FEAPM Position Paper 1

The EA Pharma Policy Incentive Package

Proposed Policy for the Growth of the East African Pharmaceutical Manufacturing Sector

Background

Countries such as Ghana, Bangladesh and India have managed to develop a very healthy local pharmaceutical industry which has reduced the reliance on imports and the prevalence of sub-standard and counterfeit medicines in the market. This Policy Incentive Package is based on the successful experience of these countries in supporting local pharmaceutical manufacturing.

Research clearly indicates that well-balanced and flexible policy measures can lower prices, reduce donor and import dependencies, eliminate sub-standard and counterfeit medicines as well as tackle stock-outs and expirations in the supply chain.

Policy Measures

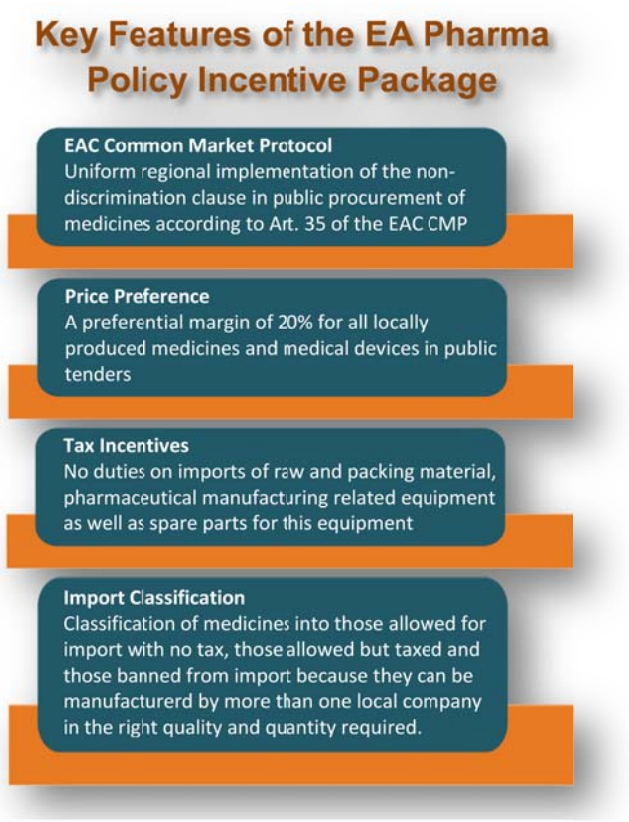
Measures applied in successful pharmaceutical policy packages in other LDCs and DCs include: preferential price margins for domestic manufacturers, price ceilings for selected medicines, tax and import duty exemptions, import restrictions and bans, marketing/advertisement limitations for foreign based companies, utilization of TRIPS Flexibilities through approximation of national law, public investment, facilitation of technology transfer, reverse engineering and other R&D activities.

In addition, the EAC Common Market Protocol, in Art. 35, provides for a non-discrimination clause: The Partner States shall not discriminate against suppliers, products or services originating from other Partner States, for purposes of achieving the benefits of free competition in the field of public procurement. Full implementation can improve the competitiveness and economies of scale of the local industry by enabling access to a sizeable regional market.

Ghana's Policy Impact

In 20 years of local pharma-oriented policies, many positive effects have been achieved in Ghana:

- Number of local companies increased from **9 to 39**
- Increase in employment from **150 to 6,500 persons**
- Reduction of the share of sub-standard and counterfeit medicines in the market from **40 to 3%**
- Improved trade balance:
  - Drop of share of imported medicines from **90 to 70%**
  - Medicine exports increased **six fold**
- Local production of Active Pharmaceutical Ingredients (APIs)



Bangladesh's Policy Impact

- Prices for medicines decreased by **more than 50%** in real terms
- Local production of essential medicines increased from **30 to 80%**
- Share of substandard drugs fell from **36 to 9%**
- Import savings of USD 600 million
- Local API production introduced
- Sector employs over **100,000 people**

