TOWARDS A REGIONAL RESEARCH AGENDA ON PHARMACEUTICAL MANUFACTURING AND ACCESS TO MEDICINES IN SUB-SAHARAN AFRICA

FINAL TECHNICAL REPORT

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EXECUTIVE SUMMARY

The overall objective of this project was to define a regional research agenda geared towards understanding *"whether, and under what conditions and contexts can local pharmaceutical production lead to access to affordable, quality medicines while remaining competitive against cheap imports from international producers?"* To achieve this goal, the project had proposed the following specific objectives, methods and activities: (i) to conduct horizon scanning/scoping interviews with selected key informants to refine the key issues/questions of immediate concern to users/beneficiaries (ii) to conduct a systematic review of past and on-going research and identify research/knowledge gaps (iii) to identify funding agencies and research organizations supporting programmes on health innovation, access to medicines and local pharmaceutical production and map their priorities (by diseases, geographical localities, target groups etc) and (iv) to facilitate dialogues between national/regional Associations of Pharmaceutical Manufacturers, representatives of the African Union and three main RECs (EAC, ECOWAS and SADC) and research organizations and funding agencies to deliberate on the knowledge/research gaps identified under objective 2 (systematic review) and 3 (mapping); and propose a research agenda.

This final technical report provides (i) a review of the activities undertaken in the implementation of the project, achievements and challenges (ii) a reflection on the process and lessons learned including feedback/proposals for future projects and (iii) a summary of key project outputs, reports and publications.

PART 1: REVIEW OF KEY ACTIVITIES

Objective 1: Key Informant Interviews

At the conclusion of the project, we have interviewed some 45 key informants representing various organizational categories including the African Union Commission, the RECs (East African Community, SADC and ECOWAS); private sector representatives (individual companies); industry associations (such as FKPM, EAPM and FAPMA); international NGOs/Civil society actors; research organizations such as ANDI and UN bodies such as UNIDO, UNCTAD, WHO amongst others. The interviews were guided by an interview checklist. The interviews were audio-recorded and transcribed and thematic analysis applied to distil the key issues and gaps. The key issues and gaps formed the basis of further stakeholder discussions and literature review to refine the proposed agenda (*see attached agenda document*).

Objective 2: Review of existing literature to identify knowledge/research gaps

Building on the key informant interviews in objective 1, the review under this objective focused on: understanding the international context, political economy; technology transfer; quality assurance and intellectual property rights. The outcome of these reviews provided the state-of-the-art regarding local pharmaceutical manufacturing in Africa. The reviews not only formed the foundation for the research agenda, but also guided in-depth interviews with key policy and practice actors.

Objective 3: Mapping of key organizations and funding agencies working in/supporting local pharmaceutical manufacturing including their focus and priorities

During the key informant interviews (objective 1) as well as the systematic review (objective 2), key organizations and their involvement in the pharmaceutical sector have been identified. The priorities, geographies and focus have been mapped. A report of this mapping exercise is attached. As part of a wider dissemination strategy, these maps will be used in infographics and blogs to highlight concentrations and gaps in the local pharma manufacturing sector

Objective 4: Facilitate dialogues towards a common research agenda based on issues/gaps identified through objectives 1 – 3

Regional workshops and conferences provided the platforms to further engage with key stakeholders and share out the evolving draft agenda. We received insightful comments and suggestions from participants in these conferences and broadened the range of stakeholders interviewed. A number of such workshops/seminars and conferences include:

a) 5th ANDI Stakeholder Meeting slated for November 23 – 25, 2015 at the United Nations Office in Nairobi (UNON)
b) 6th Pharmaceutical Manufacturing Plan for Africa Technical Committee Meeting 28-29 November 2015, Addis Ababa, Ethiopia.
c) WHO/NEPAD Scientific Conference, 30 Nov – 01 Dec, 2016 in Addis
d) Pharma East (24 – 25 February, 2016 in Nairobi, Kenya (*see pp. 17 of the attached report*)
e) NACOSTI National Science Week (May, 2016) (*See day 4, 19th May of* the *programme attached*)
f) Pharma West (September 2016, Lagos, Nigeria)

PART 2: REFLECTIONS ON THE IMPLEMENTATION PROCESS

Reflection Questions	*Explanation*
1. How has this phase of implementation differed from your expectations	What unexpected things happened? What was a surprise? Why do you think things developed as they did?

