Government, civil society and WHO partnership: A catalyst for better access to medicines

The case of the WHO-HAI Africa Regional Collaboration for Action on Essential Medicines

Nel Druce

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1 Summary

Lack of affordable and quality medicines, and other essential health commodities, is a significant barrier to achieving the health MDGs. WHO estimates that one in three people do not have regular and affordable access to essential medicines[1].

Government and partners, including civil society, share major objectives in improving this situation, such as ensuring an affordable and sustainable supply, improving accountability and transparency, and communicating better with consumers. But collaborative working in the pharmaceutical sector is challenging, particularly in countries where civil society is young and there is limited experience of government-civil society engagement in policy processes.

This paper describes an innovative and effective approach to collaborative working developed over the last five years in Ghana, Kenya and Uganda. HAI (Health Action International) Africa, the Africa region's civil society network for action on access to essential medicines, has been working in new ways with ministries of health, through national partnerships facilitated with the support of the World Health Organization[2]. The flexible approach of the funder, DFID UK, in providing complementary but separate funding streams to WHO and HAI Africa, has enabled the partners to develop these new and productive ways of working together.

Prior to the Collaboration project, there was limited history of joint working between government and civil society on medicines in the three countries. The partnership has provided a new and unique space for dialogue and collaborative activities to help meet national priorities in improving access to quality medicines. It has helped to change attitudes and introduce new working approaches for both civil society and government in the pharmaceutical sub sector. Through its facilitatory role and the technical expertise provided by the WHO National Medicines Advisers, WHO has helped to broker civil society's contribution as a respected and strategic partner in policy making and implementation processes related to essential medicines.

The partners, ministries of health, HAI Africa and WHO, are effectively managing a co-ordinated approach to achieve shared and complex policy goals, in for example, protecting public health safeguards in new trade laws in Kenya and Uganda, and removing taxes and tariffs on selected essential medicines and raw materials in Ghana. This is being achieved through a complementary mix of approaches: collaborative research, civil society advocacy and campaigning, parliamentary lobbying, and policy dialogue with government ministries for health, trade and justice.

Working together has produced a substantial, independent and robust evidence base on the availability, affordability and pricing of medicines across the countries' public, not for profit and private sectors. Assessment of the pharmaceutical sector in these three countries was carried out at the start of the project in 2002, using WHO tools. These assessments provided baseline information on the national pharmaceutical sector and policies on areas such as rational use, quality, availability and affordability of medicines). Since then, WHO and HAI Africa have facilitated new initiatives in medicines pricing research, such as national surveys and regular monitoring; and supported regional consultations for sharing results and defining policy and advocacy interventions, including a meeting in 2007 for members of the East African

[1] The World Medicines Situation, WHO 2004

[2] In 2001, the WHO-HAI Africa Regional Collaboration for Action on Essential Medicines was formed with DFID funding. The Collaboration is nested within separate HAI Africa and WHO programmes, which respectively support civil society development and medicines advocacy, and a network of WHO Medicines Advisers (National Professional Officers, NPOs), which now covers 18 countries in Africa. This paper is based on a participatory and qualitative review commissioned by partners in 2007/8, and draws on information gathered from over 70 structured interviews with partners and stakeholders at country, regional and global levels.

Community on the alignment of policy recommendations for improving medicines affordability.

Led by the government partner, with WHO and HAI Africa, the partners are also working with other national stakeholders to generate timely and policy-relevant research with direct relevance to policy makers. For example, In Kenya, the partners supported the national regulatory agency and the malaria programme in surveying the anti-malarial market, to assist the implementation of the new antimalarial treatment policy and the withdrawal of unregistered and poor quality products. In Uganda, the medicines pricing research methods have been adapted to provide a baseline for the pilot of the new global antimalarial subsidy. In Ghana, the partners have worked with the National Health Insurance Authority to provide data for setting the reimbursement prices of essential medicines for all accredited providers in the new insurance system. As a civil society member in Ghana commented, *'The Collaboration is a good catalyst – working for change without being seen'.*

The review resulted in eight recommendations, which focus on increasing impact through seeking greater institutional relevance and sustainability, on enhancing effective communications and working with a wider group of stakeholders in both civil society and government, and on a range of approaches for taking collaborative activities forward in different country contexts.

2 The context – opportunities and challenges for partnership

The collaboration between ministries of health, HAI Africa and WHO has developed during a period of significant change in both national and global health arenas. Medicines policy and access have become more prominent as, for example, developing countries comply with the World Trade Organisation's requirements for trade legislation and the implications for public health. Funding to the health sector has increased dramatically, especially through the global health partnerships, for essential medicines and other commodities for AIDS, TB, malaria and immunisation.

However, support to targeted programmes contributed to some fragmentation and duplication in the health sector. Following the 2005 Paris Declaration for Aid Effectiveness, the new International Health Partnership and related initiatives (IHP+) seek to foster harmonisation by development partners, and greater alignment with national priorities and plans. There is growing emphasis on strengthening the health system, which includes issues such as the financing and supply of essential medicines and other health commodities, human resources development, and improved transparency and good governance.

