Informal Consultation on Expanding Schistosomiasis Control in Africa

Geneva, Switzerland, 26 January 2010

Further information is available at:

Information Resource Centre, World Health Organization, 1211 Geneva 27, Switzerland

Fax: + (41) 22 791 4285, e-mail: ntddocs@who.int

WHO/HTM/NTD/PCT/2010.2

Table of Contents

List of Figures and Tables

Figures

Tables

List of Acronyms

API	Active Pharmaceutical Ingredient
ADG	Assistant to Director General of the World Health Organization
BMGF	Bill and Melinda Gates Foundation
CMSC	Coordination mechanism for schistosomiasis control
CPS	Contracting and Procurement Service
DfID	Department for International Development
EMRO	Eater Mediterranean Regional Office
IDA	International Dispensary Association
MDG	Millennium Development Goal
NTD	Neglected Tropical Diseases
QSM	Quality and Safety: Medicines
PZQ	Praziquantel
RTI	Research Triangle International
SCH	Schistosomiasis
SCI	Schistosomiasis Control Initiative
STAG	Strategic Technical Advisory Board
UN	United Nations
USAID	United States Agency for International Development
WHO	World Health Organization

1. Introduction

The meeting was opened by Dr H. Nakatani, Assistant to the Director General ("ADG"), HIV/AIDS, TB, Malaria and Neglected Tropical Diseases.

Dr L. Savioli, Director of the World Health Organization Neglected Tropical Disease department ("WHO/NTD") chaired the meeting. Dr Wendy Harrison (Schistosomiasis Control initiative ("SCI"), Imperial College) was rapporteur assisted by Dr Lester Chitsulo and Ms Munjoo Park (WHO/NTD).

2. Consultation objectives

The aim of the informal consultation was to discuss the needs of schistosomiasis ("SCH") control, especially, a coordinated effort to increase access to praziquantel ("PZQ"). Recognizing that SCH is a major public health problem particularly in Africa and Middle East and access to PZQ is the key issue for scaling up control of SCH, the objectives of the informal consultations are shared with participants as follow:

- to review the global status of schistosomiasis control and PZQ needs
- to analyse funding availability for PZQ procurement
- to address market failure of PZQ to identify a sustainable solution for PZQ supply
- to anticipate issues for quality assurance of PZQ
- to develop a purpose-specific coordination mechanism for the procurement and provision of PZQ for the expansion of preventive chemotherapy coverage which will optimize the use of available resources, and result in a significant reduction in SCH morbidity and transmission in the endemic countries

3. Definition and scope

In 2001, WHO Member States *established*[1] the goal for the control of schistosomiasis (SCH) *of attaining a minimum target of regular administration of chemotherapy to at least 75% and up to 100% of all school-age children at risk of morbidity by 2010*". They have also indicated that WHO approach to combating SCH should include *"advocating new partnerships with organizations of the United Nations system, bilateral agencies, nongovernmental organizations and the private sector, and by continuing to provide international direction and coordination".* January 2010 estimates indicate that less than 10% of the population at risk of morbidity receives praziquantel (PZQ) preventive chemotherapy and that the coverage goal established in 2001 is far from being achieved.

There is insufficient knowledge as to how much PZQ is procured by endemic countries out-side of externally funded public health programmes. It may be that sporadic, uncoordinated and often

[1] Resolution WHA54.19, 22 May 2001

inconsistent strategies for the procurement of NTD medicines led to delays, medicines of questionable quality and high prices. This may have been the case of PZQ. Recently, the UK and US governments have decided to significantly increase their contribution to Neglected Tropical Diseases (NTD) elimination and control, including programmes based on preventive chemotherapy. This is expected to further increase the demand for PZQ, involving both the API and the finished drug product. Examination of market capacity to supply this demand and how resources can be most optimally allocated is therefore timely and essential to ensure the goal of significantly reducing SCH morbidity and transmission in the endemic countries is achieved.

4. Discussion of strategic objectives of informal consultation

4.1 Global Status of SCH control and PZQ needs [2]

Progress towards the sustainable control of schistosomiasis has been made in many endemic regions and most recently a major effort for schistosomiasis treatment is under way in Yemen. While more than 90% of people with schistosomiasis are in the WHO African region and there is a need for scaling up schistosomiasis control in this region, there is also need for scaling up control in the Philippines, Somalia, and Sudan (North and South).