This phase included a no-cost extension of the project by six months. This was necessitated by the increasing interest of other stakeholders in the project and their need to be included in the remaining stages as well as begin a process of building strategies of engagement to advance the evolving agenda. Notable here was the keen interest from the African Union Commission (AUC) and the New Partnership for Africa's Development (NEPAD). Both are key to the pharmaceutical agenda both at the policy and technical levels: At the policy level, because of their continental mandate and convening powers, and at the technical level because they are officially mandated to oversee the implementation of the continent's pharmaceutical manufacturing roadmap, the Pharmaceutical Manufacturing Plan of Action (PMPA). The project also received a lot of interest and support from other regional bodies including in the research domain (ANDI); the Private Sector (FAPMA), UN Bodies (UNIDO) and Development partners/funders (GIZ).

This interest arose out of our deliberate efforts to reach out to, sensitize and engage with as many and diverse stakeholders during the implementation process. From the onset, we took every opportunity afforded by a gathering of relevant stakeholders to present the project, ask provocative questions, seek out new actors (who were not included in our initial lists).

Additionally, we received a lot of support from the IDRC team of Sue Godt and Ellie Osir, who not only shared valuable contacts, but also made the necessary introductions/connections to a wide variety of stakeholders. Sue and Ellie also shared with us critical information and literature on new reports, signaled us to upcoming meetings and events and occasionally arranged for meetings with high-level officers within and beyond IDRC.

2. In thinking about this project and your initial expectations, what do you think has gone well?	What happened? For what reason? Who/what factors contributed to the current state of affairs or influenced the results? What part did the evolving context play?

The interest and engagement with new actors with regional - and continental-level mandate is really exciting to us. The interest generated by this project and its key output, the continental research agenda, both at the African Union Commission (AUC) and NEPAD means it stands real chance of informing policy debates and dialogues at the regional (RECs) and continental (African Union) level. The inclusion of technical staff responsible for the implementation of the PMPA at the AUC (Janet Byaruhanga) and NEPAD (Margareth Sigonda) as co-authors of the agenda signals this keen interest and potential for on-going collaboration and partnership in taking forward the agenda.

Already, both AUC and NEPAD have indicated they will use this as the baseline report in drafting the continental health research agenda (especially in sections that deal with pharmaceuticals). The Scinnovent Centre is being considered for institutional membership of the working group (WG) to spearhead the continental health research agenda and discussions with NEPAD are on-going in this regard.

Reflection Questions	*Explanation*
	Secondly, the agenda has been embraced by major regional Networks including ANDI in the research domain and FAPMA on behalf of the private sector. The endorsement by the continental private sector association is particularly key. This is because ultimately, the research agenda must answer to the interests of the manufacturers. ANDI's support is equally very important because as a research network, they will pick up issues raised and incorporate in their programmes, but can also rally their stakeholders (mainly universities and research institutes across the continent) to accord attention to the issues covered in the agenda. Amongst the development partners, UNIDO and GIZ have been particularly excited and engaged with the project. To demonstrate their level of interest/involvement, their staff have participated in writing up the research agenda and both Dr. Wilberforce Wanyanga (a Kenyan National Pharmaceutical Expert on Local Manufacturing and Access to Medicines) and Mr. Wesley Ronoh (GIZ Policy Advisor for the East African Community) are co-authors of the report. Several factors have contributed to these developments but at least three key amongst them are timing, evolving international context/debates e.g. the TRIPs and disease outbreaks such as the ebola crisis in West Africa. (i) This project came at a time when the PMPA is celebrating its 10th anniversary (having been officially endorsed by the African Union in 2005 and implementation began in 2007). It was therefore a good time to take stock of achievements, implementation challenges and new emerging issues. At the same time some of the RECs were at the final stages of implementing their pharmaceutical manufacturing business plans and revising or developing new strategic plans. Stakeholders were eager to share their experiences on what works and what doesn't both at the policy as well as the actual operations. (ii) The Ebola outbreak in West Africa in 2014/2015 exposed the continent's unpreparedness and the fact that there was no vaccine and the slow nature of the response directed attention at the need to develop strategies for quicker and more coordinated response and the role that research and development (R&D) could play in enhancing the continent's capacity to respond to emergencies. (iii) At the international level, the TRIPS flexibilities (as they relate to pharma innovation and access to medicines) were coming to a close and the attention of developing countries drawn to the likely implications on access to medicines, particularly the manufacture of generics such as ARVs. Issues of intellectual property rights and trade, technology transfer and the flexibilities accorded to developing countries took centre stage at the WTO negotiations.
3. In thinking about this project, what challenges were confronted?	Why? How did you identify them? How were you able to resolve the difficulties? Who/what factors contributed to the current state of affairs or influenced the issues? What part did the evolving context play?
In this phase of the project, the implementation has been largely smooth albeit slower. This has arisen	

