

Public-Private Dialogue

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Pharmaceuticals sector:

Tunisia's sector competitiveness enhancement through PPDs

by

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1- Background and Context

The Competitive Industries and Innovation Program (CIIP) - launched in 2013 in partnership with the Tunisian government - aims to identify and help strengthen promising clusters in Tunisia based on cross-sectoral diagnostics and extensive public-private dialogue (PPD). The program will unleash private sector growth and fulfill the country's pressing need for more jobs, this will be done over 3 stages: (i) sector diagnostics and prioritization of binding constraints on sector competitiveness, (ii) elaboration of sector specific action-plans and (iii) establishing implementation mechanisms. CIIP's 4 pilot sectors are: Electronic components, Pharmaceuticals, Garments, and IT service.

The diagnostics and PPDs helped prioritize binding constraints and propose policy recommendations based on a technically informed participatory process. This ensured a large buy-in among stakeholders and built consensus behind reforms needed to tackle the most binding constraints on competitiveness and growth.

Pharmaceuticals were amongst the included sectors in CIIP's pilots because it's one of Tunisia's most promising sectors. Manufacturing of human drugs (generics and subcontracting) represents a market of about 1.8 billion DTN in Tunisia, with a 15% growth rate per year on average in the past decade. Local production now accounts for 49% of the local market needs (2012), but only 6% was exported in 2010. Although the sector only employs 6,000 people, 38% of the jobs are highly skilled (pharmacists (11%), but also doctors, engineers and veterinarians. (*Source: World Bank Report - Human Medicine Cluster Diagnostic in Tunisia, 2014*).

2- Youth and Inclusion dimension

The sector has a relatively young workforce distributed as follows: 40% is qualified or highly qualified, while 60% are not qualified workers (factories). The growth of the sector will participate in offering interesting career perspective to highly qualified youth that would otherwise immigrate to other countries where pharmacists and scientists are also in demand.

3- Partnership, Structure and Processes

Main entities involved in the PPD process

The project, facilitated by the MENA T&C team, works with a number of ministries, public institutions and professional associations in the sector:

- Ministry of Health
- Ministry of Industry & Trade
- Department of Pharmacy and Medicine (DPM)
- National Drug Control Laboratory (LNCM)
- Department of Pharmaceutical Inspection (DIP)
- Central Pharmacy of Tunisia (PCT)
- National Health Insurance (CNAM)
- Pharmacovigilance National Center (PVNC)
- National Council of Pharmacists (CNOPT)
- National Chamber of Pharmaceutical Industry – *local manufacturers* (CNIP)
- Association of Pharmaceutical companies of Innovation and Research - *multinationals* (SEPHIRE)
- Experts of Scientific & Technical Committees

Sector diagnostics and Prioritization of binding constraints on sector competitiveness

In the pharmaceutical sector, the first phase of the project identified and prioritized the following bidding constraints:

- Inefficient and unclear pricing procedures, with significant distortive impacts on the trade of Tunisian pharmaceutical products
- Extremely long delays (up to 2 years) in delivering marketing authorizations (MA)
- Market distortions and barriers to entry (often in favor of imported products) resulting from some procurement procedures of the Pharmacie Centrale de Tunisie (PCT- sole public purchaser of medicine), eventually deterring investment in R&D and innovation
- Restriction on clinical trials regulation that needs to be updated to international standards

Elaboration of Sector Specific Action-plans

The second component consists of elaborating action-plans to tackle the binding constraints, providing a cost-benefit analysis of potential measures when possible. This component is organized on two levels:

- **Focused Working Groups:** gathering key actors in small working groups to address specific topics in order to ensure productivity and propose draft action-plans to be approved from the project steering committee led by the Ministry of Health (and including the Ministry of Industry and Commerce). Five specific PPF working groups have been organized on the following topic:
 - Modernization of the pharma-economic governance
 - Optimization of the Marketing authorization procedure
 - Efficiency of the public drug procurement system and the impact on investment in innovation

