory support to countries in their assessment of health financing system performance. This serves as the basis to identify and explore policy options for health financing reform. WHO has also been involved in assisting countries to develop their health financing strategy with a view to clarify a country's vision for UHC, objectives, targets and specific reform measures. A key area of work is capacity development in health financing policy analysis and guidance. The link between HTA and health financing is related to strategic purchasing and benefit package design. Benefit package design, however, is not just about defining a list of interventions to be covered. It is a policy instrument with the aim of improving equity, increasing efficiency (e.g., health value for money), "more health for money"), improving financial protection, and increasing transparency in health care, medical product purchasing and financing systems. HTA as one component of benefit package design is relevant in health insurance systems, as well as in other health financing arrangements.

As requested in the WHA Resolution 67.23, an assessment of the status of health intervention and technology assessment in Member States has been conducted. A survey of Member States has been completed, including data on the methodology, human resources, institutional capacity, governance, linkage between health intervention and technology assessment units and policy authorities, utilization of assessment results and needs for capacity development. This work complements the work of the Regional Offices of EURO with EUnetHTA, PAHO and EMRO, and was also used to identify an initial focal point in every Member State for ongoing activities in relation to HTA.

The data show that formal HTA procedures are used predominantly by high income, and upper-middle income countries for assessment of medicines and medical devices. For those that are not using HTA, the most common barriers at the country level included lack of qualified human resources, and a lack of clear process embedding HTA in the decision making. With more choices in terms of medical product coming to the market, combined with uncertainty of their health impact countries are calling for greater transparency and use of evidence in decision

making. Hence countries that have hitherto not used HTA now wish to do so. In conclusion it was suggested by the WHO global survey that HTA usage, is increasingly relevant in resource limited settings, that WHO has a role to play both in HIC as well as in LMIC in this area and that there is a specific need for capacity building. A full report of the survey will be finalized by September 2015, and will contribute to the report to the WHA in 2016 on progress on the Resolution.

It was noted that the WHO global survey needs to be considered in the context of many other similar mapping exercises. The HTA professional associations and networks have some comparable information on various websites. There are many different sources of 'country profiles' and there are several academic groups and others who have prepared reports. While the existing data may serve to inform design of activities and work plans for WHO and other groups, it was also noted that the data became outdated very quickly. The question of whether there should be measurement of 'HTA' or indicators of its use was also discussed, and it was considered that focusing only on HTA would send a mixed message about the importance of it compared to other policies and processes for priority setting. The meeting suggested that therefore there is no specific need to establish indicators on the use of HTA at this point..

Other technical areas of work done by WHO that are relevant to HTA were also discussed. WHO initiated the CHOICE (CHOosing Interventions that are Cost Effective) project in 1998 to assist policy makers with decisions on interventions and programs to maximize health outcomes given available resources. Further to this, the development of a health system costing tool, the OneHealth tool which is used as part of a strategic planning exercise, has identified that countries are often ambitious when planning their national health strategic plans as they do not take into account required health system resources. CHOICE tools can be used as a priority setting exercise for predominantly low income countries or those developing public insurance schemes, to make efficient use of resources in their benefit package design.

A specific technical issue is the interpretation and use of cost-effectiveness thresholds for priority setting and decision-making. Since the publication of the Report of the Commission on Macroeconomics in Health in 2001[4], the 'WHO cost-effectiveness threshold' has been considered as between one and three times GDP per capita. Some countries have interpreted this as a fixed threshold for use in decisions about reimbursement of pharmaceuticals, which was not the intent of the threshold and also results in potentially unaffordable prices. The meeting supported that WHO publishes a clarification of the intent, use and misuse of cost-effectiveness thresholds, noting that very few countries are using explicit thresholds to inform decision-making. In addition budget impact and affordability, fairness and other system factors need to be considered in priority setting decisions.

[4] Commission on Macroeconomics and Health, Macroeconomics and Health: Investing in Health for Economic Development (Geneva: WHO, 2001)

The experience of the regional offices and countries attending was also presented.

Summaries of the key aspects of these presentations are in Tables 1 and 2 (p.11-15).

DISCUSSION

1. Need for a 'road map'/guidelines for LMICs

The group discussed how to design a `roadmap` or guidance for countries wishing to implement aspects of HTA in decision making on health care priorities. Again, noting the importance of avoiding duplication of effort, it was suggested to avoid being too detailed or prescriptive as neither the starting point nor the end goals are the same for every country. In addition, strategies will vary across systems based on unique local issues and challenges and over time because decision making contexts within each system and country change constantly. Suggested considerations were as follows:

- There needs to be a situation analysis that describes the current health care and financing status, current legislature/framework, available data and identification of overall long term specific goals or needs.
- Given the experience of most high income countries, starting with the aim of a stand-alone institution is not necessary; an initial process using available capacity and existing systems has been the starting place for most countries.
- There should be a step-by-step process for working towards the goal of applying HTA in decision making, where the entire system and context needs to be considered. It would be useful to have a number of case studies of different countries, focusing on how each country started to implement HTA for different purposes, how selected countries are using HTA today, and what challenges they face for including HTA in priority setting, pricing and other decisions. Specifically, what have other countries done that has worked, failed and what are the common themes.
- The identification of what legislation is already in place and what new legislation is needed to help implement HTA is important.
- Identifying enabling factors for using HTA in decision-making, such as a culture of evidence-based medicine
- HTA implementation is a dynamic process, and the country should treat it as a process that needs monitoring and evaluation and adaptation.
- The country must decide the appropriate level of transparency required for appropriate governance and sustainability of decision-making systems .

2. The need for data for decision making

The issue of the lack of, and need for, local or localized data in HTA assessments was a key point; as well as the need for capacity to use existing data for generating information for decision making. It was noted that

- Countries need to identify sources of local data in relation to costs, utilization and expenditures for the purpose of undertaking assessments and monitoring.
- There must be capacity to manage the data and analyze it, as well as to synthesize, interpret, and incorporate it into decision-making. Establishing a unit within a MOH to carry out this work should have a high priority.
- Countries should be able to use whatever local data they already have, or use estimates from neighbouring countries with similar epidemiological and health system profiles, as a start.

Priorities for WHO

Based on the discussion, meeting participants suggested the WHO to play a role in coordinating a network of relevant organizations and individuals, with a view to facilitating collaboration. The specific tasks are:

- Coordinating the many activities in relation to HTA that are currently being undertaken by different agencies to ensure that countries get the support that they need and to avoid duplication of effort or conflicting messages;
- Consolidating the existing guidance from WHO, with that in development by other groups, initially by providing a clearing house for resources, networks, training programs and capacity development;
- Defining the possible roles, purpose and scope of HTA fully for countries so that scientific and organizational components are understood and used appropriately;
- Promote better understanding on the roles of HTA in the context of other aspects of health system decision making and that HTA is not seen as a 'magic bullet' solution to priority setting, financing and decision-making needs of countries moving towards universal health coverage;
- Promote the use of HTA is appropriately linked to other policy tools for managing resources efficiently, especially with regard to pricing and reimbursement policies;
- Setting standards for technical tools used in HTA, such as economic models, to ensure that they are fit for purpose especially when used in LMIC settings. Clarifying the role of the so-called WHO 'cost-effectiveness threshold' is essential;
- Supporting countries to use and define the local data needed for priority setting, managing expenditure and finances in the context of developing universal health coverage;
- Developing guidance for countries that are developing systems for using HTA.
- Supporting countries in using assessment reports from existing HTA systems

As initial steps, WHO will:

- Prepare a series of case studies on countries that have implemented HTA in decision making on funding priorities. These case studies would examine how

the countries started implementing HTA and what were the contexts success factors, and barriers, with a view to identifying common themes. These case studies will emphasize the process and history of development of approaches

- Based on these case studies, develop of a set of guidelines or options for countries who are at the start of implementing HTA and wish to use HTA further.
- Create an online clearing house on HTA tools, courses, training programs and networks, in collaboration with WHO's existing partners in relation to HTA activities.
- Prepare publications and a communication plan to clarify the definition and use of 'HTA' and the use of the 'WHO cost-effectiveness threshold'
- Based on existing standards, develop an internal WHO quality standard for commissioning and using cost-effectiveness evaluations.

Table 1: Country experience and expert perspectives

Country	Health Care System and Pricing Policies	Status of HTA	Key Challenges Discussed	Lessons learned	Role of WHO
Indonesia	Universal health coverage from 2014, developing guidelines with the help of the WHO and other international organizations. Current pricing policy linked to drug registration and selection by the National Formulary committee under the Directorate General of Pharmacy, at the Ministry of Health.	Legal framework established. Started to use HTA and is looking to further implement it, for revising benefits package.	Lacking long-term staff and sufficient training programs, marked disparity in drug costs across the country.		Urgent need for clear coordination, help to develop a common path for pharmaceutical pricing between HTA agencies and the Directorate General, MOH, help in coordinating the various organizations and agencies that are coming with input and guidance, and for assistance with training programs.
Jordan	Mixed of private and public programs.	HTA at the King Hussein Cancer Centre (KHCC) setting since 2007: Due to a lack of capacity and expertise, it has taken time to mature. Have started with medicines and plan to work towards other technologies and devices. HTA in Jordan is only implemented at the KHCC through adopting a hospital based HTA model. KHCC started to engage other public institutions in capacity building activities through training and education e.g. A pharmacoeconomic course was held on September 2014 as a collaborative activity between KHCC, WHO and the University of Newcastle.	Lack of local trained individuals, limited technical expertise, cost of capacity building for the country, introduction of HTA to non-pharmaceutical technologies, and cost-effectiveness thresholds for oncology medicines.	Improved access to oncology medicines, improved efficacy in resource utilization, increased stake-holder communication, improved use of evidence in policy development and decision making and building capacity through hands on learning	Continued support for networking and capacity development, can serve as a case study to provide guidance for other countries working to implement HTA.