India's Policy Impact

- India is among the top 20 pharmaceutical exporting countries
- Exports have grown at around **19% p.a.** and Indian medicines are exported to around **200 countries**
- The industry currently employs about **450,000 people**
- Creation of a rich talent pool of pharmaceutical researchers, scientists and project managers

Conclusion

Success stories like these can serve as best practice examples to support the development of a sustainable local pharmaceutical manufacturing industry in less developed economies. In addition, WTO trade agreements and the WTO TRIPS agreement are specifically designed to allow less developed countries to support upcoming industries through these kinds of policy measures, especially with regard to public health interests and the development of infant industries.

Through the adoption of the East African Community Regional Pharmaceutical Manufacturing Plan of Action (RPMPOA) and the EAC TRIPS the EAC and her Partner States have made progress in promoting local pharmaceutical production in the region.

These achievements, the lessons learnt from various country success stories and favorable international trade-related agreements, highly justify the introduction and enforcement of the EAC Pharma Policy Incentive Package. The EAC can significantly strengthen a sustainable and competitive local pharmaceutical industry in the region through regional policy measures regarding procurement, taxation and import of medicines. These measures must be uniform for the entire region and adjusted to changing context factors as required.

FEAPM's Position 2015

- Full implementation and enforcement of Art. 35, EAC Common Market Protocol (non-discrimination clause in public procurement);
- Uniform price preference of 20% for local manufacturers registered in the EAC;
- Zero taxation of all raw materials (incl. packaging) and pharmaceutical manufacturing related equipment (incl. respective spare parts) acquired by local manufacturers registered in the EAC;
- Import restrictions for finished pharmaceutical products that can be produced locally, based on regional capacity and quality audits of local manufacturers.

FEAPM Policy Background Paper

Feasibility of Implementing Industrial Policies
to Support Local Pharmaceutical Manufacturing
in East Africa

1

A look at international trade law and existing best practices

Background

This analysis is based on the FEAPM position paper N0. 1 “The EA Pharma Policy Incentive Package”. Knowledge of the content of this paper is necessary for the understanding of this feasibility study.

The *EAC Pharma Policy Incentive Package* incorporates three policy tools: **Price preferences, Tax incentives and Import classification**. Figure 1 introduces the measures in detail.

This proposed set of policies builds upon an approach that proved highly successful in several countries before. The FEAPM position paper calls on policy-makers to adapt this model to the East African Community and put into place the proposed policy measures as part of the implementation of the Regional Pharmaceutical Manufacturing Plan of Action (**EACRPMPoA**) with the aim of *increasing access to regionally-produced affordable quality essential medicine in the EAC*.

This paper aims to assess the **feasibility** of implementing the EAC Pharma Policy Incentive Package: Firstly, checking its compatibility with international trade legislation. Secondly, comparing the proposal to existing practices in the EAC and, thirdly, to previous industrial policy implementation in other low-income countries.

Price Preference	• A preferential margin of 20% for all locally produced medicines and medical devices in national tenders
Tax Incentives	• No duties on imports of raw and packing material, pharmaceutical manufacturing related equipment as well as spare parts for this equipment
Import Classification	• Classification of medicines according to the production capabilities of local manufacturers. Medicines that can be produced locally will be taxed or even banned from import.

Legal Assessment of Policy Interventions

The implementation process of the EAM needs to take the regional perspective into account. This applies especially for the pooled public procurement: Preferential pricing needs to be applied on an EAC level and include manufacturers from all Partner States in order to promote regional industrial development.

Price Preference:

- No EAC Partner States has signed the WTO Agreement on Government Procurement. Thus, they are not bound by WTO rules governing public procurement.
- The national treatment[1] clause of the General Agreement on Tariffs and Trade (GATT 1994: Art.3) does not apply to laws, regulations or requirements governing government procurement.