There is increased commitment to the involvement of all stakeholders, including civil society in poverty reduction, in health sector governance and policy dialogue. This is highlighted in, for example, the Ouagadougou Declaration on primary health care and health systems in April 2008, and in the IHP+. These commitments provide a more favourable environment for stronger MOH and civil society partnerships, and also for WHO's role in advice and guidance on these issues. However, civil society continues to face many challenges in terms of capacity and resources. NGOs must both develop competence and be recognised as strategic partners in policy dialogue processes as well as in service delivery.

Multi-stakeholder working is also central to the new Medicines Transparency Alliance (MeTA) launched in 2008 by DFID and multilateral, civil society and private sector partners. MeTA supports increased transparency and accountability in the medicines supply chain. Pilot activities are taking place in seven countries including Ghana and Uganda, where partners' experience of the Collaboration is already contributing to planning for MeTA as a country led initiative.

3 Developing good practice in multistakeholder working

The achievements of the partners have been enabled by effective working processes and structures, which build on – and are greatly facilitated by – the established relationships between ministries of health and WHO. Collaboration partners typically include the MOH lead (the chief pharmacist or essential medicines programme manager), the WHO Medicines Adviser and the HAI Africa member, and other partners, depending on country context and planned activities.

In each country, Country Working Groups – informal groups involving the three lead partners - have been set up with terms of reference that define partner roles, responsibilities and expectations. For example, Ghana's terms of reference acknowledge the existence of 'different interests among the diverse stakeholders', but emphasise 'that all are working to the same objectives', and 'the benefit of harmonising strategies and action plans'. Both WHO and the HAI Africa partner have independent budget lines which have contributed to the partnership's ability to deliver results. In Uganda and Ghana, HAI members developed increasingly independent capacity as civil society groups, with the support of HAI Africa's regional office in Kenya.

Co-ordinated by the MOH in each country, the Working Groups develop annual joint work plans based on priorities in the national strategic and annual plans for the pharmaceutical sub-sector. These issues include national medicines policies, drug pricing and availability, rational medicines use and protecting public health safeguards in trade legislation. Criteria are used to determine where collaborative activities can best contribute, focusing on the added value brought by civil society and WHO's involvement.

Technical support to country and regional activities is provided by the WHO Medicines Adviser, in liaison with WHO Geneva and WHO AFRO, and HAI Africa. The Collaborative work at country level is backed-up by the project's management group which has enabled synergies and learning between national, regional and global levels. The flexible approach of the funder, DFID UK, in providing complementary but separate funding streams to WHO and HAI Africa, has helped the partners to develop these new and productive ways of working together.

4 Achieving results in research and policy

Working together, the partners have an impressive track record of research outputs, and activities to support medicines policy development and to monitor implementation. Table 1 provides a full summary, to complement the examples below.

4.1 A robust and independent evidence base

The emphasis has been on research and data generation, with significant achievements in generating a high quality and independent evidence base on drug pricing, affordability, availability, and rational use, all essential for developing and implementing national pharmaceutical policy. Uniquely, the research provides comparable data across public, faith based and private sectors, which enables consideration of factors affecting prices and availability across the market and across the three countries surveyed.

Data generation and analysis activities include:

- joint assessment of the baseline pharmaceutical situation (2002);
- pricing, availability and affordability surveys (2004);
- medicines pricing monitoring (2005-ongoing)
- monitoring information for technical audiences, such as national disease and reproductive health programme staff, and NGOs (2006 – ongoing);

- pricing components surveys (2007)
- assessment of pharmaceutical situation and house hold surveys (2008)

The three countries were among the first to join the WHO/HAI Pricing Project, which has supported pricing surveys in over 50 countries since 2001[3]. With support from WHO and HAI Africa, the partners have adapted and improved the survey methodology and tools for wider use. In each country, the partnerships have enabled more rapid and timely data collection, analysis and dissemination of survey results. WHO methodology and tools were also used for baseline surveys (2002) and for the updated assessment of the pharmaceutical situation and household surveys (during 2008).

The various training sessions and workshops organized by WHO and HAI Africa as part of the 2002 baseline assessments of the pharmaceutical situation and the pricing surveys in 2004 helped build capacity in data collection and monitoring in countries. They also, importantly, created a shared understanding of the situation and priorities for collaborative work plans, and provided a platform for early dialogue and development of mutual respect and trust.

The three countries have also been among the first to implement regular monitoring of medicines price, affordability and availability, a key recommendation of the pricing surveys. In each country HAI Africa has taken significant responsibility for the implementation of the surveys, WHO has contributed technical inputs, and facilitated linkages with other health sector initiatives and programmes, and the MOH has provided the authority to carry out the activities within the public health system. Progress has been made in institutionalising the process, especially in Kenya, where the Pharmacy Division is taking on the management of the monitoring, while HAI Africa and WHO will provide independent technical review, and HAI Africa is leading on dissemination to consumers.