Morocco	Regulation of health insurance by the National Agency of Medical Insurance Responsible for national medical negotiations since 2006. For drug and device reimbursement decisions, the Ministry of Health decides which are to be reimbursed. Two commissions, to perform the economic evaluations and make recommendations to the MOH. Pricing controls are being introduced	Currently they are not using HTA, but are working toward collecting national health insurance data.	Need to have an understanding of all the actors involved, the basic rules to start working, and have clarity in the system, need to work towards an integrated information system to have all the data available for exchange and dissemination	Need to have economic evaluation capacity for adequate assessment of new medicines and technologies.	Continued technical support.
Country	**Health Care System and Pricing Policies**	**Status of HTA**	**Key Challenges Discussed**	**Lessons learned**	**Role of WHO**
Netherlands	Longstanding insurance system, reimbursement systems.	Cost-effectiveness analysis is institu-tionalized and used to inform reimbursement decisions. However the emphasis of reimbursement decision has been largely on budgetary impact.	Initial HTA processes not used in decision-making as no legislative requirement to do so	Formal legislation for consideration of HTA outcomes in decision making is required.	Collaborate with WHO on pricing policy and HTA work.
Slovenia	Health insurance mixed private and public. Price setting based on external reference pricing, pharmacoeconomic evaluation based on company dossiers and negotiations.	HTA one of several criteria for decision-making on medicines, based on applications from companies.	Access to local data. Generalisability of trial data to local setting.	Local data can be supplemented with international data, complex analyses not always necessary.	Slovenia can serve as a model for other middle-income countries to help improve their systems.

South Africa	Moving towards universal health coverage, currently mixed private and public sectors. Public sector medicines pricing through tendering, private sector pricing through regulated fees for dispensers, logistics providers, transparency from manufacturer to dispenser. Discounts prohibited. Single exit price system and generic substitution.	Pharmacoeconomics guidelines issued, legislative requirements gazetted.	Differences between public and private sectors, lack of capacity for HTA for non-medicines.		Support for capacity development, HTA evaluations of devices, as well as more available pharmacoeconomic tools.
	Current Activities	**Perceived Needs of LMICs with HTA**	**Key Challenges**	**Lessons learned**	**Perceived Role of the WHO**
Academic Perspective	Multiple research centers and organizations with research projects and programs in topics related to HTA including pharmaceutical pricing and HTA specifically and pharmaceutical and health policy more generally. Most provide masters and doctorate programs and hands-on experience.	A framework of all aspects of HTA in a health system context, not just economic evaluation. The framework should also clarify the purpose of HTA: It is not about encouraging HTA use in and of itself, but using HTA to achieve a particular goal, eg moving towards UHC. Need to be able to assess the current status - current needs, current data, current utilisation of pharmaceuticals and technologies as baseline. Any framework for using HTA should be adaptable to the local setting and to changing needs over time.	HTA should not be perceived as a tool used in isolation and there is an over expectation of what HTA can do. Needs of different countries for different aspects of HTA vary across countries and within country over time. Capacity strengthening for and cooperation across different stakeholders within systems are critical to ensure the evidence-informed policy links between financing, provider payment and reimbursement policies, utilization and quality of care and medicines. Capacity strengthening and cooperation across stakeholders are also crucial to determine, establish, and use local data for information generation and decision making.	HTA - either in full or in component - is only one component in decision making. Considerations of the health care and financing systems, their structures and processes at a given time are needed.	Communicating what HTA is and what it can, and cannot and should not be used for; coordination of current global activities, including assistance with capacity development; facilitation of connections and networks between researchers, policy makers and local decision makers; recommendation of quality models and validated methodology.