Policy Insight #1

- *Partner States **are not bound** by any WTO trade legislation and are free to support local pharmaceutical manufacturing through preferential pricing in national tenders.*

Tax Incentives:

- Freeing specific goods like pharmaceutical packaging or related equipment from all duties and taxes is in line with the most-favored nation principle[2] of Art.1.1 GATT 1947.
- Attention needs to be given to include all "like" products in the incentive scheme in order to stay within the WTO agreements. That means equal treatment for all products, which share the same physical properties, serve the same end-uses, are perceived as substitutes by consumers and share the same international classification for tariff purposes[3].

Policy Insight #2

- *As long as like-products are not discriminated against, Partner States **are free** to give tax incentives for the import of goods required for pharmaceutical production.*

[1] The national treatment clause prohibits governments to treat imported products different from nationally produced goods (e.g. for domestic taxes or other national legislation)
[2] The most-favored nation principle prohibits governments to discriminate between its trading partners. A country would not be allowed to liberalize only imports from a single or a group of states.
[3] "Like Products", WTO rules and environmental policies: key GATT disciplines. Retrieved from: http://www.wto.org/english/tratop_e/envir_e/envt_rules_gatt_e.htm

Import Classification:

- Art. 11.1. GATT 1994 generally forbids import bans. Moreover, different custom duty rates depending on each pharmaceutical product are likely to violate the most-favored nation principle. Nevertheless, EAC Partner States can still use this policy tool, as subsequently explained.
- Under the **economic development exception** of Art.XVIII GATT 1994 developing countries are allowed to "*deviate temporarily from the provisions of the other Articles of this Agreement, as provided in Sections A, B, and C of this Article".* Protecting an infant industry like the pharmaceutical manufacturing sector from import competition falls under this exception.

Policy Insight #3

- *Partner States **are allowed to** use import classification to support their infant industry.*

Existing Practices of the East African Model in EAC Partner States

Figure 2 demonstrates that Partner States have already begun to implement measures of the Pharma-Policy Package and can serve as positive examples for the feasibility of this policy-mix.

	Preferential Pricing	Regional Preferential Pricing?	Tax and Custom Incentives	Import Classification
Tanzania	15% for all medicines produced in Tanzania. Factoring in clearance costs of imports, preference is really only **6.5%**	**No**	**All relevant inputs free of customs.** VAT can be reimbursed up to 8 months later	**None**
Kenya	15% for all medicines produced in Kenya 10% for all imported medicines traded by a company with at least 51% Kenyan ownership. Thus, real price preference for local producers **5%**	**No**	Imported **raw and packaging materials free of customs and taxes**. Yet, VAT levied on locally procured products.	**None**
Uganda	**15%** for all medicines produced in Uganda (implementation problems)	**No**	**Raw and packaging materials free of customs**. Machines and spare parts face 10% customs duty. VAT can be reimbursed later for all goods.	**None**
Burundi	**15%** for all medicines produced by companies with more than 50% Burundian ownership	**Yes, if reciprocity exist with Partner State**	**All relevant inputs free of customs and taxes.** Inputs that are produced in Burundi are excluded from the incentive scheme	**None**

Cases of Pharmaceutical Industrial Policy from other developing countries

Figure 3 compares several examples of developing countries which have implemented similar Industrial Policy measures to successfully support local pharmaceutical manufacturing.

