Report

Second meeting of the WHO Advisory Group on Innovative Technologies

World Health Organization
Regional Office for Europe
Copenhagen
27-29 April 2010
List of Abbreviations

AGIT Advisory Group on Innovative Technologies
EHT Department of Essential Health Technologies
EURO WHO Regional Office for Europe
GIHT Global Initiative for Health Technologies
LMIC Low- and Middle-Income Countries
MDGs Millennium Development Goals
MoH Ministry of Health
WHA World Health Assembly
WHO World Health Organization
# Table of contents

1. Executive Summary...............................................................................................................4

2. Background on WHO Global Initiative for Health Technologies.................................5

3. Meeting proceeding ...........................................................................................................7
   3.1 Introduction and background information (Day 1) ...........................................................7
      3.1.1 Welcome by Dr Steffen Groth ..................................................................................7
      3.1.2 Welcome by Dr Hans Kluge ..................................................................................7
      3.1.3 Innovative technologies for effective health care delivery - Objectives and outcomes of the meeting.................................................................7
      3.1.4 Global Initiative for Health Technologies (GIHT) and the WHA resolutions ........8
      3.1.5 Report from the first Meeting of the Advisory Group on Innovative Health Technologies..................................................................................................................8
      3.1.6 Overview of the call ..............................................................................................9
   3.2 The WHO pre-screening (Day 1) ..................................................................................10
      3.2.1 The selection process ..........................................................................................10
      3.2.2 Screening outcome WHO ..................................................................................10
      3.2.3 Selection process by the University of Toronto .......................................................11
      3.2.4 Selection process by EuroScan .............................................................................11
      3.2.5 Results of the selection process .........................................................................12
      3.2.6 Introduction to break-out sessions for the following day .......................................13
   3.3 Key concerns raised by advisors (Day 1) .........................................................................13
   3.4 Final selection (Day 2) ..................................................................................................14
      3.4.1 Break out session ...............................................................................................14
   3.5 Presentation on selection and discussion (Day 3) ............................................................14
      3.5.1 Presentations of reviewed technologies, recommendations and comments per group ....14
4. Summary of recommendations from the meeting...............................................................15
   4.1 Recommendations on final selection and communication of results.........................15
   4.2 Recommendations on the way forward for future calls .............................................15
5. Next steps..........................................................................................................................16
6. Closing of the meeting ........................................................................................................16

Short-listed Technologies .......................................................................................................17
   Category 1 - commercialized/-able products .....................................................................17
   Category 2 - products in a non-commercialized/-able stage .............................................17

List of Participants ..................................................................................................................18

Provisional Program of Work ...............................................................................................22
1. Executive Summary

The second Meeting of the Advisory Group on Innovative Technologies was held in Copenhagen on 27-29 April 2010, hosted by the World Health Organization, Regional Office for Europe in Copenhagen, Denmark.

The Essential Health Technologies department (EHT) at the World Health Organization in Geneva launched The Global Initiative on Health Technologies (GIHT) in 2009. The GIHT has been designed to help make available the benefits of core health technologies at an affordable price in low resource settings. The Call for innovative technologies that address global health concerns is one of the activities central to the Global Initiative. The call has been created to challenge the business and scientific communities to identify and adapt innovative technologies that can have a significant impact on public health in developing countries.

A first Advisory Group meeting held in June 2009 established the list of relevant health concerns to be addressed by the call as well as the selection criteria the submissions should be judged against. The call was closed on 31. January 2010. An initial application screening and pre-selection was completed by the Essential Health Technologies department at WHO with support from EuroScan and the University of Toronto prior to this meeting.

Participants of the Second Meeting of the Advisory Group on Innovative Technologies were asked to assist in the final selection of applications, to advice on dissemination strategies for the technologies selected and to provide recommendation for future calls. The meeting consisted of 29 participants in total, 17 technical advisors, two representatives of collaborating centers, six staff from regional WHO offices and four from EHT at WHO headquarters. The meeting was held over two and a half days.

On the first day the department of Essential Health Technologies presented the background of the call, the activities accomplished to launch and promote the call, the statistics on applications received as well as the pre-selection procedure. All three institutions (WHO, EuroScan and the University of Toronto) subsequently presented their screening process and outcomes.

During the second day the meeting participants split into four groups; each group reviewed a set of preselected applications and gave their recommendation on whether or not to select those for publication on the WHO website. The meeting participants reconvened on day three to make the final decision on the list of technologies to be published. The group also discussed how best to portray the chosen technologies on the website without disclosing the product identifiers. Equally consideration was given on how to communicate the selection process to applicants and the public.