Table 2: Regional Summary

Region	Networks/Meetings	Capacity development	Integration of HTA/ current drug pricing mechanisms	Needs
PAHO	RedETSA[5], AdvanceHTA[6], 6 meetings and 2 workshops since 2011	Virtual forum for members, webinar program, short professional exchange, virtual campus for introduction to HTA and economic evaluation (EE) in collaboration with the Institute of Clinical Effectiveness and Health Policy, Argentina. Project AdvanceHTA, (a 'toolbox' with best practices, HTA strengthening, implementation in emerging settings, case studies on decision making informed by HTA). Courses in Spanish, Portuguese and English	HTA institutionalization in Argentina, Colombia, Chile, Uruguay, Mexico and Brazil. RedETSA members include Argentina, Brazil, Bolivia, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Mexico, Paraguay, Peru and Uruguay. AdvanceHTA members include Barbados, Belize, Bermuda, Costa Rica Dominica, Dominican Republic, El Salvador, Guatemala, Guyana, Honduras, Jamaica, Nicaragua, Panama, St. Lucia, St. Maarten, Suriname, Trinidad and Tobago, Venezuela.	The Caribbean and Central America are not as advanced as South America, where HTA institutionalization is more integrated. General barriers include linkage - having the HTA performed but not included in the guidelines or that result adopted.
AFRO	Networks of WHO medicine advisors and Health Economists in AFRO exist. EVIPNet Africa[7] could be a potential partner. Using WHO-HAI methodology, twenty two countries in AFRO have undertaken surveys to measure prices and availability of medicine.	Assessment of pricing and reimbursement of medicines in health insurance schemes underway in Ghana, Gabon, Ethiopia, Rwanda and South Africa. AFRO is preparing to hold a Regional meeting (November 2015) on pricing and reimbursement of medicines in health insurance schemes.	38 countries have developed their essential medicines list, health insurance is emerging in some countries such as Ghana, Gabon, Ethiopia, Rwanda and South Africa. National health insurance agencies in the public sector use their EMLs as a guide for reimbursement. As of yet HTA adoption is not prominent.	Building capacity to improve the use of existing pharmaceutical data for managing expenditure, and finances, pricing and reimbursement decisions is a priority. Furthermore, HTA methodology, and guidelines need to be introduced incrementally along with building a critical mass of experts and institutions to support countries in the Region.

[5] Red de Evaluación de Tecnologías Sanitarias para las Américas: www.who.int/medical_devices/Sat_am_HTA_4_LEMGRUBER.pdf
[6] www.advance-hta.eu
[7] EVIPNet Africa is a regional network of WHO-sponsored evidence-to-policy partnerships in 11 sub-Saharan African countries with a steering group and country teams.

Region	Networks/Meetings	Capacity development	Integration of HTA/ current drug pricing mechanisms	Needs
EURO	Networks: EUnetHTA[8], first established by the European Commission in 2005 EUROSCAN, a collaborative network for horizon scanning for new technologies, plus other projects and networks including Advance_HTA, HTA forum Russia[9], EU meetings on price support twice a year, WHO CC meetings once a year	There are multiple regional and sub-regional meetings and an active online network with information sharing. Trying to work with countries individually on cost efficiency in their system. Focus on countries in transition.	Wide range of HTA implementation across Europe. Price control does exist in European countries - external reference pricing, value based pricing. Pricing often involves direct negotiations, and tendering. but great variety in country experiences – and opportunity for strengthening procurement strategy development and use of spend analysis	Collaborations between countries for price negotiations, more transparency. Managing inpatient drug prices and use ie through use of prioritization principles when making treatment choices as need be. Strengthen negotiation capacity and use of negotiation as a tool in public procurement. WHO support on HTA implementation, particularly for Central and Eastern Europe as well as 'small-population' countries.
EMRO	Regional HTA Network hosted via EZCollab[10]. Two network meetings had been organized since 2013. EZCollab members include 100 members, including 22 countries from EM region and 11 countries from SEA Region.	A roadmap for developing successful HTA at the national and/or hospital level. A regional HTA network platform, mapping of existing essential HT resources, guidelines on established HTA programmes. EZcollab discussions include technical queries, consultancies, news and resources.	Very diverse region in terms of country conditions. Of the 15 member states - academic institutions, regional experts, MOH – about half are using or coordinating HTA (of HTA related activities), predominantly clinical effectiveness, and economic evaluations relating to cost.	decisions 1) Political commitment and using HTA results in decision-making 2) Human and financial resources 3) Proper sharing of knowledge and information

[8] http://www.eunethta.eu/
[9] http://forum-hta.ru/
[10] http://ezcollab.who.int/