4.2 Impact on national policy, regulation and legislation

Partners are effectively managing a co-ordinated approach to achieve shared and complex policy goals through separate and joint actions. They are drawing on the evidence base - robust, timely and independent datasets produced through multi stakeholder processes – which has direct relevance to policy makers.

Including consumer interests in national medicines policy

Kenya's revised national medicines policy represents a substantial development from the first policy, published in 1994, and reflects wider trends in the pharmaceutical sub-sector and linkages with other health and development policies. Importantly, it emphasises enhancing collaboration with other sectors and with partners, including civil society. It also includes a full role for consumers, both in representation and ensuring accountability in the system, and as purchasers and users of medicines. One of its overarching objectives is improving the appropriate use of medicines.

The new policy was developed through a highly participatory and consultative process. A technical working group of the MoH undertook the first stages, with representatives of various MOH departments, health institutions, as well as the private sector, training institutions, professional associations, and civil society. WHO has been closely involved in this process through WHO Country Office. In addition, specific technical expertise on medicines policies issues was provided from HQ. The Collaboration process – which involved detailed discussion and review with civil society - helped ensure that civil society was fully engaged and that consumer

[3] http://www.haiweb.org/

interests were well represented. As a MOH official commented, '*The chances of implementing the new policy are much greater now with stakeholder consensus.'*

Protecting public health safeguards in new trade legislation

The inclusion of public health safeguards in trade and intellectual property rights legislation is critical to affordable access. In both Uganda and Kenya, the Collaboration has helped partners to develop a strategic approach that draws on the partners' comparative advantages for mobilising civil society advocacy and campaigning, for well informed inter-ministry dialogue and representations by the MOH, and for parliamentary lobbying.

Kenya's Industrial Property Act 2001 complies with international regulations for the protection of intellectual property rights (TRIPS), which enable the use of public health safeguards such as compulsory licensing and parallel importation of medicines. HAI Africa and other civil society groups were engaged in its original development. Collaborative efforts by the partners have helped to prevent the introduction of amendments that would remove the potential to use some TRIPS flexibilities in the Act.

Activities include a multi-disciplinary advisory group and taskforce for intellectual property rights and health, set up by the MOH, and continued high level dialogue with ministry of trade and the attorney general. Government efforts have been complemented by advocacy and campaigning by HAI Africa working with its NGO partners, such as the United Civil Society Coalition on AIDS, TB & Malaria, which mobilised over 800 people to demonstrate outside Parliament in 2006.

Collaboration partners continue to closely monitor the legislative process to ensure that any further amendments can be effectively rejected. Kenya's regional expertise in intellectual property rights and health issues continues to be demonstrated through the high profile of MOH officials and civil society in regional fora (such as the various regional meetings for IGWG, the Inter-Governmental Working Group on Public Health, Innovation and Intellectual Property). HAI Africa has also provided technical backup and the resources to help establish a pan-African civil society coalition on IGWG.

Reducing taxes and tariffs on essential medicines

In Ghana, taxes and tariffs have long been recognised as a contributor to high medicines prices and low affordability. The Collaboration's 2004 pricing survey provided valuable evidence to demonstrate that import duties, and taxes and tariffs such as VAT contribute 30 to 40% of consumer prices.

Sixty-six medicines on the essential drugs list and some raw materials were exempted from tax in 2002. However, the 2007 national budget threatened once again to re-introduce taxes and tariffs on the raw materials and products already exempted.

Collaboration efforts, again effectively combining civil society lobbying and inter-ministry representations, using the existing high level multistakeholder ATM Advisory Group as a platform, have contributed to reducing the burden. Civil society, with support from WHO, developed briefings and advocacy with parliamentarians, and there was publicity in the media. The issue was taken up by Parliamentary Select Committee for Health. The issue was discussed by the MOH at the ATM Advisory Group, and appropriate representation made to ministries of trade and the customs and excise authority. Mobilisation of other stakeholders included the Ghana Manufacturers Association.

The Government agreed not to add to the tax burden on essential medicines and raw materials, and to zero rate the 66 exempted products, which protects them from all duties and taxes. Furthermore, it also agreed to remove taxes and tariffs on all APIs, including VAT, and on further medicines in all sectors.