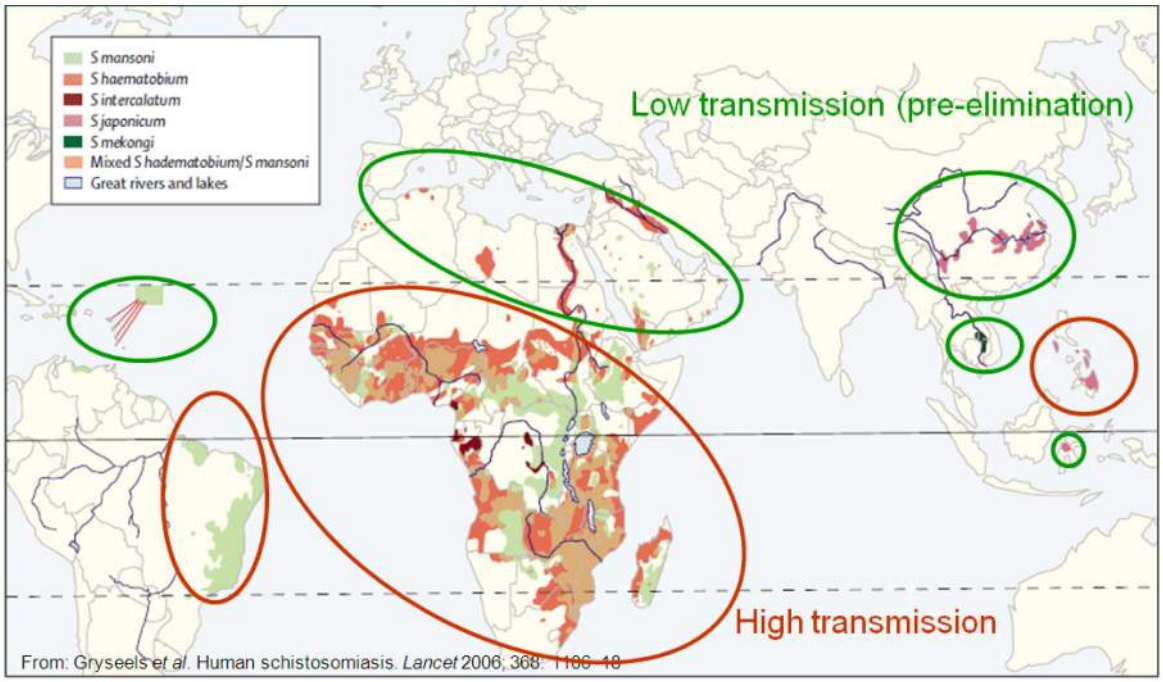

Figure 1: Global distribution of schistosomiasis

Approximately 240 million people were estimated to be infected with schistosomiasis in 2008, according to data reported to the WHO only 17.5 million were treated[3],. Of those treated, 33% were in 8 countries outside of the African region, mostly in China, Egypt and Yemen. A total of 11.6 million people were

[2] Presentation given by Dr L. Chitsulo WHO/NTD

[3] A better and more understandable number of those eligible for preventive chemotherapy for schistosomiasis needs to be determined.

treated for schistosomiasis in 8 countries in the African region, accounting for 67% of all those treated globally. Except for Madagascar and Nigeria, all the reported schistosomiasis treatment campaigns in the African region had been initiated or associated with the Schistosomiasis Control Initiative (SCI). The 10 most endemic countries in sub-Saharan Africa account for 62% of the estimated global total of infected cases. Only 3 (Ghana, Madagascar, and Nigeria) of these had national treatment programmes. Data reported for schistosomiasis treatment in Africa by mid 2009 showed that there would be a significant increase in the number of people treated over the previous year. Some of this increase is due to the PZQ donation of Merck Serono through the WHO.

