

AMENDMENT

TO THE MEMORANDUM OF UNDERSTANDING
("MOU")
BETWEEN WORLD HEALTH ORGANIZATION AND EUROSCAN
Dated 12 March 2010

This Amendment is intended to amend and supplement the existing provisions of the MOU referred to above to which it becomes an integral part. It is understood and agreed that the provisions of this Amendment supersedes any conflicting provisions of the MOU.

1. Section 1 of the MOU – Areas of Collaboration - is amended as follows:

1.1 WHO and its network of Regional and Country Offices and EuroScan will work collaboratively in the following three areas of mutual interest:

1.1.1 Promoting and supporting the implementation of the World Health Assembly resolution WHA67.23, attached hereto as Annex 3.

1.1.2. Providing support to Member States in capacity-building to develop methodology for prioritization, selection and early-assessment of health interventions and technologies to facilitate evidence-based policy decisions.

1.1.3 Evaluating and sharing of key information on selected new and emerging health technologies and new applications of existing health technologies in order to address the effects and anticipated short term and long term consequences of their use on health care and more broadly on society.

1.2 EuroScan will collaborate with WHO in the sharing of information and by contributing, as appropriate, with technical advice, expertise, regional workshops, and training materials related to new or emerging health interventions and technologies, in order to strengthen information systems for decision making in Member States.

1.3 At a time mutually agreed by the Parties, a Work Plan will be created that identifies specific activities in the general areas of collaboration identified above. This Work Plan will be revised from time to time as mutually agreed by the Parties. A Work Plan for the period 2015-2017 is provided in Annex 4.

1.4 Each Party will establish focal points for the purpose of overseeing and guiding the implementation of this MOU. Meetings between the representatives of the Parties will be convened at regular intervals to review cooperation and to provide guidance concerning opportunities for improved collaboration.

2. Annex 3 is amended as follows:

Annex 3. Resolution WHA67.23 Health intervention and technology assessment in support of universal health coverage

3. Annex 4 is amended as follows:

Annex 4. WHO/EuroScan collaboration plan for the years 2015-2017

Activity 1: Selection of new and emerging technologies

EuroScan will provide a list of emerging health technologies and new applications of existing health interventions identified by EuroScan Member Agencies and included in the EuroScan database on an annual basis.

EuroScan Member Agencies through EuroScan will provide publicly available early assessment reports for any emerging health technologies of interest to the WHO.

EuroScan Member Agencies through EuroScan agree to allow WHO to publish or link to publicly available early assessment reports on the WHO Health Technology Assessment website.

Activity 2: Systematic approach for the early evaluation of health interventions

At the request of the WHO, EuroScan will provide expertise for the evaluation and grading of innovative technologies in a systematic approach, using previously agreed criteria and methodologies. WHO and EuroScan will work on the development of an explicit and systematic approach for the early assessment of health interventions and technologies

Activity 3: Communication and collaboration on Early Awareness and Alert activities (EAA)

WHO and EuroScan will together continue to strengthen communication with other health technology assessment organizations to support the identification and early assessment of new health technologies of interest.

Activity 4: Capacity building, workshop on early assessment for emerging technologies

In accordance with the implementation for the Resolution WHA67.23, in order to strengthen capacity for health intervention and technology assessment at country level, EuroScan, in coordination with WHO, will propose a workshop on EAA activities specifically addressed, but not limited, to low-middle-income countries during the HTAi annual conferences.

Organisation of similar workshops and other capacity-building initiatives may be considered upon request from the WHO, WHO Regional Offices or Member States with the financial or in-kind support from WHO.

4. The following provisions are hereby added to the MOU :

4.1 Each Party hereto shall be fully responsible for the funding of its activities under this MOU, except as may otherwise be agreed expressly in this MOU or in a sub-agreement thereto.

4.2 Any transfer of funds between the Parties shall be made under an appropriate separate agreement, to be negotiated in good faith between the Parties. Each party shall administer the funds handled by it in accordance with its financial regulations, rules and administrative practices.

4.3 Nothing in or relating to this MOU shall be deemed a waiver of any of the privileges and immunities of WHO in conformity with the Convention on the Privileges and Immunities of the Specialized Agencies approved by the General Assembly of the United Nations on November 21, 1947 or otherwise under any national or international law, convention or agreement.