Annexure

Annex A. List of participants

Annex B. Meeting agenda

Annex C. List of main international HTA agencies

Annex D. List of guidance documents

Annex E. List of training courses related to HTA

Annex A. List of participants

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Annex B. Meeting agenda

1. Opening remarks and objectives of the meeting
2. Introduction of participants
3. An overview of WHO's work on health financing - Inke Mathauer
4. WHO and HTA – update so far: – Adriana Velazquez
5. Brief background, WHA Resolution Summary of country survey
6. Country perspectives addressing the following questions:
   What HTA activities are currently taking place?
   What pricing policies are being used?
   What are the gaps?
   What support is needed?
   - Slovenia- Jurij Furst
   - Indonesia – Sudigdo Sastroasmoro
   - South Africa – Fatima Suleman
   - Jordan – Saad Mahdi Jaddua
   - Morocco – Lalla Karima Cherkaoui
7. Regional activities on HTA (and pharmaceutical pricing, where relevant), focussing on country needs, activities, unmet priorities
   - AMRO/PAHO – Francisco Caccavo
   - AFRO – Abeynah Desta
   - EMRO – Marthe Everard
   - EURO – Hanne Bak Pedersen
8. PPRI summary view of country needs for pricing and HTA support - Nina Zimmermann
9. Academic perspectives
   what you have been working on in relation to pricing/reimbursement /insurance / health technology assessment
   what you see as the needs from LMIC
   what you think WHO should be doing
   - Anita Wagner
   - Panos Kavanos
   - Rosalie Viney
   - Kirsten Howard
   - Hans Severen
10. What has been done so far in terms of activities? What is missing? What should be done and by who?
    - Cost-effectiveness thresholds and CHOICE – Melanie Bertram
    - Reflections from an established system – Ad Schuurman
11. Discussion of questions that have arisen during the meeting
12. Developing a generic road map for countries working towards HTA – should WHO do this?
13. Taking an inventory of existing WHO publications that are potentially useful to guide countries
14. Scoping options for capacity development that would be needed to initiate HTA in decision-making
15. Planning for November meeting

Annex C. List of main international HTA bodies

Name	Domicile	URL
HTAi	Canada	www.htai.org
EuroScan	UK	euroscan.org.uk
NICE International	UK	www.nice.org.uk/about/what-we-do/nice-international
HITAP	Thailand	www.hitap.net/en/
INAHTA	Canada	www.inahta.org
IDSI	UK	www.idsihealth.org/
RedETSA	New York	TBC
Advance_HTA	UK	www.advance-hta.eu
EVIPNet	25 countries	global.evipnet.org/
EUnetHTA	Denmark	www.eunethta.eu/
EZCollab		ezcollab.who.int/
European Observatory on Health Systems and Policies	Belgium	www.euro.who.int/en/about-us/partners/observatory

Annex D. List of guidance documents

Title	Year	Brief summary of content	Link
General guidance			
WHO guideline on country pharmaceutical pricing policies	2015	Guidelines to assist national policy-makers and other stakeholders in identifying and implementing policies to manage pharmaceutical prices. Special consideration was given to implementation needs in low- and middle-income countries. Recommendations include: • Regulation of mark-ups • Tax exemptions/reductions • Application of cost-plus pricing • Promoting generic meds use • Use of HTA	http://apps.who.int/iris/bitstream/10665/153920/1/9789241549035_eng.pdf?ua=1
Medicines in Health Systems: Advancing access, affordability and appropriate use	2014	A proposed framework based on systems approach: • Access to medicines and their appropriate use as an explicit focus in health system strengthening and efforts towards UHC; • Recognize the needs for transparency and governance in the medicines sector within and across health systems, and then strengthen governance capacities; • Build more robust connections between information, medicines and decision-making.	http://apps.who.int/iris/bitstream/10665/179197/1/9789241507622_eng.pdf?ua=1
Access to essential medicines - Report by the Secretariat (see area of activities)	2014	Communicate a list of areas of activity to promote ATM: Supporting UHC, supporting HTA capacity, monitoring and use of information, access to medicines for non-communicable diseases, rational use of medicines, antimicrobial resistance, Access to medicines for HIV/ADIS, TB and malaria, reproductive and maternal and child health, innovation and the local production of medicines	http://apps.who.int/iris/bitstream/10665/158961/1/A67_30-en.pdf?ua=1
Making fair choices on the path to universal health coverage. Final report of the WHO Consultative Group on Equity and Universal Health Coverage	2014	Key issues of fairness and equity that arise on the path to UHC by clarifying these issues and offering recommendations for how countries can manage them.	http://apps.who.int/iris/bitstream/10665/112671/1/9789241507158_eng.pdf?ua=1
Medicines in Health Systems: Advancing access, affordability and appropriate use	2014	To provide an analysis of essential medicines using a health systems approach. Chapter 3 of this report argues for an explicit focus on medicines when moving towards UHC. The chapter discusses how two key aspects for implementing UHC – information and financing – can support policies that facilitate the equitable and affordable access to, and appropriate use of, medicines. The chapter describes medicines management strategies used in financial risk protection schemes in several countries at different stages of implementation of UHC.	http://apps.who.int/iris/bitstream/10665/179197/1/9789241507622_eng.pdf?ua=1