4.3 Making the most of opportunities for research-policy linkages

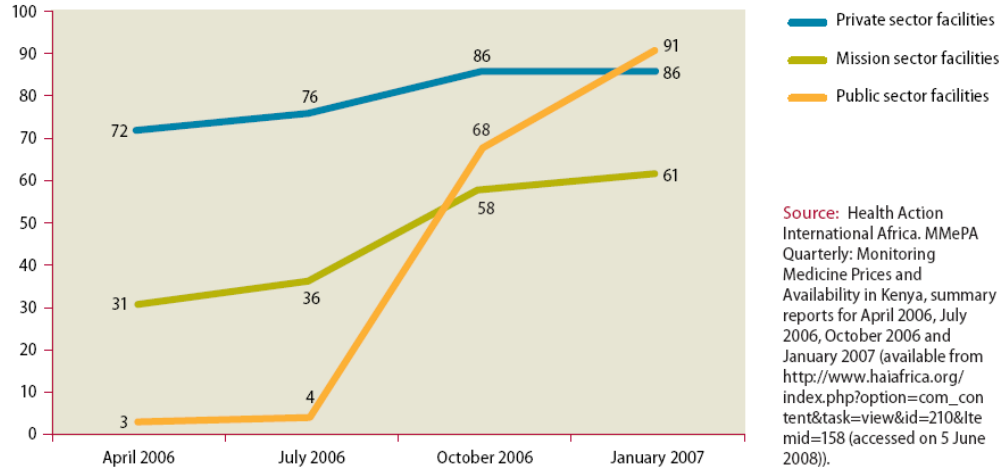
Collaboration partners are increasingly working with other stakeholders to generate timely and high quality research, which is having a direct impact on policy. Involving decision makers as advisers in the research process through multistakeholder working is a key factor in ensuring that the data is perceived as relevant, and hence used by them in developing and implementing policy.

Supporting implementation of the new antimalarial policy, Kenya 2006/7

Kenya introduced new malaria treatment guidelines for combination therapy in 2006. However, knowledge of existing malaria medicines in the market was limited. Before scaling up public sector distribution, the regulatory agency, (the Pharmacy and Poisons Board), with the Divisions of Malaria Control and Pharmacy, carried out an extensive survey in eight regions, to collect data on the range, registration status and quality of antimalarial medicines available from public and mission facilities, and from formal and informal sector retail outlets. Data on availability was already available from the regular monitoring carried out by the Collaborative partners, which showed that the newly introduced combination therapy was increasingly available in facilities.

The multistakeholder approach bought credibility as well as technical know-how to the results and their dissemination. The survey was initiated through linkages made by WHO, including funding from a DFID-funded malaria project. The advisory group was a multi-stakeholder one, including the MOH, WHO, Management Sciences for Health, and HAI Africa. WHO and HAI Africa supported the Pharmacy and Poisons Board to develop the survey methodology, drawing on their respective expertise. WHO advised on the quality control aspects, and facilitated linkages with a WHO pre-qualified laboratory for sample testing.

Availability of artemether/lumefantrine 20/120 mg in Kenya, April 2006–January 2007 (*percentage*)



Source: Health Action International Africa. MMePA Quarterly: Monitoring Medicine Prices and Availability in Kenya, summary reports for April 2006, July 2006, October 2006 and January 2007 (available from http://www.haiafrica.org/index.php?option=com_content&task=view&id=210&Itemid=158 (accessed on 5 June 2008)).

Source: MDG Gap Task Force Report, MDG 8: Delivering the Global Partnership for Achieving the MDGs, 2008

A large proportion of the medicines (over 40%), most of which were from Kenya and India, were not registered in the country. Almost 20% of the medicines analysed failed quality tests, raising concern of treatment outcomes and possible development of drug resistance. The Board has already initiated the phase-out of non-complying

imported and locally produced products, and artemisinin monotherapies are being withdrawn from public and mission sector pipelines.

Developing drug pricing guidelines, Ghana National Health Insurance Authority 2007

The Collaboration partners have adapted the WHO/HAI pricing survey methodology with the Ghana National Health Insurance Authority (NHIA) to establish standard price reimbursement to all accredited providers. These include the Ghana Health Service, the mission sector and over 600 private facilities. The survey was carried out in 2007, in all five regions and for the full 500 products on the NHIA Medicines List.

The survey was overseen by a technical advisory group set up by the NHIA, which included the national programme manager and the WHO Medicines Adviser, and was carried out by HAI Africa's partner, the Health Access Network. Stakeholders have agreed that the median price for the generic product (or the lowest priced innovator brand where there is no generic equivalent) across all three sectors should be the guide for reimbursement.

As a senior figure in the NHIA's Technical Group said, *'This was the only data source available across the public, mission and private sectors. Using the survey methodology from WHO and HAI Africa, and involving external experts in data collection and analysis, helped each sector to accept the results as independent and credible.'*

Piloting the new subsidy for anti-malarial medicines, Uganda 2007

Uganda has agreed to be a pilot for the new global subsidy for the costly combination therapies for malaria, through a partnership with the national MOH Malaria Control Programme and the Medicines for Malaria Venture. The initiative aims to subsidise the purchase of combination treatments from pre-qualified suppliers, thereby reducing the prices of new antimalarials to consumers, especially in the private sector, where many seek treatment.

In order to inform the subsidy pilot with baseline information, the pricing survey approach was used to analyse the antimalarial medicines market in six districts of Uganda. The tripartite Country Working Group partnership was extended for this work beyond the MOH Pharmacy Division to include the Malaria Control Programme at the MOH and National Drug Authority, working with WHO medicines and malaria advisers. HAI Africa's member, HEPS Uganda, was a key strategic and implementing partner based on its expertise in measuring medicine prices in collaboration with WHO and the MOH.