The Advisory Group reviewed 43 applications out of 84 received; 8 commercialized products and 9 non-commercialized products were recommended. It was acted that technologies will be published on the WHO side as generic concepts only. The list of selected technologies will be made available on the Essential Health Technologies website on 30 June 2010. The selection process will be described and the rules of the call will remain available on the web site. All applicants will be notified whether or not their submission has been selected.
2. **Background on WHO Global Initiative for Health Technologies**

(As described in the report of the 1st Meeting of the WHO Advisory Group on Innovative Technologies)

Successful health care delivery requires effective medical devices and supporting health technologies as tools for prevention, screening, diagnosis, treatment and rehabilitation. Despite the exponential growth in scientific and technological development, low- and middle-income countries are still largely excluded from access to appropriate and affordable health technologies. Furthermore, attainment of the health-related Millennium Development Goals (MDGs) and effective control of many health-related problems will not be possible without certain basic technologies.

The World Health Assembly in its resolution WHA 60.29 Health technologies (2007) emphasized the role of medical devices and health technologies, as well as their current sub-optimal contribution to health outcomes:

"Understanding that health technologies, and 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 that do not meet high-priority needs, are incompatible with existing infrastructures.....".

In order to facilitate equitable access to health care and the necessary core technologies, one of the goals of the WHO Department of Essential Health Technologies is to identify and promote innovative technologies addressing global health concerns and to stimulate their further development. To contribute to the achievement of that goal the Department of Essential Health Technologies has launched a Global Initiative for Health Technologies.

The overall goal of the Global Initiative for Innovative Health Technologies (GIHT) is to help address important health problems associated with communities in resource-limited settings by making available the benefits of core health technologies, through equitable access and acceptable levels of affordability. This also requires technological innovation, either in the technologies themselves or in the processes designed to facilitate their dissemination, application and utilization. The two specific objectives of the initiative are:

I. To challenge the international community to establish a framework for the development of National Health Technology Programmes that will impact the burden of disease and ensure effective use of resources;

II. To challenge the business and scientific communities to identify and adapt innovative technologies that can have a significant impact on public health in developing countries.

Outputs for Objective I will include needs assessment and gap analysis tools for Member States as well as a technology prioritization model.
Activities under Objective II will include:

- Establishing partnerships with institutions that have experience in identifying health trends or forecasting and evaluating health technologies;
- Identification of key global health concerns and emerging health trends based on disease burden data;
- Outreach (including Call) to industry, universities, associations and other role-players to identify suitable technologies to address the identified health concerns;
- Selection of innovative health technologies meeting the criteria of this Initiative;
- Promotion and diffusion of selected technologies through training, media coverage and other channels.

The project aims to optimize public health outcomes by encouraging innovation through:

- Increasing understanding among decision-makers about the critical role of health technologies in promoting public health;
- Stimulating the development of new technologies;
- Expanding the use of existing health technologies that are not widely used, and
- Identifying new uses of existing non-health technologies that can have a significant and immediate impact on public health.
3. Meeting proceeding

3.1 Introduction and background information (Day 1)

3.1.1 Welcome by Dr Steffen Groth

Dr Steffen Groth, Director of the Department of Essential Health Technologies, opened the meeting by welcoming all participants. Dr Groth handed over to Dr Hans Kluge, representative of the WHO Regional Office in Copenhagen, for further welcoming words and an introduction to the meeting.

3.1.2 Welcome by Dr Hans Kluge

Dr Hans Kluge, representative of the Regional Office in Copenhagen, welcomed and thanked all participants for attending the second meeting of the WHO Advisory Group on Innovative Technologies (AGIT) in Copenhagen. Dr Kluge highlighted the following points:

- Health Technologies, and in particular medical devices, are crucial for the prevention, diagnoses, rehabilitation and treatment of illness and diseases. The global medical technology market is estimated to be over US$ 700 billion in 2007 in the US alone. Markets are expected to grow steadily at 5% annually and it is important for low and middle-income countries to participate in the growth and the development of innovative technologies. He furthermore explained that the investment focus currently lies in high-income countries, and that solutions are now required to reach low- and middle-income countries. Dr Kluge emphasized that it is essential for industry to gain insights into actual needs in low-resource settings.
- Dr Kluge highlighted that the WHO call for innovative technologies aligned itself to the key health concerns identified in Singapore during the first meeting of the Advisory Group in 2009. He summarized that numerous applications have been received which signals a willingness of industry to enter a dialogue on the subject and confirms that the time is right to move forward with the effort of getting appropriate technologies to those in need.
- Dr Kluge welcomed again and expressed special thanks to Dr Groth, Mrs Adriana Velazquez-Berumen and Mr Björn Fahlgren of the Department of Essential Health Technologies in Geneva.