	Measures	Industry Growth	Quality of Medicines	Employment
Ghana	Similar to EAM	The share of local production increased from 10% to 30% with 39 local manufacturers in 2014 compared to just 9 in 1989	The quality improved significantly: For example, the share of sub-standard malaria medication in circulation fell from 39% to 3%.	Employment more than ten-folded: Currently about 6500 jobs in the industry
Bangladesh	Import classification and price ceilings	The share of local production increased from 35% to 97% with more than 170 approved & operating companies in 2013 compared to just 80 active in 1982.	The quality improved significantly. The industry began recently to export their products to countries in Asia, Latin America and Southern Europe and also to developed countries including USA, where the safety regulation is most stringent in the world.	Employment: currently about 100,000
India	Import duties and export subsidies	India's industry has been growing at an average annual growth rate of 19%. In 2013 it was the third biggest exporter of medicines by volume	India is among top 20 pharmaceutical exporting countries. Indian drugs are exported to around 200 countries including high-regulated countries like the UK or the US	The industry currently employs about 450,000 people and has contributed significantly in creating a rich talent pool of researchers, scientists, doctors and project managers

Concluding Policy Insight

Implementing the "East African Model" in EAC Partner States can be done without violating any WTO agreements or other trade legislation. In fact, some measures are already in place in EAC countries. The Partner States are called on to follow their lead and implement *price preferences, tax incentives* and *import classification* in order to develop local pharmaceutical manufacturing as successfully as other low-income countries did in the past.

FEAPM Policy Background Paper

Best Practice Examples of Implementing Industrial Policies to Support Local Pharmaceutical Manufacturing

2

A look at Ghana, Bangladesh and India

Background

This paper highlights best practice examples from developing countries or former developing countries that introduced measures and policy incentives for industrial policies to support local pharmaceutical manufacturing. It includes Ghana, Bangladesh and India; three examples that represent success stories of aligning industrial policy for the local production of pharmaceuticals. They played a key role in increasing access to medicine and reducing sub-standard and counterfeit medicines in their respective countries.

Ghana

Before Ghana introduced a policy to incentivize pharmaceutical production, there were few active industries in Ghana. Up to the 1990s, the market was largely dominated by a state owned company. Private companies had no incentives to enter the market or only produced on a very small scale. Additionally, the import of sub-standard and counterfeit medicines was a big challenge for Ghana. Several countries had introduced export premiums to support their pharmaceutical industry (e.g. India) which led to an excessive supply of substandard and counterfeit products that were mainly imported from China and India. Overall, 70% of all locally available medicines were imported into Ghana in an unregulated manner.

In 1989 the Ghanaian government clearly committed to local pharmaceutical manufacturing as a priority and set the following policy incentives:

- Companies receive an exemption from corporate tax in the first three years after establishment;
- The government banned the import of about 44 medicines, which either can be locally manufactured or need to be regulated due to health reasons;
- Local pharmaceutical manufacturers are exempted from VAT;
- Basic materials required for production are exempt from import duty.

As an outcome of the policy mix of the Government of Ghana the share of local production increased from 10% to 30% with 39 local manufacturers nowadays compared to just 9 in 1989. Through regulating manufacturing and thus controlling local production, quality of local products improved. While in 2008, 39% of all anti-malaria medication circulating in Ghana was sub-standard, this share decreased to 3% by today. Moreover, employment increased by more than ten times to currently about 6.500 jobs in the industry. Positive developments also include increased tax revenue for the government, an independent and self-sufficient pharmaceutical industry that can react to crisis and a significantly reduced inflow of counterfeits[1].

Bangladesh

Before the National Drug Policy was launched in 1982, the country's medicine market was dominated by multinational firms that were able to set very high prices for live-saving medicines because of their monopolistic power.

The National Drug Policy intended to lower prices to secure access to essential medicines for all and to reduce the power of MNCs by promoting local production of medicines. It included three main measures:

- Prohibition for multinational firms to sell antacids and vitamins, which were relatively easy to produce for local firms. Multinational firms were asked to instead concentrate on the development and production of innovative, sophisticated and high-tech products, such as antibiotics.
- Restriction of the import of substitutes for the finished medicines and intermediate inputs that can be produced by at least two local firms.
- Promotion of the local medicine industry through prohibition of those multinational firms without any production facilities in Bangladesh from advertising their products produced by other firms on a toll manufacturing basis. As a result, multinational firms were incentivized to establish their own factories in Bangladesh.