A key finding was the low availability of combination therapies in the private sector compared to the public and mission sectors, which has implications for access strategies. A future role for the partners is likely, once the subsidy is introduced, to monitor price and availability changes. Civil society could also have a part to play in advocating for and monitoring compliance by providers.

5 Added value of the Collaboration

Prior to the Collaboration project, there was limited history of joint working between government and civil society on medicines. The added value of the Collaboration is mainly in terms of process benefits – but without these, the results described above would have been unlikely. In each country, the partnership is viewed by the partners and other stakeholders in government and civil society as providing a new and unique space for dialogue and collaborative activities. This mechanism has helped to change attitudes and introduce new working approaches for the government, civil society and WHO, in the pharmaceutical subsector.

The qualitative review in 2008 found that the Collaboration project has generated added value in three main areas in this sector: 1) a space to generate synergies, among stakeholders with diverse interests and expertise for fulfilling national medicines policy needs; 2) an enabling mechanism for the MOH and civil society to increase mutual trust and respect and to engage as strategic partners in policy processes; and 3) a process for consultative, policy-relevant research that directly involves decision makers, meets country needs and increases the likelihood of policy implementation.

1) A space to generate synergies among stakeholders with diverse interests and expertise for fulfilling national medicines policy needs

The approach has created the stimulus and provided resources for joint work, drawing on the existing effective partnership of WHO and ministries of health, and the regional and global reputations of WHO and HAI Africa. The Collaboration partners, especially at national level, appreciate the space provided by the project to learn from different perspectives and expertise – which has enriched the Collaboration's outputs in terms of relevance, quality and efficiency. The approach also brings in the private and faith based sectors, which are key players in the health system, but have been little involved in joint initiatives in this area, and for which there has been comparable data on medicines availability and pricing.

The Collaboration has contributed to building MOH capacity and profile, by for example, enabling MOHs to generate and analyse evidence for policy making and produce credible reports such as on medicines pricing for consumers across the sectors, providing information which does not otherwise exist. This is most developed in Kenya, where an institutionalized system is in now place within the MOH for monitoring medicines availability and pricing, with trained data collectors and national technical expertise. The multistakeholder way of working of the Collaboration has also provided a platform for engaging further partners, such as the Medicines for Malaria Venture, Ghana's National Health Insurance Authority, and national disease programmes (in Kenya and Uganda).

'Each member brings benefits, enabling skills transfers, and better understanding of each other's roles and strengths. The Collaboration is working because we have defined the rules of engagement in our terms of reference, and we have respect for what each partner stands for. We have a joint workplan, coordinated by the MOH, but each partner leads on deliverables that we can jointly own.'
MOH, Ghana

'WHO brings the normative role, HAI Africa the consumer perspectives, and the MOH the mandate and authority to get things moving. The combination increases credibility and the chances of making things work better.'
MOH, Kenya

2) An enabling mechanism for the MOH and civil society to increase mutual trust and respect and to engage as strategic partners in policy processes

Civil society has an established role in service delivery in the three countries, but has been less involved as a working partner in policy development and implementation processes. The Collaboration model has helped to legitimise civil society's contribution, and mitigated the sometimes negative perceptions of government by providing a concrete platform for coming together and developing trust and mutual respect. It has enabled greater recognition of the constructive contribution that can be played by well informed and competent civil society groups in the policy process. The Collaboration has also provided an opportunity for ministry officials to fulfil health policy commitments to strengthen engagement with civil society and develop partnerships.

WHO, and the WHO Medicines Advisers, have played an important brokering role. Although some civil society groups do engage at a policy level with ministries of health, involvement as a strategic partner in joint activities would have been less likely without this contribution.

The impact of the project on civil society capacity to address medicines issues is also significant. In all three countries, HAI Africa/its member works with other NGOs, is recognised by them as an effective lead on access to medicines issues with the MOH, and is able to muster effective campaigning support for specific issues. Activities implemented through the project have enabled civil society to be fully involved and for consumer interests to be better represented in pharmaceutical policy.

'Government cannot be the activist – civil society can have a free hand. We need their independent point of view, based on evidence, including Collaboration outputs.'
MOH, Uganda

'We are now part of the process – we no longer have to lobby at the door.'
Civil society, Uganda

'As part of the sector wide approach, the government has committed to involving relevant stakeholders in policy and implementation – we are expected to do this. The work with HAI Africa reflects this commitment in the pharmaceutical sector.'
MOH, Kenya

'The Collaboration has proved to be an opportunity to look at how partnerships work – to move from policy commitments to working in a public-private partnership in practice. We had limited experience before, but now such partnerships feel doable. This is a best practice to build on as a doable thing and can be replicated.'
MOH, Ghana

3) A process for consultative, policy-relevant research to meet country needs and increase the likelihood of policy implementation

The combined efforts of the three partners to produce jointly owned research, under the banner of the MOH, technically supported by WHO, and with full engagement of an independent civil society group, enables more robust and reliable data. The joint approach brings greater likelihood that research processes will be transparent, that results will be disseminated, and that stakeholder confidence will be greater, and therefore have more influence in the wider policy environment. Evidence suggests that getting research into policy and practice requires early engagement of policy makers in the research process. The Collaboration project has enabled this to happen by involving the policy makers from the initial priority setting stage through to research dissemination.