5. All the other terms and conditions of the MOU shall remain the same to the extent they are not in contradiction with this Amendment.

For WHO

Dr Marie-Paule Kieny
ADG Health Systems and Innovation

Signature and date

N. Atmberger
25.08.2015

For EuroScan

Dr Roberta Joppi
Chair, EuroScan Executive Committee

Signature and date

Roberta Joppi
07/09/2015

MEMORANDUM OF UNDERSTANDING ("MOU")
between

**the World Health Organization,
20 avenue Appia, 1211 Geneva, Switzerland
("WHO")**

And

The International Information Network on New and Emerging Health Technologies
Birmingham, United Kingdom
("EuroScan")

WHEREAS WHO, through its Department of Essential Health Technologies, aims to promote and to ensure improved access, quality and use of health technologies;

WHEREAS WHO, recognizing that health technologies are indispensable for prevention, diagnosis, treatment and rehabilitation and is therefore committed to provide support in the prioritization, selection and use of health technologies;

WHEREAS EuroScan is a collaborative network of member agencies for the exchange of information on emerging new drugs, devices, procedures, programmes, and settings in health care. The long-term aim of EuroScan is to support a permanent network among agencies and organizations involved in early awareness and alert activities to: exchange information on new and emerging health technologies; evaluate the sources of information used for identification; share applied methods for identification, filtration, prioritization and early assessment; disseminate information on early identification and assessment activities.;

WHEREAS WHO and EuroScan, hereinafter also referred to as "the Parties", believe that technical collaboration between the two organizations will contribute to the shared goal of promoting the wide availability of information for the assessment of safe, effective and affordable health technologies to promote better health care;

WHEREAS the Parties furthermore believe that agreement in advance on certain aspects of individual collaborative projects (as the Parties may identify on a case-by-case basis) will facilitate the early implementation of such projects, in particular by facilitating the conclusion of the agreements to which such projects would be subject;

NOW, therefore, the Parties hereby agree as follows:

1. Objective of the collaboration

Within the context of their respective constitutional, managerial and operational frameworks, WHO and EuroScan agree to pursue closer collaboration in areas of mutual interest and to develop synergies towards common goals building on respective comparative strengths and advantages.

2. Areas of collaboration

EuroScan will collaborate with WHO in the implementation of the World Health Assembly Resolution 60.29 of May 2007, attached hereto as Annex 1, including assisting WHO, as appropriate, in providing support to Member States in the prioritization, selection and use of Health Technologies, in particular medical devices.

EuroScan will further collaborate with WHO in the evaluation and sharing of key information on selected emerging Health Technologies and new applications of existing Health Technologies in order to address the effects and anticipated short term and long term consequences of their use on health care and more broadly on society in general. More specifically, EuroScan will collaborate with WHO in the implementation of the activities described in Annex 2 hereof which may be amended or expanded by separate letter of agreement between the Parties.

WHO will collaborate with EuroScan in the sharing of information and by contributing, as appropriate, with technical advice, expertise, regional workshops and training materials related to innovative Health Technologies.

Subject to WHO rules and regulations, EuroScan members may be invited to participate in Health Technologies meetings organized by WHO and representatives of WHO may participate in meetings organized by EuroScan. Neither Party shall provide financial assistance to the other Party for participation at meetings, unless expressly agreed between the Parties prior to the meeting.

Each Party will establish focal points for the purpose of overseeing and guiding the implementation of this MOU. Meetings between the Executive Heads of the Parties will be convened at regular intervals to review cooperation and to provide guidance concerning opportunities for improved collaboration.

3. Collaborative activities

Any collaborative activity as outlined in article 1 above shall be subject to the availability of sufficient financial and human resources for that purpose, as well as each Party's programme of work, priority activities, internal rules, regulations, policies, administrative procedures and practices. Each collaborative activity shall thus be agreed on a case-by case-basis, subject to an exchange of letters or agreement specific to that activity.