Title	Year	Brief summary of content	Link
Promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade	2012	A joint document by the WHO, WIPO and WTO which discusses essential elements of the international framework in relation to innovation and access to health technologies – health policy, IP and trade policy.	http://apps.who.int/iris/bitstream/10665/78069/1/9789241504874_eng.pdf?ua=1
WHO medical device technical series	2011		
Development of medical device policies		Develops policies, strategies and action plans, organisational systems and measurement of policy progress	http://apps.who.int/medicinedocs/documents/s21559en/s21559en.pdf
Needs assessment for medical devices		Outlines approach for determining health service requirements, availability, medical devices, human resources, finances and option appraisal	http://apps.who.int/medicinedocs/documents/s21562en/s21562en.pdf
Health technology assessment of medical devices		Discusses links between HT regulation, management and HTA and HTA for evidence-informed context based decision making	http://whqlibdoc.who.int/publications/2011/9789241501361_eng.pdf?ua=1
Procurement process resource guide		Discusses procurement processes and special considerations (e.g. local regulations, replacement, refurbishment)	http://apps.who.int/medicinedocs/documents/s21563en/s21563en.pdf
Medical device donations considerations for solicitation and provision		Discusses best practices for donors and donation solicitors (e.g. “Ensuring that the needs of the end-users and patients are met”)	http://whqlibdoc.who.int/publications/2011/9789241501408_eng.pdf
Introduction to medical equipment inventory management		Discusses types of inventory, items and data included in an inventory and how to use inventory as a tool	http://apps.who.int/medicinedocs/documents/s21565en/s21565en.pdf
Options for financing and optimizing medicines in resource-poor countries	2010	This discussion paper argues that successful financing of medicines is contingent upon a number of factors: Political commitment; Effective design and administrative capacity ; Clear implementation strategies; Financial sustainability; Rational selection and rational drug use; Affordable prices; Reliable medicine supply systems and low taxes	http://apps.who.int/iris/bitstream/10665/85708/1/HSS_HSF_DP.E.10.7_eng.pdf?ua=1

Title	Year	Brief summary of content	Link
Health systems financing: the path to universal coverage	2010	This report outlines how countries can modify their financing systems to move more quickly towards universal coverage and to sustain those achievements. The report synthesizes new research and lessons learnt from experience into a set of possible actions that countries at all stages of development can consider and adapt to their own needs. It suggests ways the international community can support efforts in low-income countries to achieve universal coverage.	http://www.who.int/whr/2010/en/
Continuity and change: Implementing the third WHO medicines strategy	2009	This report outlines the strategic direction and priorities for 2008-2013 and strategic tools to support implementation. It also reviews the strengths and weakness of Medicines Programme, the trends and challenges in the global pharmaceutical situation and the strategic landscape in 2008.	http://apps.who.int/iris/bitstream/10665/70301/1/WHO_EMP_2009.1_eng.pdf?ua=1&ua=1
WHO guide to identifying the economic consequences of disease and injury.	2009	A defined conceptual framework within which the economic impact of disease or injury can be considered and appropriately estimated, with a view to enhancing the consistency and coherence of economic impact studies in health.	http://www.who.int/choice/publications/d_economic_impact_guide.pdf?ua=1
WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations : guide for coordinators and data collectors	2007	This document provides practical operational guidance for assessing, monitoring, and evaluating policy development and strategic planning for activities related to pharmaceuticals (e.g. survey forms for various indicators, selection of survey participants etc)	http://apps.who.int/iris/bitstream/10665/69927/1/WHO_TCM_2007.2_eng.pdf?ua=1
Measuring medicine prices, availability, affordability and price components	2008	A joint document by WHO and Health Action International to outline the approach for facilitating reliable data collection and analysis.	http://apps.who.int/iris/handle/10665/70013
Equitable access to essential medicines : a framework for collective action	2004	Provides a check list for policy makers with four domains: rational selection and use of essential medicines; affordable prices; sustainable financing; reliable supply system.	http://apps.who.int/iris/bitstream/10665/68571/1/WHO_EDM_2004.4_eng.pdf?ua=1
Procurement of vaccines for public-sector programmes : a reference manual	2003	A document prepared jointly by USAID, WHO, BASICS, PATH, and UNICEF, which details the complex procedures and safeguards in managing vaccines, procurement, quality assurance and distribution.	http://apps.who.int/iris/bitstream/10665/69675/1/WHO_V-B_03.16_eng.pdf?ua=1
Guidelines for price discounts of single-source pharmaceuticals	2003	The document discusses factors for consideration when planning and negotiating offers of price discounts of single source products (e.g. eligible population should be selected on the basis of agreed criteria).	http://apps.who.int/iris/handle/10665/68157#sthash.Owrojb9D.dpuf