3.1.3 Innovative technologies for effective health care delivery

Objectives and outcomes of the meeting

Dr Groth proceeded with background information on the Global Initiative for Health Technologies. Dr Groth also summarized the outcome of the call so far. 84 submissions were received, and reviewed and pre-selected by experts in WHO, 14 agencies of EuroScan and the University of Toronto. The speaker expressed his thanks to those who helped to screen and evaluate proposals by grading submissions for their support.

Dr Groth summarized the objectives of the meeting with the following two challenges:

1. To generate a final list of recommended submissions that fulfils the selection criteria.
2. To sketch out the way forward, how to proceed once the list has been compiled.

Dr Groth emphasized that the call is challenging as it is acting on the interface of what is possible for WHO; WHO can’t promote brands, but principles and ideas only. With regard to the call, all actions have to comply with the rules and regulations of WHO. Dr Groth concluded that the Global Forum for Medical Devices in September in Thailand would provide a suitable platform to present the outcomes of this meeting.
The following rapporteurs were designated for this meeting: Ms Lisa Stroux and Dr Joseph Mathew.

All participants of the Advisory Group on Innovative Technologies introduced themselves briefly.

### 3.1.4 Global Initiative for Health Technologies (GIHT) and the WHA resolutions

Ms Adriana Velazquez-Berumen summarized the objectives of the initiative accomplished so far and talked through the timeline of the project. The goals of objective 2 of the GIHT were reiterated as being to challenge the scientific and business communities, to raise awareness of the role of technological innovation and to make available core benefits at an affordable price in low-resource settings. Whilst the first meeting of the WHO Advisory Group on Innovative Technologies produced a list of key concerns and diseases to address as well as selection criteria, the second meeting’s goals are the following:

1. Review and select submissions
2. Provide Recommendations on the way forward

Ms Velazquez-Berumen confirmed that selected technologies were to be published on the WHO website in the last week of June (by 30 June 2010).

WHO as well as the University of Toronto and the member agencies of EuroScan have been reviewing and pre-selecting the submissions received.

It was highlighted by Ms Velazquez-Berumen that all submissions had been anonymized for the selection panel and were to be considered confidential. Background documents provided to the participants of the second meeting of the WHO Advisory Group on Innovative Technologies are: Landscape analysis, Singapore meeting report, the submission form and the brochure for the Call. Ms Velazquez also noted the recognition of the importance of medical device in the WHA resolution WHA60.29 Health technologies.

### 3.1.5 Report from the first Meeting of the Advisory Group on Innovative Health Technologies

Mr Albert Poon gave a short summary of the first meeting of the WHO Advisory Group on Innovative Technologies in Singapore 20-21 June 2009. The deliverables of the meeting were summarized as:

- A list of health concerns addressed by the call;
- A list of criteria to guide technology selection.

Please refer to the report of the first Meeting of the WHO Advisory Group on Innovative Technologies for further details.
3.1.6 Overview of the call

Mr Björn Fahlgren gave a presentation on the call procedure so far and the response to the call. Reference was made to the call brochure for all essential information regarding the call. Mr Fahlgren emphasized that the biggest challenge was still ahead: the final selection of applications and their dissemination.

A brief overview of the call is as follows:

The call was launched at the annual World Congress on Medical Physics and Biomedical Engineering in Munich on 11. September 2009. An important effort on outreach has been undertaken since then to promote the call, for example with presence during the world's largest medical device fair Medica in Dusseldorf, Germany, and through adverts on websites and in newsletters of biomedical engineering and clinical engineering federations or manufacturers associations.

The call targeted a number of health concerns, which are listed in the call documentation, which also includes all selection criteria the submissions are judged against. The call has been open to anyone, including academia, industry and individuals. Products in a commercialized state (commercialized in developed countries) could be submitted as well as technology proposals at a conceptual stage. The biggest task, Mr Fahlgren stressed, would be give substance to the opportunities for submitting entities following the call; this has been kept generic in the brochure, namely as follows:

- To highlight generic product concepts on the WHO website;
- To share information with governments, donors and other stakeholders with a view to generally fostering the development, availability of and access to innovative health technologies, particularly in low- and middle-income countries.