4. Confidentiality

Except as explicitly provided in this MOU, each party shall take all reasonable measures to keep confidential any information specifically marked "confidential" about the other party that comes to its knowledge during the implementation of this Agreement. However, there shall be no obligation of confidentiality where: (i) The information is publicly available, or becomes publicly available, otherwise than by action or omission of the receiving party, or, (ii) The information was already known to the receiving party (as evidenced by its written records) prior to its receipt; or, (iii) The information was received from a third party not in breach of an obligation of confidentiality owed to the other party. In the event that a Party is in possession of special confidential information, which is proprietary to it or to third parties collaborating with it, that Party may require the conclusion of a separate confidential disclosure agreement for the sharing of such information with the other Party.

5. Publications

5.1 Subject to each Party's proprietary rights and/or the proprietary rights of others, and without prejudice to obligations of confidentiality, the results of any collaborative activity under this MOU may be published by either Party. The Parties are encouraged to publish the results of their joint work in a collaborative fashion. Guidelines for authorship of major, international, peer-reviewed journals will be used to establish authorship of collaborative publications. In regard to separate publications, it is agreed that in order to avoid prejudicing proprietary rights and the confidentiality of information, the publishing Party shall transmit to the other party for its review the material intended to be published at least 60 (sixty) days before a proposed publication is submitted to any editor, publisher, referee or meeting organizer. In the absence of any objection by the other Party within that 60 day period, concerning prejudice to proprietary rights or confidentiality of information, the publication may proceed. Any publication as referred to above shall duly acknowledged both Parties. In addition to review of the content of publications as referred to above, each Party shall have the right to review the acknowledgement and request reasonable changes to the use of its name, or request that its name be deleted altogether.

5.2 Copyright in any jointly prepared publications resulting from or relating to any of the collaborative activities under this MOU shall be vested in WHO and EuroScan jointly, who shall each independently and severally be entitled to exploit such copyright in any manner and for any purpose as they may each in their sole discretion deem appropriate, except that no use shall be made of such publications for or in conjunction with commercial and/or promotional purposes.

5.3 Copyright in any publications resulting from or relating to any of the collaborative activities under this MOU, and prepared by one of the Parties hereto on its own, shall be vested in that Party, provided however, that any such publication shall be submitted to the other Party for review and comments in accordance with paragraph 5.1 above.

6. Liability

6.1 Each Party shall be solely responsible for the manner in which it carries out its part of the collaborative activities under this MOU. Thus, a Party shall not be responsible for any loss, accident, damage or injury suffered or caused by the other Party, or that other Party's staff or sub-contractors, in connection with, or as a result of, the collaboration under this MOU.

6.2 The Parties shall make appropriate arrangements to cover liability risks for any collaborative activities involving product research and development.

7. Use of the Parties' names

Except as explicitly provided in this MOU, neither Party shall, in any statement or material of a promotional nature, refer to the relationship of the other Party to the collaboration pursuant to this MOU, or otherwise use the other Party's name, acronym and/or emblem, without the prior written consent of the other Party.

8. Relationship of the Parties

For the purposes of this MOU, each Party is an independent contractor and not the joint venturer, agent or employee of the other Party. Neither Party shall have authority to make any statements, representations, or commitments of any kind, or to take any action which shall be binding on the other Party, except as may be explicitly provided for in this MOU or authorized in writing by the other Party.

9. Term and Termination

This MOU will be deemed to be in effect on the date upon which it is signed by both parties and will remain in effect subject to the conditions of termination below.

This MOU may be terminated by either Party, subject to six months advance written notice to the other Party. Notwithstanding the foregoing, it is agreed that any termination of this MOU shall be without prejudice to: (i) The orderly completion of any ongoing collaborative activity; and, (ii) Any other rights and obligations of the Parties accrued prior to the date of termination of this MOU.

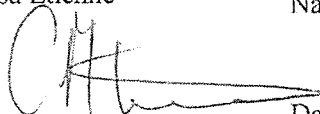

10. Amendments

This MOU may only be amended in writing by mutual consent of the Parties.

11. Settlement of disputes

Any dispute relating to the interpretation or execution of this MOU, or of any subsequent exchange of letters or agreement with respect to individual collaborative activities shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the Parties, or in the absence of agreement, in accordance with the rules of arbitration of the International Chambre of Commerce. The Parties shall accept the arbitral award as final.

