Improving access to medical devices in low-resource settings through local production and technology transfer: WHO 2013 survey results

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BACKGROUND

WHA 60.29 Resolution requests WHO:
- To develop guidelines and tools, norms and standards relating to medical devices
- To provide support to member states (MS) to assess national needs of medical devices
- To develop methodological tools to analyze medical devices needs
- To provide technical guidance to implement policies on medical devices
- To work with other UN organizations and professional bodies to support MS in prioritization, selection and use of medical devices
- To establish a database, which will provide guidance on appropriate medical devices
- To provide support to identify and put in place appropriate medical devices to facilitate access to primary health care
- To improve delivery and access

WHA 61.21 and WHA 62.16 Resolutions requests WHO to implement the global strategy and plan of action on public health, innovation and intellectual property, specifically:
- Prioritizing research and development needs
- Promoting research and development
- Building and improving innovative capacity
- Transfer of technology
- Application and management of intellectual property to contribute to innovation and promote public health

INTRODUCTION

Phase I Project: Overview of the landscape of medical devices for local production (2012)
- Scoping Study: Global medical devices market, Innovation of medical devices, Research and development for medical devices, Technology transfer and intellectual property, Governance and regulation, etc
- Survey: A survey on access to medical devices was developed to collect more information on key elements involved in technology transfer and local production of medical devices and to fill gaps in the literature search.
- Country case studies:
  - Brazil: Americas Region
  - China: Western Pacific Region
  - Ethiopia: Africa Region
  - India: South-East Asia Region
  - Jordan: Eastern Mediterranean Region

Phase II Project: In-country work to build capacity in local production of selected medical devices (2013)
- Country focus: Ethiopia, Nigeria, South Africa and Tanzania
- Survey and feasibility tool: The Country Survey gathered information regarding the environment for medical device development and deployment. The Feasibility Tool was used to assess the feasibility of local production of selected medical devices. This poster reports preliminary results from the Country Survey.
- Workshops (to be held in 4 participating countries): Provide targeted capacity building in issues related innovation and local production of medical devices to a representative group of all significant stakeholders and draft an action plan for that country, while exploring possibilities of regional collaboration

METHODS

The survey included questions in the following areas:
- Research and development environment
- Policy and partnerships
- Intellectual property protection
- Technology transfer
- Regulation
- Acquisition, procurement and reimbursement

Data were collected using a web-based survey tool, but a print version was provided on request. A request to complete the survey was distributed to 195 stakeholders in 47 countries

RESULTS

Survey Participants’ Distribution and Background

Geographic distribution of survey respondents

Survey respondents’ fields of expertise (total responses: 195)

Respondents’ sector of work (total responses: 195)

Research & Development

Ratio of developers in development stages of a medical device for low-resource settings (total responses: 127)

Intellectual Property (IP)

Ratio of developers who considered IP rights in different income levels (total responses: 50)

Procurement and Reimbursement

Are locally produced medical devices included in the list for procurement or reimbursement in low-income countries (total responses: 14)

Are locally produced medical devices included in the list for procurement or reimbursement in middle-income countries (total responses: 30)

Are locally produced medical devices included in the list for procurement or reimbursement in high-income countries (total responses: 50)

PRELIMINARY FINDINGS

- The top 3 perceived barriers for medical devices development in low-resource settings are: 1. Financial resources 2. Local facilities and 3. Markets
- Developers in low- and middle-income countries are less aware of the IP-related issues than those from high-income countries; developers from Tanzania and Nigeria are less aware of the IP rights than those from Ethiopia and South Africa
- More than 50% of the respondents from low-income countries indicated their countries do not have medical devices procurement and reimbursement lists, in contrast to middle- and high-income countries (where over 50% of respondents indicated that they did)