Mr Fahlgren summarized the selection process as follows:

The initial grading was completed in collaboration with EuroScan and the University of Toronto. WHO received a total of 84 submissions of which 46 % belonged to category 1 (commercialized/-able products), 35% to category 2 (non commercialized/ commercialisable products) and 19% were not considered. Submissions came from 29 countries, representing a good geographical distribution.

There were several options, described in the documentation of the call, how to qualify for the prerequisite of being innovative. Most submissions claimed innovativeness on the basis of being a novel product, followed by those products being adapted to low- and middle-income countries. The smallest number was existing technologies that innovated by adapting a product from another field of application for a health purpose.

The majority of applications came from the business establishment and educational institutions. Health concerns most frequently represented were reproductive health and infant and child mortality, followed by tuberculosis and other infectious diseases. Some technologies were applicable to several or all categories, such as certain software products. All categories of medical device applications listed in the brochure, such as preventatives or therapeutic have been represented. The same applies to the use environment; similarly all levels of health care facilities were considered. However only a small number of submissions are intended to be used by the patient.
The category of medical equipment was most represented; the category of implants the least. The majority of submissions are IP protected. Applicant indicated that the biggest hurdle for bringing their products to market (in low and middle income countries) is financing, followed by distribution and manufacturing concerns.

3.2 The WHO pre-screening (Day 1)

3.2.1 The selection process

Dr Noboru Takamura from WHO summarized the pre-selection process and outcomes. In total WHO received 84 submissions, 16 of those were not included as they were not considered medical devices, or as they were not received on time (received after the 31. January 2010). 68 remained of which 39 belong to Category 1 (commercialized/able products), 29 to Category 2 (products in a non-commercialized/able stage). The three institutions (WHO, EUROSCAN and University of Toronto) evaluated the applications using the six selection criteria for grading. Each reviewer graded the submission against each criterion using a scale from 1 to 5. The reviewers were also asked to assign the degree of innovation to the product as either high or low.

It was clarified by Ms Adriana Velazquez-Berumen that during the selection process only information provided by applicants was used to inform the decision. She confirmed that the selection process during the meeting would also be based on the information provided in the individual applications, with no possibility of corresponding with applicants to seek clarifications.

3.2.2 Screening outcome WHO

Dr Iyad Mobarek of WHO gave a summary of the selection process representing the WHO reviewers. The deadline for accepting submission was set as 1pm Geneva time on 1 February 2010. No indication on the time zone had been given in the call documentation; the deadline has therefore been set to when the last time zone concluded 31 January 2010.

A total of 84 submissions were received, each application was given a unique identification number, all other identifiers were removed to render the submission anonymous. All applications were screened for formal eligibility by WHO staff. In agreement with the external reviewers it was decided to exclude 15 applications as their submissions were not considered medical devices. It was also decided to determine innovativeness of the products as a group. Reviewers were asked to give the submission a high or low score with respect to innovativeness. Applicants who did not sign their submission were reminded and did so. Document formats other than PDFs were accepted. Late submissions were disqualified.

In summary:

- 83 submissions (+1 late submission) were received,
- 45 in Category 1, 38 in Category 2,
- 15 (+1 late submission) were disqualified,
- 68 applications remained, 39 in Category 1, 29 in Category 2.

Types of submissions received were medical equipment, software, instruments, telemedicine, test kits, implants, medical solutions such as disinfectants, wound treatment and others.

Care was taken to select evaluators from different backgrounds.
All three WHO evaluators (Dr Iyad Mobarek, Dr Noboru Takamura, Mr Björn Fahlgren) graded independently using the prepared grading forms. The reviewers calculated the average for each application subsequently. A very high correlation between evaluators was noted.

Dr Mobarek highlighted the following challenges: not all criteria were equally appropriate for all submissions; it was also difficult to apply the same criteria for submissions in different development stages. Whether or not to verify or complement information provided by the applicant was a discussion point; the decision was made that only information given would be used when grading the applications. Another challenge was that some applicants misjudged their own innovation (e.g. use environment) or claimed innovativeness, even though only incremental modifications have been made to previous version of products.

Dr Mobarek concluded that the call so far has been an immense learning experience that will inform future calls. WHO received great responses from institutions around the World. The call also has put WHO’s concerns strongly on the agenda.