Reflection Questions	*Explanation*
out of two main issues: a) Slow bureaucratic approval processes at the regional bodies: Working with inter-governmental agencies such as AUC/NEPAD require strict adherence to procedures for approvals, some with defined timelines. These have caused delays in the calendar of activities as initially mapped out. Additionally, some of these agencies are thinly staffed and handle many responsibilities with frequent travels. These have further contributed to delays in finalizing activities that required approvals in one stage before the project could move to the next set of activities. b) The huge interest shown by various actors in the project was an exciting and positive development. However, it also meant more consultations and consensus building around the key issues. This lengthened time for decision making causing further delays. Expanding the list of contributors/authors to the report made for a wider appeal but managing the different viewpoints required more time to build consensus and ensure you carry everybody along.	
4. What would you do differently if you had to repeat the experience?	The aim is not to just draw out lessons but to find ways to apply the lessons. This could translate into identifying new activities or changes to the project in the future.
• We would pay closer attention to the procedures/modus operandi of key potential partners and engage more proactively at the proposal design stage. This is an important lesson from this project, particularly because despite identifying and supporting the issues raised in the agenda, two of the key new partners AUC and NEPAD are constrained to provide formal endorsement statements to include in the report because of procedural matters. Whereas they embrace and identify with the report (both Janet Byaruhanga (AUC) and Margareth Sigonda (NEPAD) are co-authors), for the CEO or other senior official to sign the endorsement letter then the process needs to have been approved within their (political) structures. We didn't see/know of this requirement at the initial stages. In future (and for other projects), these institutional procedures/constraints need to be taken into account when designing projects that would need their participation, endorsement or buy-in. • We would plan for more strategic, focused engagement with stakeholders, taking advantage of other planned initiatives. Our project design anticipated a big final meeting to endorse/validate the final outcome/report. Our experience has shown that regular engagement with stakeholders at other conferences/workshops/seminars with similar objectives/mandates accorded us the opportunity to meet more diverse stakeholders, present the various versions (at different stages/section) and obtain focused feedback (on specific issues rather than omnibus report). While it may not be possible to have a full calendar of activities/events that would happen during the life of the project, efforts should be made to map out key meetings/conferences planned during/coinciding with the life of the project and plan how to plug into them. • We would allocate some resources for "mobilizing political support". Engaging with regional political bodies is key to the acceptability and buy-in of the project's recommendations. Yet, winning this political support goes far beyond the technical implementation of the project and has cost implications. Face to face briefings, phone calls, attending specific meetings (even if only to show face as a demonstration of support of their initiatives, some of which may not be directly relevant – and therefore chargeable on the project – as well as honouring requests to make presentations at specific meetings organized by these bodies (sometimes at own expense) etc require that some resources are budgeted for these unforeseen activities.	

Reflection Questions	*Explanation*
5. Has the project added value to Scinnovent? How?	

This project has added value to the Scinnovent Centre in many fronts:

Participation in Committees/working groups in national/regional initiatives: Implementing this project has provided the platform for the Centre to showcase its work on health R&D/Innovation. As a result, the Centre is a member of the East Africa Community – Regional Manufacturing Plan of Action (EAC-RMPOA) coordinated by the Ministry of industrialization (Kenya), member the Steering Committee of Health R&D Policy Advocacy Coalition (CHREAD) which is a coalition of civil society organizations working to improve financing for health R&D and access to medicines. Scinnovent is leading the Policy and Regulation sub-committee.

New institutional collaborations, particularly the private sector: Beyond the institutional partnerships with PATH, CHREAD and the [1]Pan African Civil Society Platform on Access to Medicines (highlighted in the interim technical report), this phase has seen deepening partnerships with the private sector. For example, mediated by the Ministry of Industrialization (Kenya), Scinnovent is negotiating a memorandum of understanding with the Federation of Kenya Pharmaceutical Manufacturers (FKPM) to support their policy and advocacy activities. The scope of this support will entail conducting policy analyses and writing focused policy briefs and position papers on matters affecting pharmaceutical manufactures.