'I run one of the (private) community pharmacies surveyed for price and availability. Although I was initially concerned about how the findings would be used, I was reassured by the involvement of civil society that it was a neutral and independent assessment.'
Representative, Pharmaceutical Society of Ghana

6 Lessons from experience

Government and civil society can face challenges in working together as strategic partners, especially where the latter may have limited experience of engagement in policy processes. There is much to learn from the partners' experience of collaborative working for partnership initiatives in the pharmaceutical sector (such as MeTA), and for the wider health sector.

6.1 Consider the benefits of starting small and informally

Limited engagement of civil society in policy dialogue is often accompanied by low levels of trust and confidence. Although there has been some linkages before the project, the informal and low profile mechanism provided by the Collaboration's country working groups enabled civil society, government officials and WHO to work together more intensively on specific outputs. The informal process has also helped champions in the MOH and WHO to promote the partnership in a non-threatening way.

This way of working is proving to be a stepping stone to more formal and sustainable engagement, in processes linked to sector policy, implementation and monitoring, where both government and civil society as a whole are keen to see higher levels of meaningful involvement. For example in Uganda, the civil society partner is now a member of the health sector's technical working group for medicines. In Kenya, the partnership serves as a core group, which informs a number of advisory groups to involve more stakeholders and wider consultation. It is important for partners to promote more formal recognition over time, to reduce the vulnerability of civil society to losing their new place in policy dialogue, as for example, personnel changes in the MOH or WHO.

6.2 Build national ownership through country-led institutional sustainability

New multistakeholder partnerships bring the risk of new donor-led and unsustainable parallel structures and processes. Partners keen to develop new ways of working need to ensure that these are appropriately linked to, or part of, existing structures and processes at both sector and sub-sector level.

In Kenya, although medicines pricing monitoring was led by WHO and HAI Africa, the MOH's Pharmacy Division has now institutionalized processes for data collection and analysis. This is an important step in ownership by the MOH. Transparency and quality of the data is assured through the multi-stakeholder advisory group for the monitoring activity. For the antimalarial monitoring, previous market assessments had been carried out by independent research groups, but the results had not been owned by government nor widely disseminated. Leadership by the government means key decisions and actions are collectively owned and there is enhanced awareness and confidence in the system.

6.3 Ensure that joint outputs respond to national needs and priorities

New approaches must also be, and perceived to be, highly relevant to national needs. In each country, the Collaboration partners had a shared vision and goals linked to the national pharmaceutical policy and strategic plan, and agreed their workplan priorities based on the plan. This included some quick and feasible wins, such as joint research and data generation, as part of an evidence based policy and advocacy approach, which both helped demonstrate the expertise of civil society and provide government with useful data.

However, it is equally important to identify ways in which activities such as medicines pricing monitoring can link with existing committees and advisory groups working on essential medicines and complement routine monitoring of essential medicines supply and broader evaluation needs of the health sector. The collaboration made its most effective contributions to policy processes when it was able to respond to specific needs of stakeholders through strategic linkages with influential stakeholders, such as national disease programmes and the regulatory and insurance authorities. This helped stakeholders appreciate the value of the new ways of working and the evidence based approach. Further opportunities are likely with regulatory and procurement agencies, especially for addressing price components

and mark-up practices, pooled procurement arrangements, registration, quality and other regulatory issues.

6.4 Strengthen credibility with global - regional – national linkages

Linkages between national, regional and global levels have enabled sharing and development of expertise and helped provide credibility at national level, especially for civil society.

The normative, technical and institutional support from WHO's global and regional technical advisors have helped to open the door for civil society to engage in policy level discussions with government officials. Committed and able medicines advisers in country offices have helped to broker new ways of working for senior government officials and civil society.

HAI Africa, as a regional organisation, (and its links with HAI Global), has been equally critical to the model's credibility, with the network's growing reputation in the region for professional expertise and its commitment to health and consumer rights. The Collaboration has contributed to the strengthening of HAI Africa as an increasingly effective regional network, one of the very few working on the broad ATM agenda, as opposed to HIV for example. In Uganda and Ghana, the Collaboration has helped HAI Africa members to develop independent capacity and good reputations for evidence based research and advocacy, while continuing to benefit from technical support from HAI Africa's secretariat.

A balance is needed between providing global and external support for quality and innovative approaches, with ensuring national ownership and sustainability, so that new ways of working and outputs respond to country led demands and add value to national processes.