### 3.2.3 Selection process by the University of Toronto

Mr Tony Easty introduced the research activities and facilities based at the Centre for Global eHealth Innovation at the Toronto General Hospital. The main focus of the research team is the usability testing of medical technologies using state-of-the-art lab testing environments. Mr Easty and his colleague Ms Anjum Chagpar reviewed and graded the applications. After the first six applications the reviewers decided to split the remaining submissions due to time constraints and recalibrated the results afterwards to account for differences in grading between the two evaluators. Mr Easty highlighted the fact that there was considerable variability between the reviewers and emphasized the subjective nature of the evaluation process.

He furthermore raised the issue that usability and safety were difficult to assess without prototypes. Equally suitability and affordability were hard to discuss and evaluate given the fact that health care settings may differ substantially. Mr Easty also highlighted that in some cases it might be appropriate to ask the question whether the proposed technology is really required. (Example: technology to keep newborn babies warm where Kangaroo mother care is a norm).

### 3.2.4 Selection process by EuroScan

Dr Iñaki Gutierrez-Ibarluzea presented the history and background of EuroScan. EuroScan stands for International Information Network on New and Emerging Health Technologies, which is a collaborative network of member agencies for the exchange of information on important emerging new drugs, devices, procedures, programmes, and settings in health care (www.euroscan.org.uk).

After the invitation by WHO to participate in the selection of technologies EuroScan members decided to pursue this as a joint effort, 14 members volunteered to take part in the assessment. Each technology was evaluated by two members during a timeframe of three weeks. The EuroScan secretariat collated the results.
There was a high degree of agreement between members, the assessment process was perceived as coherent and accountable by the members. Dr Gutierrez-Ibarluzea summarized some issues raised by the participating member institutions as follows:

- Some questions were difficult to assess due to the low quality, lack or inadequacy of information provided by the applicant.
- Difficulties were experienced using the grading system of 1-5, for example there was no 0 option where there was too little information provided to make a judgement.

Dr Gutierrez-Ibarluzea proposed several ways to improve the current procedure:

- A centralized web platform for submission and evaluation,
- A more comprehensive and may be more restrictive definition of innovation,
- Workshops on how to submit proposals (to improve quality) and
- An improved scoring system that considers weighting criteria and defines cut-off points for each criterion (thresholds).

Dr Gutierrez-Ibarluzea concluded by thanking the members of EuroScan for their support.

3.2.5 Results of the selection process

Mr Fahlgren presented the consolidated outcomes of the three reviewing teams. He compared the total grade given by each team for all applications. Mr. Fahlgren noted that there were differences in grading between the evaluating institutions; the University of Toronto’s grades were on average lower than those of EuroScan and WHO.

The three evaluating teams used the following elimination criteria for short-listing submissions for presentation to the AGIT:

1. Only medical devices\(^1\) were considered.
2. At least two out of the three reviewing institutions needed to confirm that product is innovative.
3. The cut off threshold was set at 18 points (average of the three scores awarded by the different reviewing teams). (For ref.: The maximum that could be achieved is 30 points). 18 points is based on the average of 3 points per criterion.
4. The maximum difference in grading between two teams of evaluators was not considered.

Mr Fahlgren explained that some evaluators with a high spread had given many low and high grades. However the average grades given by evaluators were rather similar.

Mr Fahlgren also mentioned that a threshold of \(\geq 18\) points produced an appropriate output in terms of numbers of applications.

---

\(^1\) As defined by the Global Harmonization Task Force for Medical Devices
3.2.6 Introduction to break-out sessions for the following day

Ms Adriana Velazquez-Berumen introduced the procedure for the break-out sessions to be held the following day. Four groups were formed with six advisors per group. An effort was made to achieve a good balance with regard to gender, professional background and origin (developed versus developing country) of the members in each group. Two working groups were asked to review pre-selected commercialized products (Category 1), the two other groups reviewed the category of products under development (Category 2). The submissions were split in equal numbers between the groups. Each reviewing team was asked to designate a rapporteur to report back to all meeting participants on the third day. WHO prepared a binder for each group including all relevant information for each submission assigned for review to the group.

Ms Velazquez also kindly requested each group to complete a review form for each application, to note whether or not the group recommends the technology for selection and the reasoning behind the decision. Furthermore the groups were asked to provide comments on how well the applications complied with the selection criteria and recommendations for the applicant.