Agreed and accepted:

For:	The World Health Organization	For:	EuroScan
Title	Assistant Director General In health Systems and Services	Title	Chair
Name	Dr. Carissa Etienne	Name	Dr Iñaki Gutiérrez-Ibarluzea
Date	 12-01-2010	Date	 12-03-2010

SIXTIETH WORLD HEALTH ASSEMBLY

WHA60.29

Agenda item 12.19

23 May 2007

Health technologies¹

The Sixtieth World Health Assembly,

Having considered the report on health technologies;²

Recognizing that health technologies equip health-care providers with tools that are indispensable for effective and efficient prevention, diagnosis, treatment and rehabilitation and attainment of internationally agreed health-related development goals, including those contained in the Millennium Declaration;

Understanding that health technologies in particular medical devices represent an economic as well as a technical challenge to the health systems of many Member States, and concerned about the waste of resources resulting from inappropriate investments in health technologies in particular medical devices that do not meet high-priority needs, are incompatible with existing infrastructures, are irrationally or incorrectly used, or do not function efficiently;

Acknowledging the need for Member States and donors to contain burgeoning costs by establishing priorities in the selection and acquisition of health technologies in particular medical devices on the basis of their impact on the burden of disease, and to ensure the effective use of resources through proper planning, assessment, acquisition and management;

Noting the need to expand expertise in the field of health technologies in particular medical devices;

1. URGES Member States:

(1) to collect, verify, update and exchange information on health technologies in particular medical devices as an aid to their prioritization of needs and allocation of resources;

(2) to formulate as appropriate national strategies and plans for the establishment of systems for the assessment, planning, procurement and management of health technologies in particular medical devices, in collaboration with personnel involved in health-technology assessment and biomedical engineering;

¹ The term "health technologies refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives".

² Document A60/26.

- (3) to draw up national or regional guidelines for good manufacturing and regulatory practices, to establish surveillance systems and other measures to ensure the quality, safety and efficacy of medical devices and where appropriate participate in international harmonization;
- (4) to establish where necessary regional and national institutions of health technology, and to collaborate and build partnerships with health-care providers, industry, patients' associations and professional, scientific and technical organizations;
- (5) to collect information that interrelates medical devices, which deal with priority public-health conditions at different levels of care and in various settings and environments, with the required infrastructure, procedures and reference tools;

2. REQUESTS the Director-General:

- (1) to work with interested Member States and WHO collaborating centres on the development, in a transparent and evidence-based way, of guidelines and tools, including norms, standards and a standardized glossary of definitions relating to health technologies in particular medical devices;
- (2) to provide support to Member States where necessary in establishing mechanisms to assess national needs for health technologies in particular medical devices and to assure their availability and use;
- (3) to develop methodological tools to support Member States in analysing their health technologies in particular medical devices needs and health-system prerequisites;
- (4) to provide technical guidance and support to Member States where necessary in implementing policies on health technologies, in particular medical devices especially for priority diseases, according to different levels of care in developing countries;
- (5) to work jointly with other organizations of the United Nations system, international organizations, academic institutions and professional bodies in order to provide support to Member States in the prioritization, selection and use of health technologies in particular medical devices;
- (6) to establish and update regularly an evidence and web-based health technologies database to serve as a clearing house which will provide guidance on appropriate medical devices according to levels of care, setting, environment, and intended health intervention, tailored to the specific needs of country or region;
- (7) to provide support to Member States with vulnerable health-care systems so as to identify and put in place appropriate health technologies in particular medical devices that facilitate access to quality services in primary health care;
- (8) to report on implementation of this resolution to the Executive Board and the Sixty-second World Health Assembly through the Executive Board.

Eleventh plenary meeting, 23 May 2007
A60/VR/11

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Annex 2

WHO/EUROSCAN collaboration plan for the years 2010-12¹

Activity 1: Selection of innovative technologies

WHO has launched, starting in September 2009, a call for innovative technologies that address global health concerns. Within the framework of that activity EuroScan will provide assistance in the following activities.

1.1 Provision of expertise for the evaluation and grading of submissions for the WHO call for innovative technologies in accordance with agreed criteria between the Parties. The grading will have been completed by April 15 2010.