Table 1 : Schistosomiasis estimated infected and populations treated in 2008 as reported to WHO/NTD

Region	Estimated infected population	Estimated population at risk of infection	Population received treatment	Proportion of estimated infected population treated % *
African	214,216,248	582,062,770	11,700,618	5.5
European	745	76,947	0	0
Eastern Mediterranean	14,038,111	106,638,907	2,665,029	19.0
Americas	7,138,100	51,066,739	65,335	1.0
South-East Asian	242	11,717	0	0
Western Pacific	1,332,264	20,797,325	3,069,475	>100
Global	**236,725,709**	**760,654,405**	**17,500,475**	**7.4**

* Proportion of the number treated in the region compared to number estimated to be infected in the region

The major factor hindering schistosomiasis treatment continues to be the availability of in-kind PZQ donations from industry and finance with which to purchase. In the WHO/NTD business plan – Procurement of essential medicines for the expansion of preventive chemotherapy for neglected tropical disease, 2008 - it had been planned to scale up schistosomiasis treatment to 69 million (30% of those estimated to be infected) in 2009. This would have required 171 million PZQ tablets. Due to limited financing, only 50 million PZQ tablets where procured for the public sector in sub-Saharan Africa in 2009, through USAID/RTI funding and the Merck Serono donation. Thus for 2009, there was a gap of 121 million PZQ tablets. The NTD business plan projected PZQ need rising from 286 million in 2010 to 571 million tablets in 2013.

Even though scale up of schistosomiasis treatment will require increased donor funds with which to purchase PZQ, experience from countries that have successfully controlled schistosomiasis shows that the amount of PZQ required stabilizes after a few years of preventive chemotherapy, and gradually declines. Data from Egypt on schistosomiasis control show that with the use of mass treatment without individual diagnosis, the number of treatments for schistosomiasis was reduced from 9.9 million in 1997 to 1.8 million in 2007. In Burkina Faso, high treatment coverage of the target population with a single PZQ treatment resulted in an epidemiological impact where retreatment within two years would not be required for most of the country, except for high transmission foci. Thus while, the amount of PZQ required would be significant at the beginning of scale up, this demand for PZQ would not be open-ended, but would be reviewed in each endemic setting, after a few years of high coverage implementation. WHO East Mediterranean Regional Office (“EMRO”) intended to replicate the experiences and successes achieved in Egypt to Yemen , Sudan and Somalia.

4.2 Funding availability for PZQ[4]

If there is to be investment in quality production of PZQ active pharmaceutical ingredient ("API") and finished product, manufacturers need to be assured that there is an adequate market to support such investment. Therefore, in order to increase the probability of engaging manufacturers, UK Department of International Development ("DfID"), commissioned a study to make public a reliable estimate of likely demand, based on known donor financing[5] (see annex 3).

Analysis of the known donor financing for PZQ procurement and supply identified the Unites States Agency for International Development ("USAID"), DfID and Merck Serono as the major potential donors with some additional contributions from private donors and the World Bank ("WB"). Other than Egypt, Brazil and China, governments do not generally fund their own PZQ for public health use.

There was confirmation of USAID's increased interest on NTDs with USD$ 65 million per year pledged for U:S. Fiscal year 2010 for NTD control. USAID support for NTD control is expected to continue from 2011 - 2014, however it should be noted that US funds are appropriated on an annual basis and subject to approval by the US Congress each year. Based on the current USAID NTD programme and assuming current global funding sources for drugs, it is estimated that the proportion of funding that will be allocated to ensuring an adequate drug supply will likely be 15% - 20% of the overall USAID's NTD Initiative. Based on the FY2010 budget level of $65 million it is estimated that approximately $9.75 - $13 million will be allocated to drug supply. Praziquantel will likely comprise the majority of this expenditure. Assuming 85% of drug supply expenditures would go towards PZQ purchase, between $8.29 and $11 million USD annually would be available for PZQ purchase, equating to 104 and 138 million tablets annually. USAID's fiscal year 2010 funding of $65 million will likely become available in October 2010. Therefore 2010 procurement levels – estimated below and marked with an asterisk - have been adjusted and represent only a slight increase on current procurement levels. USAID support is based on need, therefore the level of funding for PZQ will vary based on epidemiology and funding gaps.

For the same time period, 2010-2014, DfID, has also pledged USD$3.2 million, which will allow purchase of 40 million PZQ tablets, per year. Historical data shows that other funding sources support purchases of an additional 10 million PZQ tablets per year. With the Merck Serono donation of 20 million PZQ tablets per year, the total pledged amount of PZQ is approximately 208 million tablets per year. See table 2 for summary.