3.3 Key concerns raised by advisors (Day 1)

The advisors expressed the following concerns and recommendations during discussion on day 1:

1. Grading and criteria:
   - The questions was raised whether a scale of absolute numbers could be replaced with alternative criteria and grading mechanisms that are more suitable given the diversity of applications.
   - The weighting of criteria was suggested to differentiate between the criteria and their importance.
   - Criteria thresholds should be established, especially for safety and effectiveness.
   - Quality (assured quality control) was highlighted as a criterion that could be taken into account in the future.
   - Applying the same criteria for Category 1 and 2 was raised as a concern. Different criteria for separate categories of medical devices might need to be established.

2. Communication with applicants and the general public:
   - The advisors highlighted the importance of appropriate communication. They recommended transparency and comprehensive description of the selection process when publishing the result. It was agreed that WHO will notify all, whether selected or not. It was also reiterated that WHO has no obligation to give justification for selection or exclusion as stated in the call brochure.
After discussion the advisory group agreed on the following points relevant to the final selection procedure:

Maintain the general principles which have been applied in and only apply suggested modifications to a second edition of the call as appropriate.

Attribute ‘innovative’: Applications will be considered when at least two evaluating centers rated the product as highly innovative.

Selection threshold: A minimum of 18 points is acceptable.

Validate inclusion: Pre-selected submissions that scored very low (1 point) for a criterion need to be re-evaluated. The most important criteria in this context are safety and effectiveness.

Validate exclusion: Submissions that have been excluded based on just one assessment centre’s low ranking should be revisited. Those outliers will be identified and included in the final selection the following day.

3.4 Final selection (Day 2)

Ms Velazquez-Berumen presented the ‘outliers’ (ranked high by two centers, very low by one) as defined in point 3.3 that were excluded by the pre-selection teams based on their average score. Those were then distributed over the four groups to be included in the final review.

3.4.1 Break out session

The four expert groups reviewed the original selection as well as the outliers identified. Each member of the group read the information provided on the application (all answers relevant to judging against the criteria). Subsequently the groups discussed the submissions with regard to the six selection criteria. All groups provided their recommendation for or against selection including reasoning and general comments on the evaluation forms.

After reviewing all submissions, the two teams reviewing the same category presented their results to each other and engaged into further discussions.

3.5 Presentation on selection and discussion (Day 3)

3.5.1 Presentations of reviewed technologies, recommendations and comments per group

Both groups presented their outcomes, recommendations and reasoning to the other meeting participants. The Advisory Group reviewed 43 applications; 8 commercialized products and 9 non-commercialized products have been selected.
4. **Summary of recommendations from the meeting**

4.1 **Recommendations on final selection and communication of results**

Several discussion points arose during the meeting on how to best enter into and complete the final phase of the current Call for innovative technologies that address global health concerns. The key concerns discussed were the lack of information provided by several applicants, the importance of appropriate communication with applicants and other stakeholders and the presentation of the selected technologies on the website.

The following recommendations were formulated and agreed on by the meeting participants:

- The final decision has been made that only information provided by the applicant should be taken into account. No additional information should be actively acquired.
- This applies also to technologies, which received a conditional recommendation. It has been decided that those submissions will be included without contacting applicants for further information. Equally, those being rejected due to a lack of information won’t be revisited.
- Participants advised to communicate clearly the selection process and limitations of the call to applicants and other stakeholders.
- Selected submissions are to be kept anonymous as WHO may not recommend or endorse products as such. Hence no names should be mentioned on the website and all concepts should be presented in a generic manner.

4.2 **Recommendations on the way forward for future calls**

The following paragraph summarizes the advisor’s recommendations regarding *Calls for innovative technologies that address global health concerns* that may be launched in the future. Advisors saw potential for improvement regarding the selection process and methodology employed the choice and definition of the selection criteria to judge the submissions against and finally the specification of the call’s scope and its communication.

The following points were discussed and agreed on by the participants:

- Criteria should be more clearly defined.
- The concept of risk has a reduced scope in the call would be preferable to use the definition in ISO standards for medical devices.
- The applicant needs to understand what information is required to increase the quality of the submissions.
- Criteria need to be tailored to different development stages.
- Criteria may need to be weighted.
- Categories could be differentiated even more. A further distinction between development stages was suggested (e.g. product ideas, product in proof of concept stage, market ready technology and commercialized products).
- A more rigorous process is advised to guarantee consistency in grading.
- A tighter scope was suggested. For example targeting one or a limited number of specific health concerns only.
- The use of information and the scope of the initiative should be better communicated prior to submission of applications.
5. **Next steps**

To conclude the first Call for innovative technologies that address global health concerns, the following steps will be taken:

- Every group will submit their list with reviewed technologies to WHO. Meeting participants are invited to contribute and complement the list if necessary.
- The meeting will be documented in a report and distributed amongst the meeting participants.
- WHO will notify applicants whether or not their submission was selected.
- WHO will publish selected technologies as generic concepts on the website on 30 June 2010. Meeting participants are invited to review and comment on the generic technology descriptions prior to publication. [http://www.who.int/medical_devices/call/en/index.html](http://www.who.int/medical_devices/call/en/index.html)
- The call will be presented at the First Global Forum for Medical Devices in Thailand in September 2010.