1.2 Assist the WHO in the selection process for Innovative Technologies at the Second Advisory Group for Innovative Technologies Meeting to be held in Copenhagen, Denmark April 26-29, 2010.

Activity 2: capacity building, workshop on assessment for emerging technologies

To review the implementation for the Health Technologies resolution WHA60.29, in order to have accessible and appropriate technology, the EHT department is organizing the First Global Forum on Medical Devices from 9 to 11 September 2010 in Bangkok, Thailand.

The assessment of innovative technologies is a key element to achieving access to affordable safe and effective health care. EuroScan will provide assistance to develop information on methodologies for early awareness and alert systems for new technologies.

Activity 3: information on emerging technologies

Ensure continued communication with other health technology assessment organizations with which the WHO has relations to ensure synchronized efforts. Provision of information of emerging and new technologies, from Euroscan database, as needed by WHO.

¹ Participation in WHO governing body meetings is not considered to be a joint activity and thus it is not necessary to report it as such.

Health intervention and technology assessment in support of universal health coverage

The Sixty-seventh World Health Assembly,

Having considered the report on health intervention and technology assessment in support of universal health coverage;¹

Recalling resolutions WHA52.19 on the revised drug strategy, WHA58.33 on sustainable health financing, universal coverage and social health insurance, WHA60.16 on progress in the rational use of medicines, WHA60.29 on health technologies, WHA63.21 on WHO's role and responsibilities in health research, and WHA64.9 on sustainable health financing structures and universal coverage;

Recognizing the importance of evidence-based policy development and decision-making in health systems, including decisions on resource allocation, service system designs and translation of policies into practice, as well as reaffirming WHO's roles and responsibilities in provision of support to strengthen information systems and health research capacity, and their utilization in Member States;

Noting that the efficient use of resources is a crucial factor in the sustainability of health systems' performance, especially when significant increases in access to essential medicines, including generic medicines, to medical devices and procedures, and to other health care interventions for promotion, prevention, diagnosis and treatment, rehabilitation and palliative care are pursued by Member States, as they move towards universal health coverage;

Noting that *The world health report 2010*² indicates that as much as 40% of spending on health is being wasted and that there is, therefore, an urgent need for systematic, effective solutions to reduce such inefficiencies and to enhance the rational use of health technology;

Acknowledging the critical role of independent health intervention and technology assessment, as multidisciplinary policy research, in generating evidence to inform prioritization, selection, introduction, distribution, and management of interventions for health promotion, disease prevention, diagnosis and treatment, and rehabilitation and palliation;

Emphasizing that with rigorous and structured research methodology and transparent and inclusive processes, assessment of medicines, vaccines, medical devices and equipment, and health

¹ Document A67/33.

² *The world health report 2010. Health systems financing: the path to universal coverage.* Geneva: World Health Organization; 2010.

procedures, including preventive intervention, could help to address the demand for reliable information on the safety, efficacy, quality, appropriateness, cost-effectiveness and efficiency dimensions of such technologies to determine if and when they are integrated into particular health interventions and systems;

Concerned that the capacity to assess, research and document the public health, economic, organizational, social, legal and ethical implications of health interventions and technologies is inadequate in most developing countries, resulting in inadequate information to guide rational policy, and professional decisions and practices;

Recognizing the importance of strengthened national capacity, regional and international networking, and collaboration on health intervention and technology assessment to promote evidence-based health policy,

1. URGES Member States:¹

(1) to consider establishing national systems of health intervention and technology assessment, encouraging the systematic utilization of independent health intervention and technology assessment in support of universal health coverage to inform policy decisions, including priority-setting, selection, procurement supply system management and use of health interventions and/or technologies, as well as the formulation of sustainable financing benefit packages, medicines, benefits management including pharmaceutical formularies, clinical practice guidelines and protocols for public health programmes;

(2) to strengthen the link between health technology assessment and regulation and management, as appropriate;

(3) to consider, in addition to the use of established and widely agreed methods, developing, as appropriate, national methodological and process guidelines and monitoring systems for health intervention and technology assessment in order to ensure the transparency, quality and policy relevance of related assessments and research;

(4) to further consolidate and promote health intervention and technology assessment within national frameworks, such as those for health system research, health professional education, health system strengthening and universal health coverage;