Enhanced human and institutional capacity at the Centre: Through this project, the Centre has expanded its footprint in the health innovation/access to medicines programmatic area. New publications, presentations at conferences, meeting new actors, engaging with thought leaders and advisors have contributed to institutional capacity strengthening. Our interactions and engagement of short-term consultants, our staff have gained valuable experience/skills by tapping into the specialized knowledge, leading to enhanced in-house capacity in health research.

6. How would you evaluate the role and engagement by IDRC in the project until the present?	What kind of engagement and support has there been from IDRC? Are you satisfied? Why? Why not?

We have received excellent support, advice and understanding from IDRC. Dr. Sue Godt and Prof. Ellie Osir have been on standby to provide advice, reviews, contacts and any other form of facilitation requested. The following examples would highlight this support:

- We have held regular review/update meetings with both Sue and Ellie and these helped to shape the project, address any emerging challenges and provide really useful feedback.

- Both Sue and Ellie reviewed draft documents, provided insights, suggested literature, new contacts and referrals that enriched the project. In effect, fitting more into the role of project advisors

- When other regional bodies began to express interest in being engaged in the project and we

[1] For more on this see Qn. 2(3)

Reflection Questions	*Explanation*
noticed this would affect the delivery time-table, we requested and were offered a no cost extension of the project, thanks to the understanding of both Sue and Ellie • Further, Sue Godt has been very instrumental in connecting us to other organizations, leading experts and key contacts in the health sector across Africa. We have gained so much from these introductions and beyond the support and responses to the subject matter of the project questions, new collaborations have emerged as a result. • Finally, the IDRC library and database has been such a resource in this project and providing the project team access has been extremely useful.	
7. Highlight any specific issues around the administration and management of the project.	
• The admin team at IDRC, particularly Joyce Wairimu (and later Imelda Wasike), were extremely supportive and helpful in working through the administrative issues of the project, including budgets, contracts etc. • The program management team at IDRC (Sue Godt and Ellie Osir) provided the intellectual guidance and support that have immensely benefitted the project.	
8. To conclude, do you have any other comments to make?	This is an opportunity to discuss any aspect you think is important and that you haven't been able to raise when answering the other questions.
Our conclusion revolves around the next steps in this project. **a) Follow-on programmes/projects: what next?** Setting the agenda is only part of the journey. Now that most of the actors are embracing the agenda, the bigger question is what next? How could/should we catalyze the actual implementation of the agenda (even if parts of it) and what role could IDRC play in this regard? While the agenda is designed as "an open menu" with different actors being encouraged to pick and choose which sections/issues are of interest to them, IDRC's support to at least one of the themes would send strong signals to other partners/funders. Already, AUC/NEPAD have indicated interest in discussing ways of taking forward the agenda and Scinnovent is in discussions with them in this regard. We'd be glad to bring these discussions to IDRC's doorstep and jointly explore areas that might be of interest to IDRC and possibly how IDRC could assist rally other partners/funders around the agenda. **b) Influencing regional/continental policy processes** Having been embraced by the regional bodies (particularly AUC/NEPAD/ANDI and FAPMA), this project has real chances of informing policy debates and processes at the regional/continental levels. However, the policy space is congested with many vested interests and ensuring effective influence will need some push. While we expect AUC/NEPAD and other agencies to take leadership in pushing forward the agenda, there's room for IDRC (and Scinnovent) to remain engaged. For example, NEPAD is considering drafting Scinnovent into a *technical working group* mandated to develop a continental health R&D strategy and have indicated they would like to use the report and agenda as their starting point in the pharmaceutical sector. Regional economic communities (RECs) are either revising their pharmaceutical business plans or developing new ones altogether. These processes provide opportunities for influence. This will depend on available resources and current IDRC programmatic focus and we welcome the opportunity to discuss further.	

PART 3: RESEARCH OUTPUTS, REPORTS AND PUBLICATIONS

The following publications are attached as annexes to this report:

1. Pharmaceutical Manufacturing in Africa: *A research agenda towards competitiveness and social inclusion.* This is the main output of this project

2. Pharmaceutical Manufacturing in Africa*: Knowledge gaps and emerging research issues.* This is a high-level, abridged version of the agenda (A5) for the quick reader.

3. Technical Briefing Note 1: Incentivising African Pharmaceutical Manufacturing: *Policies for sustaining the take-off*