6. **Closing of the meeting**

Dr Groth, Ms Velazquez-Berumen and Mr Fahlgren thanked the participants for a very fruitful meeting and the WHO Regional Office for their support.

Dr Kluge concluded the meeting and addressed his thanks to those who organized and supported the meeting. The meeting was closed at noon on Thursday 30 April 2010.
Short-listed Technologies

Category 1 - commercialized/-able products

- Stool sample collection and preparation kit (#5)
- LED phototherapy unit (#20)
- System for on-site production of wound irrigation solution (#25)
- SMS smoking cessation education system (#28)
- Reusable neonatal suction system (#36)
- Fluorescence visualization system for cancer screening (#44)
- Transcutaneous bilirubin measurement system (#56)
- Isothermal nucleic acid amplification system for tuberculosis diagnosis (#74)

Category 2 - products in a non-commercialized/-able stage

- Simplified anaesthesia delivery unit (#10)
- Single use assistive vaginal delivery system (#15)
- Portable diagnostic laboratory (#27)
- Portable on site cell sorter and counter for HIV and malaria diagnosis (#38)
- Decision support system for paediatric HIV (#57)
- Single use circumcision device (#61)
- Transcutaneous anaemia monitoring system (#69)
- Solar-powered sterilizer (#79)
- Portable infant warmer (#82)
Second Meeting of the Advisory Group on Innovative Technologies
World Health Organization, Regional Office for Europe
27-29 April 2010 Copenhagen, Denmark

List of Participants

MEMBERS OF THE TECHNICAL ADVISORY GROUP

Dr José ASUA
OSTEBA
Donostia-San Sebastian, 1
01010 - Vitoria-Gasteiz
SPAIN

Ms Anjum CHAGPAR
Centre for Global eHealth Innovation
Toronto General Hospital
190 Elizabeth Street, RFE 4-430
Toronto, Ontario, M5G 2C4
CANADA

Dr Tony EASTY
International Committee Chair
Medical Engineering
University Health Network
Toronto
CANADA

Dr Iñaki GUTIÉRREZ-IBARLUZEA
OSTEBA, Department of Health
Donostia-San Sebastian Kalea
1, Vitoria-Gasteiz
01010 Basque Country
Basque Office for Health Technology Assessment
SPAIN

Mr Tsinko ILUNGA
The African Development Bank
Rue Des Ghana
Tunis, Belvedere
BPV 323-1002, Tunis
TUNISIA
Dr Carole LONGSON  
National Institute for Health and Clinical Excellence  
MidCity Place  
71 High Holborn  
WC1V 6NA London  
UNITED KINGDOM

Dr Joseph MATHEW  
Assistant Professor (Pediatric Pulmonology)  
Department of Pediatrics  
Advanced Pediatrics Centre, PGIMER  
Chandigarh 160012  
INDIA

Mr Rodolphe MUNOZ  
Cosmetics and Medical Devices  
European Commission  
B-1049 Bruxelles  
BELGIUM

Mr Noah PERIN  
PATH  
PO Box 900922  
WA 98109, Seattle  
UNITED STATES OF AMERICA

Mr Albert POON  
Flat 1603, Block B, 16/F, Villa Lotto  
18, Broadwood Road  
Happy Valley  
HONG KONG

Ms Laura SAMPIETRO-COLOM  
Evaluation of Innovation and New Technologies, Hospital Clinic  
c/Villarroel 170, 1.7.  
08036 Barcelona  
SPAIN

Mr Ludo SCHEERLINCK  
Health Technology Centre  
UNICEF Supply Division  
Copenhagen  
DENMARK
Professor Kathleen SIENKO
The University of Michigan
College of Engineering
2350 Hayward, 3116 G.G. Brown
Ann Arbor - Michigan 48109-2125
UNITED STATES OF AMERICA