6.5 Make enough time and resources for effective multistakeholder working

Partners report that it has taken several years to establish the level of trust and respect required to work effectively together. Prior to the project, there was little history of civil society, WHO and MOH working jointly on essential medicines issues at policy level. Previously negative attitudes were recounted by several interviewees.

Given these attitudes, there has been a major and rapid shift to a mature partnership, where, with MOH leadership, a division of labour coupled with joint ownership of outputs has been achieved. Effective working is linked to agreement on the goals, the joint diagnosis of the problem, the clear division of roles and responsibilities and the ability for civil society to make concrete contributions using independent funds.

6.6 Support civil society's contribution to policy processes

HAI Africa is one of the few civil society networks advocating for a holistic approach to access to medicines as a right to health and as an issue for systems strengthening, rather than a concern specific to HIV, for example. The technical input provided by HAI Africa to medicines policy issues has increased government's confidence that civil society can make a competent contribution to both research and policy processes. It is critical that HAI Africa continue to expand and strengthen its network in countries and establishes a sustainable strategy for resource mobilization and career development for its staff.

The separate HAI budget line has helped the civil society partner to make strategic and independent contributions to policy development and implementation, and to deliver planned activities. Development partners should consider how best to fund this role, and to develop the technical expertise needed.

Sustained and effective civil society involvement in policy dialogue continues to face challenges, and there has been limited support from external partners. However, in most countries, national policy, reinforced by regional governmental and UN declarations, enshrines commitments to government-civil society partnerships.

Support for multistakeholder working is needed from all levels within each agency, to ensure that staff at national level can deliver this function confidently and effectively. The partnership provides a model to support WHO's role in facilitating engagement between civil society and the MOH. As one WHO country representative commented, the project has been: *'a unique opportunity to bring together the key stakeholders – the MOH and people on the ground who can bring issues to the table. WHO plays a role to facilitate and broker partnerships – we must have the strength to bring them together and help the MOH to overcome any scepticism or suspicions.'*

7 Looking ahead

Collaboration partners are keen to address continuing access challenges in countries and intend to focus more on using the data for the development, implementation and monitoring of policy objectives and for advocacy and communications activities with a wider group of policy makers, civil society organisations and consumers. Further collaborative work is needed to develop national policy and advocacy frameworks and to strengthen systems to improve the availability and affordability of quality medicines and monitor their impact.

Promoting the rational use of medicines by both providers and consumers is another major component of improving access, and one where civil society can add much value. The Collaboration supported Kenya's effective sponsorship of the World Health Assembly's Resolution for the promotion of rational use in 2007. The resolution now provides an enabling policy environment for national decision makers to prioritise rational use.

Partners are also keen to further develop processes for multistakeholder working. For medicine price monitoring activities in 2006/07, for example, technical advisory groups variously include the public and faith based procurement bodies, regulatory and insurance agencies, the national pharmaceutical association, and academic groups. This, together with the various initiatives with the disease control programmes, has generated greater interest and ownership of the approach and its products.

The approach taken by partners will inform the development of MeTA. Both Uganda and Ghana are planning pilot activities as members of MeTA. Belief in the feasibility and value of the MeTA model in part derives from the successful ways of working and results demonstrated by the Collaboration partnership. The project has created the stimulus and provided a platform and resources for developing mutual respect and trust. However, the addition of new stakeholders through the more complex MeTA partnership will present challenges for governance, management and implementation roles.

In other countries, such as Malawi, Tanzania and Zambia, medicines pricing survey and/or monitoring work has been carried out using the same Collaboration model and mechanisms adapted to the country context. In non MeTA pilot countries, stakeholders might consider starting small and informally, to develop trust and ways of working, before involving more stakeholders. Zambia is the third African country to take part in the MeTA pilot, and WHO and HAI Africa are engaged in discussions on expanding the Collaboration model to a broader multistakeholder approach.

Table 1: Summary of Collaboration research, policy and advocacy outputs 2002 – 2007