Title	Year	Brief summary of content	Link
Making choices in health: WHO guide to cost-effectiveness analysis/	2003	Outlines the framework, methods and tools for generalized cost-effectiveness analysis.	http://www.who.int/choice/publications/p_2003_generalised_cea.pdf?ua=1
Operational principles for good pharmaceutical procurement	1999	This document introduces four strategic objectives and twelve operational principles for good pharmaceutical procurement.	http://apps.who.int/iris/handle/10665/66251
Local production for access to medical products: developing a framework to improve public health	2011	This document covers an overview of local production, technology transfer and access to medical products in developing countries. It also provides guidance for building a policy framework, including Industrial policy, Health policy, shared goals with stakeholders and government supports.	http://apps.who.int/iris/bitstream/10665/77934/1/9789241502894_eng.pdf?ua=1
Regulation of pharmaceuticals in developing countries : legal issues and approaches	1985	This document provides an introduction to some of the legal issues relevant to the regulation of pharmaceuticals in developing countries and describes some of the possible approaches to the establishment of a regulatory framework. It deals mainly with the aspects that are of immediate concern to administrators in establishing modest control systems to facilitate the availability of safe and effective drugs of acceptable quality at reasonable prices.	http://apps.who.int/iris/bitstream/10665/39314/1/9241560894_eng.pdf?ua=1
Country or region specific documents			
Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research	2015	This report, with a focus on sustainable access to new medicines, reviews policies that affect medicines throughout their lifecycle (from research and development to disinvestment), examining the current evidence base across Europe	http://apps.who.int/iris/handle/10665/159405#sthash.z6FoyBun.dpuf
Improved effectiveness of generic medicine markets in Hungary. Analysis and recommendations	2015	This report provides an overview of the development of incentives to use generics in the Hungarian health system up to the end of 2011, focusing in particular on the reference pricing system and assessing what impact these incentives had on the efficiency of the generics markets, using empirical evidence from selected substance groups	http://apps.who.int/iris/handle/10665/170483#sthash.Zlo5KHkX.dpuf
Medicines Transparency Alliance Global Meeting 2014	2014	The document summarises the discussion and country experience presented at the MeTA global meeting in 2014.	http://apps.who.int/iris/bitstream/10665/176618/1/WHO_EMP_PAU_2015.1_eng.pdf?ua=1

Title	Year	Brief summary of content	Link
Medicine prices, availability, affordability and price components: a synthesis report of medicine price surveys undertaken in selected countries of the WHO Eastern Mediterranean Region	2008	The data from medicine prices surveys conducted in 9 countries (Jordan, Kuwait, Lebanon, Morocco, Pakistan, Sudan [Khartoum State], Syrian Arab Republic, Tunisia and Yemen) of the Eastern Mediterranean Region and utilizing the WHO/HAI methodology are summarized in this report.	http://apps.who.int/iris/handle/10665/116567#sthash.HyjPVCJv.dpuf
Health Technology Assessment and Health Policy-making in Europe	2008	It discusses transnational HTA collaboration in Europe to guide policy making, including different case studies on institutional arrangements, whether HTA has an impact on decision-making. It provides a framework to analyse the effects of HTA in the health system and a summary of the empirical evidence.	http://www.euro.who.int/__data/assets/pdf_file/0003/90426/E91922.pdf
Pharmaceutical policies in Finland : challenges and opportunities	2008	This report provides a policy review of the regulatory system of pharmaceutical policy in Finland. It provides guidance on policy pricings and transparency-	http://apps.who.int/iris/handle/10665/107885#sthash.Y5WiZdMz.dpuf
Technical discussion on Medicine prices and access to medicines in the Eastern Mediterranean Region	2007	This paper focuses on affordable medicine prices and draws upon findings of the 10 national medicine price surveys conducted in the Region to inform policy considerations.	http://apps.who.int/iris/bitstream/10665/122553/1/EM_RC54_Tech_Disc_1_en.pdf?ua=1
Regional strategy for improving access to essential medicines in the Western Pacific Region 2005-2010	2004	The overall objective of the regional strategy is to provide operational and practical guidance to Member States and WHO on improving access to essential medicines. It covers rational selection; rational use; affordable prices; access; trade globalization and the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS); sustainable financing; supply and management systems; quality; and monitoring and evaluation	http://apps.who.int/iris/bitstream/10665/138155/2/WPR_RC055_09_Essential_Medicines_2004_en.pdf?ua=1
Cost-containment mechanisms for essential medicines, including antiretrovirals, in China : mission report	2003	This is a mission report describes 1. The range of cost-containment options for ARVs and other essential medicines that China might consider. 2. Lessons from other countries' experience in negotiating price discounts and voluntary licensing arrangements for ARVs and other essential medicines. 3. China's WTO Trade-Related Aspects of Intellectual Property Agreement (TRIPS) compatible options to undertake compulsory licensing; and the modalities of how a compulsory licence might be issued in China.	http://apps.who.int/iris/bitstream/10665/67915/1/WHO_EDM_PAR_2003.6.pdf?ua=1