Dr Sue ROBINSON
EuroScan Secretariat
c/o National Horizon Scanning Centre
Department of Public Health,
Epidemiology and Biostatistics
The University of Birmingham
90 Vincent Drive, Edgbaston
Birmingham, B15 2SP
UNITED KINGDOM

Ms Lisa STROUX
PATH
PO Box 900922
WA 98109, Seattle
UNITED STATES OF AMERICA

Dr Yot TEERAWATTANANON
International Health Policy Program
Ministry of Public Health
Health System Reform Office Building, 3rd floor
Satharanasuk soi 6
Nonthaburi 1100, Bangkok
THAILAND

Ms Diana VELASCO
Health Technology Centre
UNICEF Supply Division
Copenhagen
DENMARK

COLLABORATING CENTRES

Ms Rosa Maria CEBALLOS
CENETEC, Ministry of Health
Reforma 450, Piso 13, Colonia Juarez
CP 06600 - Mexico
MEXICO

Dr Pascience KIBATALA
Saint Francis Designated District Hospital
P.O. Box 73- Ifakara
UNITED REPUBLIC OF TANZANIA
WHO REGIONAL OFFICE FOR THE EASTERN MEDITERRANEAN

Dr Iyad MOBAREK
Jordan Country Office

WHO REGIONAL OFFICE FOR EUROPE

Dr Hans KLUGE
Head of Unit
Country policies and systems
Division of country health systems

Mr Kees de JONKEERE
Regional Adviser
Health technologies and pharmaceuticals
Country policies and systems
Division of country health systems

Dr Valentina HAFNER
Regional Focal Point
Country policies and systems
Division of country health systems
Health Systems

Ms Maria Hayde REYNOSO
Country policies and systems
Division of country health systems

Ms Natalya TARASENKO
Country policies and systems
Division of country health systems

DEPARTMENT OF ESSENTIAL HEALTH TECHNOLOGIES

Dr Steffen GROTH
Director

Mr Björn FAHLGREN
Diagnostic Imaging and Medical Devices

Ms Adriana VELAZQUEZ-BERUMEN
Diagnostic Imaging and Medical Devices

Dr Noboru TAKAMURA
WHO Kobe Centre
Second Meeting of the Advisory Group on Innovative Technologies
World Health Organization, Regional Office for Europe
27-29 April 2010 Copenhagen, Denmark

Provisional Program of Work

Tuesday 27 April 2010

08.00  Participants registration
09.00  Welcome session
       Dr Hans Klug
09.15  Innovative technologies for effective health care delivery
       Dr Steffen Groth
09.45  Report from 1st Meeting of the Advisory Group on Innovative Health Technologies
       Mr Albert Poon
10.00  Global Initiative for Health Technologies (GIHT)
       Objectives and outcomes of the meeting
       Mrs Adriana Velazquez-Berumen
10.15  Discussion

10.30  Coffee break

11.00  The call and the selection process
       Mr Björn Fahlgren
11.15  Response to the proposal and screening outcome in WHO
       Dr Noboru Takamura
11.45  Discussion

12.15  Lunch

13.15  The health Technology Management perspective of the selection
       Mr Tony Easty
13.45  Discussion
14.00  A health technology Assessment perspective of the selection
       Dr Iñaki Gutierrez-Ibarluzea
14.30  Discussion

15.00  Coffee Break

15.30  Methodology break out sessions.
16.00  First Breakout session to select the innovative technologies
       •  New products (groups 1A and 1B)
       •  Products under development or concept stage (groups 2A and 2B)

17.15  Plenary discussion
17.30  Adjourn
18.00  Reception
Wednesday 28 April 2010

09.00  Continued breakout session to select the innovative technologies

- New products
- Products under development or concept stage

11.00  Coffee Break

11.30  Presentation of list of selected technologies within each group
12:00  Discussion

12.30  Lunch

13.30  Second breakout sessions: way forward on availability

- Steps for the selected technologies to become available on the market
- Options for providing necessary resources
- Stakeholders and strategies

15.30  Break

15.45  Presentation of recommendations within the group.
   Discussion
17.30  Adjourn

Thursday 29 April 2010

8.30  Presentations of selected technologies and ways forward by Working Group 1
9:30  Discussion and recommendations

10:00  Coffee Break

10.30  Presentation of selected technologies and ways forward by Working group 2
11.30  Discussion and recommendations
11.15  Summary by the rapporteur of the meeting and recommendations
11.45  Closing of the meeting

12.00 - 13.00 Lunch
Description of the call

Find out more about the rules of the call at:

www.who.int/medical_devices