WHO Medicines Strategy component*	Ghana	Kenya	Uganda
Policy - Implementation and monitoring of medicines policies			
Policies developed		*Developing the new National Pharmaceutical Policy, 2006/07* Kenya's revised national medicines policy represents a substantial development from the first National Drug Policy, published in 1994. The Collaboration helped ensure that civil society was fully engaged and that consumer interests are well represented.	
Policies monitored/ assessed	*National baseline pharmaceutical survey, 2002* Comprehensive assessments of pharmaceutical supply situation. Led by the ministries of health, supported by WHO medicines advisers, WHO AFRO and WHO Geneva. Undertaken prior to Collaboration's launch, HAI Africa and partners contributed to methods, data collection and research output, and contributed to timely publication. Recommendations informed national policy priorities and strategic plans, which in turn, have driven Collaboration priorities. Follow-up assessments undertaken in 2008.		
Public health safeguards in trade related legislation		*Protecting public health safeguards in Kenya's Industrial Property Act 2001, 2005-ongoing* Since 2005, the Collaboration has facilitated rejection by Parliament of TRIPS-plus amendments through a combination of civil society advocacy, parliamentary lobbying and expert intra-governmental communications. Kenya's growing regional expertise in health and intellectual property rights issues is demonstrated through the high profile of MOH officials, supported by civil society, in the IGWG and WHA resolution processes in 2007/8.	*Ongoing efforts to ensure inclusion of public health safeguards in Uganda's revised Industrial Property Bill*, a process which began in 2002 and is ongoing, with the new bill in process of enactment. The partners are co-ordinating civil society advocacy, parliamentary lobbying and expert intra-governmental communications
Access - Fair financing and affordability, and medicines supply systems			
Price information and monitoring	*National pricing, availability and affordability of medicines survey, 2004-05* The WHO/HAI Medicines Pricing Survey was an initiative of HAI Global and WHO. The 3 countries were among the first to undertake the survey, which also represents the first joint activity for the Collaboration, and the partners' experience in adapting and using the tools has informed the wider project. The medicines surveyed included a standardized core group of 30, and a supplementary group of about 20 medicines specific to each country, and included generic and innovator brands. Surveys took place in various regions in each country. Affordability, procurement price, price to patients and availability were measured, as relevant across public, private and faith based facilities. Two WHO supported workshops to facilitate follow-up on the survey findings by countries. One was held for several African countries in 2006 and one for East African Community members to support alignment of affordability recommendations in 2007. *Quarterly monitoring activities for price, affordability and availability, 2006/07- ongoing* WHO/HAI Global developed a methodology for monitoring prices, affordability and availability. Collaboration countries have been among first to implement. Uganda and Kenya have initiated and sustained monitoring over one year, with additional technical input from other stakeholder eg regulatory authority, medical stores and private sector pharmacists. Process is becoming institutionalised in Kenya (integrated into routine work of Pharmacy Division). Ghana has undertaken one monitoring activity but not published. Focus has been on generating good quality data and some dissemination through bulletins to policy makers and NGOs. Limited awareness-raising as yet among consumers.		

Pricing policies (including generic policies)	*Drug pricing guidelines for provider reimbursement, Ghana National Health Insurance Authority, 2007* Pricing survey methodology adapted by the Ghana National Health Insurance Authority to establish standard price reimbursement. Core Technical Group included national programme manager and WHO adviser, and survey was carried out by the HAI Africa member.		Pricing survey 2004 data has been used internally by the Pharmacy Division, to, for example, influence the MOH's stance on additional taxes on essential medicines when proposed in 2006, and internal negotiations on the public sector drug budget.
Other activities relevant to access	*Removal of selected taxes and tariffs, 2002-ongoing* 2004 pricing survey demonstrated contribution of taxes and tariffs to consumer prices. Partners advocated through ATM Advisory Group and Parliamentary Committees to zero rate already exempted products, and remove taxes from active pharmaceutical ingredients. Work is in progress to look at further zero-rating.		*Anti-malarial price and availability baseline survey, 2007* Uganda is a pilot for the new global ACT subsidy, through the MOH Malaria Control Programme partnership with the Medicines for Malaria Venture. The WHO/HAI Medicine Prices survey approach was used for a baseline assessment of the antimalarial medicines market in 6 districts of Uganda, working with the partners, the malaria programme and the regulatory authority.

Quality and safety - Regulation and quality assurance systems			
		Understanding the market for antimalarial medicines in Kenya, 2006/7 Kenya introduced new malaria treatment guidelines for combination therapy in 2006. With a multistakeholder advisory group, the regulatory authority and malaria programme adapted the WHO/HAI methodology to collect data on the range, registration status and quality of antimalarial medicines. The regulatory authority has initiated the phase-out of non-complying imported and locally produced products, and artemisinin monotherapies are being withdrawn from public and mission sector pipelines. This joint approach is also helping to strengthen the regulatory agency's function with programmes.	
Rational use - Rational use by health professionals and consumers			
	Promotion of rational use of medicine, Ghana 2006-ongoing Use of generics has been falling over time. Partners have developed two educational CD Roms and a video for TV distribution, and a radio series for broadcasting in all ten regions. Survey to assess consumer and provider attitudes 2006; Guidelines developed for RUM. Promotion strategy in development.	*Increasing global commitment to Rational Use of Medicines, Kenya 2007* Following the proposal for the RUM Resolution at WHA 2006, Kenya's MOH agreed to support the process, in particular through advocacy with the Africa Union health ministers. Collaboration partners to develop a briefing paper and advocacy strategy to build support in the AU meetings and the WHO Executive Board. *Promotion of rational use of medicine, 2006-ongoing* Developed National RUM Guidelines. Setting up National Pharmacy and Therapeutics Committee in process, together with hospital Diagnostic and Treatment Committee pilots.	*Promotion of rational use of medicine, Uganda 2005-ongoing* Developed National RUM Guidelines.

* Adapted from WHO Medicines Strategy 2004-2007 Components (omitting traditional medicines and global norms and standards)