Further measures included the elimination of product patents and a limitation of the use of process patents, regulation of technology transfer and licensing agreements with foreign collaborators and a price ceiling system.

An important factor for the success of the industrial policy in Bangladesh was the pharmaceutical education programs that already started in 1969. A lot of graduates from these programs worked for multinational companies where they acquired broader knowledge before they shifted to local companies. It is therefore important to include Human Capacity Development (HCD) into the industrial policy.

Outcomes of the policy include the increase in local production from 30 to 80 per cent, a stabilization of medicine prices, that increased by only 20 per cent, compared to an increase of 179 percent in the consumer price index. The drop in price in real terms of more than 50% made medicine more affordable for consumers. Bangladesh is less dependent on imports

[1] Nixdorf, Lisa (2014): "Pharmaceutical Manufacturing in Ghana – Lessons learnt for the East African Community".

and prioritization of useful products save the country approximately US$ 600 million. The quality of products improved—the proportion of medicine tested which were found to be substandard fell from 36 per cent to 9 per cent[2].

India

After its independence in 1947 western multinationals (MNCs) held about 80% of the pharmaceutical market with the remainder being served by small-scale Indian owned companies. India heavily depended on imported medicines, which were marketed directly by the MNCs established in India and local agents of MNCs that did not have a local presence. MNCs mainly imported the basic ingredients from their home countries; their contention being that the locally available APIs were not of the desired quality. In the process, not only were technological externalities and knowledge transfer absolutely minimal but Indian medicine prices were among the highest in the world. Indian consumers suffered from a shortage of essential medicines and a crisis in terms of healthcare provision[3].

To overcome this health crisis India introduced the following measures and incentives to develop the local pharmaceutical industry:

- Large Investments to establish public sector enterprises in order to reduce dependence on MNCs.
- Inward looking trade and investment policies: The 'import substitution' policy took the form of a complex system of price controls, high import duties and export subsidies.
- Indian pharmaceutical industry focused on reverse engineering and process innovation.
- Patent Act of 1970 included provisions for commercializing independently developed copies of branded medicines, if the production process was significantly different from that used to manufacture the branded product.
- Price control was introduced in 1970 for a long list of 'notified' medicine that were deemed essential → objective: to curb profit margins and promote access to medicine.

The industrial policy coupled with the dynamic response of local firms to acquire capabilities in all stages of medicine production led to a sharp reduction in import dependence and MNC domination. Fortunately, India was already equipped with scientific capabilities in the form of public laboratories skilled in creating new processes; and universities producing large numbers of science graduates. The demand side also supported the new trajectory as Indian consumers revealed being extremely price sensitive. Today, India is number one exporter of generic medicines in the world (volume). Exports have grown at around 19% and Indian medicines are exported to around 200 countries, including highly regulated markets like the USA, UK etc. India's industry has been growing at an annual rate of 10% while exports have

[2] Amin, Md. Nurul and Sonobe, Tetsushi (2013): "The success of the industrial development policy in the pharmaceutical industry in Bangladesh".
[3] Guennif, Samira and Ramani, Shyama V. (2010): "Catching up in pharmaceuticals: a comparative study of India and Brazil".

been growing at about 20%. The industry currently employs about 450,000 people and has contributed significantly in creating a rich talent pool of researchers, scientists, doctors and project managers[4].

Concluding Policy Insight

There is strong evidence in other countries that an industrial policy for the support of local pharmaceutical manufacturing can be successful, both from an economic and a pure health perspective. The examples have schown that access to and availability of medicine was increased, sub-standard and counterfeit products and dependence on MNCs reduced and employment created. The EAC can learn from these best practice examples and FEAPM has already included those insights in their propositions for the "EAC Pharma Policy Incentive Package".

[4] Guennif, Samira and Ramani, Shyama V. (2010): "Catching up in pharmaceuticals: a comparative study of India and Brazil".