(5) to consider strengthening national capacity for regional and international networking, developing national know-how, avoiding duplication of efforts and achieving better use of resources;

(6) to consider also collaborating with other Member States' health organizations, academic institutions, professional associations and other key stakeholders in the country or region in order to collect and share information and lessons learnt so as to formulate and implement national strategic plans concerning capacity-building for and introduction of health intervention and technology assessment, and summarizing best practices in transparent, evidence-informed health policy and decision-making;

(7) to identify gaps with regard to promoting and implementing evidence-based health policy, as well as improving related information systems and research capacity, and considering

¹ And, where applicable, regional economic integration organizations.

seeking technical support and exchanging information and sharing experiences with other Member States, regional networks and international entities, including WHO;

(8) to develop and improve the collection of data on health intervention and technology assessment, training relevant professionals, as appropriate, so as to improve assessment capacity;

2. REQUESTS the Director-General:

(1) to assess the status of health intervention and technology assessment in Member States in terms of methodology, human resources and institutional capacity, governance, linkage between health intervention and technology assessment units and/or networks with policy authorities, utilization of assessment results, and interest in and impediments to strengthening capacity;

(2) to raise awareness, foster knowledge and encourage the practice of health intervention and technology assessment and its uses in evidence-based decision-making among national policy-makers and other stakeholders, by drawing best practices from the operation, performance and contribution of competent research institutes and health intervention and technology assessment agencies and programmes, and sharing such experiences with Member States through appropriate channels and activities, including global and regional networks and academic institutions;

(3) to integrate health intervention and technology assessment concepts and principles into the relevant strategies and areas of work of WHO, including, but not limited to, those on universal health coverage, including health financing, access to and rational use of quality-assured medicines, vaccines and other health technologies, the prevention and management of noncommunicable and communicable diseases, mother and child care, and the formulation of evidence-based health policy;

(4) to provide technical support to Member States, especially low-income countries, relevant intergovernmental organizations and global health partners, in order to strengthen capacity for health intervention and technology assessment, including, when appropriate, the development and use of global guidance on methods and processes based on internationally agreed practices;

(5) to ensure adequate capacity at all levels of WHO, utilizing its networks of experts and collaborating centres, as well as other regional and international networks, in order to address the demand for support to facilitate evidence-based policy decisions in Member States;

(6) to support the exchange of information, sharing of experiences and capacity-building in health intervention and technology assessment through collaborative mechanisms and networks at global, regional and country levels, as well as ensuring that these partnerships are active, effective and sustainable;

(7) to report on progress in the implementation of this resolution to the Sixty-ninth World Health Assembly.

Ninth plenary meeting, 24 May 2014
A67/VR/9

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Annex 4. WHO/EuroScan collaboration plan for the years 2015-2017

Activity 1: Selection of new and emerging technologies

EuroScan will provide a list of emerging health technologies and new applications of existing health interventions identified by EuroScan Member Agencies and included in the EuroScan database on an annual basis.

EuroScan Member Agencies through EuroScan will provide publicly available early assessment reports for any emerging health technologies of interest to the WHO.

EuroScan Member Agencies through EuroScan agree to allow WHO to publish or link to publicly available early assessment reports on the WHO Health Technology Assessment website.

Activity 2: Systematic approach for the early evaluation of health interventions

At the request of the WHO, EuroScan will provide expertise for the evaluation and grading of innovative technologies in a systematic approach, using previously agreed criteria and methodologies. WHO and EuroScan will work on the development of an explicit and systematic approach for the early assessment of health interventions and technologies

Activity 3: Communication and collaboration on Early Awareness and Alert activities (EAA)

WHO and EuroScan will together continue to strengthen communication with other health technology assessment organizations to support the identification and early assessment of new health technologies of interest.

Activity 4: Capacity building, workshop on early assessment for emerging technologies

In accordance with the implementation for the Resolution WHA67.23, in order to strengthen capacity for health intervention and technology assessment at country level, EuroScan, in coordination with WHO, will propose a workshop on EAA activities specifically addressed, but not limited, to low-middle-income countries during the HTAi annual conferences.

Organisation of similar workshops and other capacity-building initiatives may be considered upon request from the WHO, WHO Regional Offices or Member States with the financial or in-kind support from WHO.