Title	Year	Brief summary of content	Link
Health care cost-containment policies in high-income countries: how successful are monetary incentives?	2002	This paper summarises eight cost containment measure through monetary incentives arrangement and makes a qualitative arrangement on the potential for success.	http://apps.who.int/iris/bitstream/10665/69027/1/EIP_FER_DP_02.2.pdf?ua=1
Documents specific to a therapeutic area			
Access to antimalarial medicines : improving the affordability and financing of artemisinin-based combination therapies	2003	This report presents a critical overview of the main policy options to improve affordability and financing. It focuses on the current situation and addresses the challenges in improving access to combination therapies in African countries, south of the Sahara, which bear the highest malaria burden and suffer the worst consequences of increasing drug resistance. These options include optimising use of government funds, waste reduction, insurances, cost-sharing mechanisms etc.	http://apps.who.int/iris/bitstream/10665/68360/1/WHO_CDS_MAL_2003.1095.pdf?ua=1
Sources and prices of selected medicines and diagnostics for people living with HIV/AID	2003	This report sets out to provide market information that can be used to help procurement agencies make informed decisions on the source of medicines and serve as the basis for negotiating affordable prices. The aim is to help increase access to medicines for people living with HIV/ AIDS in developing countries.	http://apps.who.int/iris/bitstream/10665/68130/1/WHO_EDM_PAR_2003.7.pdf?ua=1
Surmounting challenges : procurement of antiretroviral medicines in low- and middle-income countries : the experience of Médicins Sans Frontières	2003	Based on MSF's experience over the past two years, the report outlines the major parameters that ARV procurement agents need to consider. Ten country case reports illustrate how challenges were, and continue to be, overcome in specific contexts.	http://apps.who.int/iris/bitstream/10665/68468/1/WHO_EDM_PAR_2003.8.pdf?ua=1
Access to antiretroviral drugs in low- and middle-income countries: technical report	2014	The summary report presents the analysis of the price data for ARVs collected through the Global Price Reporting Mechanism.	http://apps.who.int/iris/handle/10665/128150#sthash.mwmxnJ94.dpuf
Transaction prices for antiretroviral medicines from 2009 to 2012 : WHO AIDS medicines and diagnostics services, global price reporting mechanism : summary report November 2012	2013	The summary report presents the analysis of the transaction data for ARVs in 2009, 2010, 2011, and the first two quarters of 2012 collected as part of the Global Price Reporting Mechanism.	http://apps.who.int/iris/bibitstre/10665/80271/1/9789241505062_eng.pdf?uu=1

Title	Year	Brief summary of content	Link
Other relevant documents			
Noncommunicable diseases country profiles	2014	A profile summary of a selected set of statistics on non-communicable disease in member countries	http://www.who.int/nmh/countries/en/
Standards and operational guidance for ethics review of health-related research with human participants	2011	This document is intended to provide guidance to the research ethics committees (RECs) on which organizations rely to review and oversee the ethical aspects of research, as well as to the researchers who design and carry out health research studies.	http://www.who.int/ethics/publications/9789241502948/en/

Annex E. List of training courses related to HTA

This list of courses is an initial inventory of existing programs. As additional institutions are identified, more programs will be added. WHO does not recommend or endorse any individual program, and WHO does not provide financial support to enrol in any training program. See also the following general websites for more information:

Courses available throughout the world

http://www.ispor.org/education/degreedirectory.asp

Courses available in Australia

http://www.ahes.org.au/links-resources/education/

Organization	Course title	Duration	URL
McMaster University, Canada	Masters of Science, MSc (Health Research Methodology program, specializing in Health Technology Assessment)	1.5 -2 years, full time (depending on whether you enter as a health profession, or with only a background in biological sciences)	http://fhs.mcmaster.ca/hrm/msc_admission.html
Ulysses Program	International Masters of Science, MSc	2 years	http://www.ulyssesprogram.net/program.html
University of Glasgow (Online)	Masters of Science, MSc	2-3 years	http://www.gla.ac.uk/postgraduate/taught/healthtechnologyassessment/
University of Sheffield, ScHARR (online)	Masters of Science, MSc (International HTA)	2-4 years	https://www.shef.ac.uk/scharr/prospective_students/masters/ihtapr
York University (online), United Kingdom	Masters of Science, MSc (Economic Evaluation for Health Technology Assessment)	2 years	https://www.york.ac.uk/economics/postgrad/distance_learning/progdetails/
University of Twente	Masters of Science, MSc (Masters in Health Science with a specialization in Health Technology Assessment and Innovation)	1-2 years	http://www.utwente.nl/en/education/master/programmes/health-sciences/programme/
University of Birmingham	Masters of Public Health, MPH	1 -2 years (option of up to 5 years part time)	http://www.birmingham.ac.uk/postgraduate/courses/taught/med/public-health-tech-assessment.aspx

Organization	Course title	Duration	URL
University of Cape Town	Master of Public Health, MPH	12-18 months	http://www.publichealth.uct.ac.za/phfm_master-public-health
McMaster University, Canada	PhD, McMaster University, Canada	Unspecified	http://fhs.mcmaster.ca/hrm/phd_degree.html
UMIT, Austria	PhD, UMIT, Austria	6 semesters	https://www.umit.at/page.cfm?vpath=studien/doktorat_studien/hta/aufbau-und-inhalt