- Promotion of external demand and regional integration in Maghreb and French Speaking Africa; improvement of regulatory aspects to facilitate exports
- Development of clinical trials and research
- **Interactive PPD workshops:** all actors are invited to the project’s PPD workshops in order to provide their feedback on short-term action plans proposed by smaller groups and participate in the proposal of guidelines for the mid-term reforms (which in case of the pharmaceutical sector; would take place in the context of the creation of a National Drug Agency)

4- Results so far

After 54 moderated public private workshops/meetings to develop solutions and prepare reforms, the PPD lead to the achievement of tangible outcomes on the short term that significantly improve the business / investments climate:

- In January 2016, the administrative reform of the Marketing Authorization (MA) process have led to the reduction of the delays of the Medical appraisal review (a necessary step to put a product on the market) by more than 70%: from 2.5-3 years in 2013 to 12-9 months in 2017. This was achieved through a deep-dive advisory that included the mapping of bottlenecks and identification of short term solutions, and subsequently the establishing of dedicated task force to treat the backlog of medical appraisal requests, the development of a digital monitoring system to insure timely monitoring, and the review of the process itself to remove outdated steps
- A decree modernizing the regulatory framework of clinical trials in Tunisia (October 2014). This was accompanied by an action plan for the development of clinical trials in Tunisia, and a participation in the World Economic Forum (January 2016) by the minister of health to promote investments in clinical trials.
- A market study that forecasts scenarios on pharmaceutical exports by 2030, enabling public and private actors to define a common vision, select export target markets and quantitatively assessment.

5- Expected Results

The implementation of planned or studied actions should lead to the following expected results:

- An achieved consensus on a key reform of the medical pricing process between the Ministry of Health, the Ministry of Industry & Trade, and the Ministry of Social Affairs. The reform leads to the establishment of a more transparent, efficient and inclusive process incorporated in a single “Medicine Price Committee”. The new single committee will replace the current redundant and fragmented process. This regulatory reform is currently being further articulated (decrees, operations manual for the Pricing committee, etc.) and expected by the end of 2017. It is crucial for the improvement of the investment and business climate, but also has a direct effect on the competitiveness of locally produced generics.
- Improved public procurement processes by the PCT (sole purchaser of medicine for the public health system) in manners that limits dominant positions by major actors and encourages new entrants and innovation by SMEs and local manufacturers

- A draft law to extend the regulatory framework for clinical research to all medical devices and services (not just medicine)

Based on the strong buy-in at political and private sector levels, the methodology of the project is adopted and expanded to at least six additional sectors (following a request by the government):

- The Ministry of Health also requested to extension of the approach to all value chains in the health sector
- Four sectors will be funded by the African Development Bank
- Two sectors are funded by the Let's Work Program and implemented by the World Bank Group

6- Challenges

The main challenge of this DPP is to maintain the commitment of the actors, the continuity of the dialogue and the consensus behind the reforms and actions agreed, despite the diversity political changes.

One of the major challenges remains in aligning the priorities of the various ministries involved in future reforms (such as the creation of the single "Medicine Price Committee" which involves the Ministry of Health, the Ministry of Industry & Trade and the Ministry Social Affairs), while also aligning itself with the level of ambition and excellence that would enable Tunisia to become a platform for pharmaceutical exports.

Although not part of the scope of the PPD to date, the creation of a "Drug Agency" that can bring together all the existing structures that regulate the sector has been announced for a year but is not yet concretized. This agency is essential to offer better accessibility and safety to the patients while supporting pharmaceutical exports.

Biographies of Authors:

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Mrs. Sara Masmoudi is the General Manager of a pharmaceutical company (Teriak) which manufactures and operates in Tunisia, Libya and French West Africa. She acted as the coordinator of multinational companies and local companies of the Private sector for the PPD process. She is an engineer and holds a Master of Science in Industrial Engineering of L'Ecole Polytechnique de Montréal.

Mrs. Rania Dourai is an entrepreneur and senior consultant at the World Bank, focusing on private sector development. Prior to this, she has worked at the African Development Bank and other multinationals where she acquired an extensive experience in research and sectorial analysis, business strategy and policy recommendation in North Africa region. Her industry of expertise are Pharmaceuticals, ICT and Electronics sectors. Rania holds an MBA from the University of Nice, France.