

# Supporting Sector-Focused Business Environment Reform in Developing Countries



**Business Environment Working Group**

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# DCED

The Donor Committee for Enterprise Development

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The DCED is the long-standing forum for donors, foundations and UN agencies working in private sector development, who share their practical experience and identify innovations and formulate guidance on effective practice.

The BEWG serves as a platform to share information and knowledge on donor-supported business environment reform in developing countries and to identify and support good practices and new approaches in this field. For more information on the DCED BEWG, please visit the DCED website at <http://www.enterprise-development.org/organisational-structure/working-groups/>

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## Executive summary

Building on its efforts to support donor and development agencies in their work with developing country governments to improve the business environment for private sector development, the Donor Committee for Enterprise Development commissioned a review to better understand how agencies are supporting reforms in specific industry sectors. Four sectors were examined.

### **Pharmaceuticals sector**

The review of this sector examined reforms focused on improving the local production of essential medicines. The following lessons were identified:

- Political will at the highest level is required to drive reform. However, there is also a need for this commitment to permeate the lower levels of the government bureaucracy so reforms can be understood and adopted by those who are directly affected.
- Good coordination across a range of government ministerial portfolios and sector agencies is required. Reforms in this sector affect health, industry, commerce, and trade portfolios, among others. If there is a lack of coordination, then reforms are unlikely to succeed.
- A “step-wise” approach is needed in which reforms and capacity building efforts designed to boost local manufacturing capacity go hand-in-hand.
- Government policy makers, regulators and programme managers must develop a clear understanding of the practical challenges faced by local manufacturers. This requires regular consultation and public-private dialogue, involving large and small-scale manufacturers.
- There is a need for better market information to accurately assess the market dynamics, including information on the importation of medicines.
- Laws and regulations can be used in an anti-competitive manner. There should be a consistent commitment to promoting competition within local markets and to ensuring present incumbents, whether they are multi-national enterprises or large national companies, are not allowed to unfairly protect their position in the market.
- Because local markets may be small, there is a need to support the regional harmonisation of policies, laws and regulations to promote greater cross-border trade in pharmaceutical products.
- Many regulations and standards in this sector were found to be unnecessarily costly, inefficient and biased against local producers.
- Programmes are required to build the capacity and autonomy of regulators in this sector so that they are able to fulfil their mandates effectively.

### **Renewable energy sector**

The review focused on the challenges of an entirely new industrial sector: the generation and distribution of ‘on-grid’ renewable energy (e.g., solar, wind and tidal power). The following lessons were identified:

- The development of the renewable energy sector requires an integrated, multi-sector policy framework with many elements. This can be very difficult

to design, as well as to implement and monitor. Not only do such policies affect a wide range of national government ministries, departments and agencies, they also require careful coordination and integration with sub-national government authorities. Furthermore, because of the relatively new nature of the sector (i.e., dealing with emerging technologies) the issues affecting policy frameworks are changing rapidly. Thus, new policies and practices are evolving and there is a constant need to review and revise policy directions and instruments.

- Industrial policy dominates development in this sector. It is important business environment reforms occur in tandem with these interventions and provide a supportive, complementary function. However, this appears to be difficult. There is evidence to suggest that many legal and regulatory barriers undermine government's broader development efforts in this sector.
- Sector-specialist agencies have an important role to play in advising, guiding and supporting business environment reform in this sector. These agencies have an understanding of international developments and best practices and can work with a wide range of local actors, public and private, to identify and facilitate reform efforts.
- It is important to be pragmatic when responding to business environment barriers. For example, while the unbundling of state-owned non-renewable energy production and distribution enterprises may be a typical first step in business environment reform, it may be more practical to simply create financial incentives that encourage utilities to be more open to purchasing renewable energy.
- There is clear evidence of anti-competitive behaviour in this sector, where well-established incumbents actively resist the introduction of new technologies and new actors. Business environment reform should be underpinned by a clear political-economic analysis of the power structure of the market.

### **Mining sector and small-scale suppliers**

The review focused on small-scale suppliers to the mining sector (i.e., backward linkages). The following lessons were identified:

- While policies set governments intention in terms of the development of local content, these are far from binding. The national policy framework requires a realistic and implementable legal and regulatory framework to ensure the aspirations and goals (and possibly the targets) of government in this sector are achieved.
- Supplier development programmes help local firms respond more successfully to the opportunities presented by local content provisions. This illustrates the combined use of industrial policy and business environment reform to achieve the desired development goals. However, it appears the capacity constraints of local firms are significant.

- Coordination across government ministries, departments and agencies is important. Success requires good communication and coordination across the government portfolios associated with minerals, energy, industry, commerce, labour, and the environment.
- In all aspects of this work, careful attention should be given to the economic imperatives of the sector. Mining is a long-term, high-cost business, which is typically vulnerable to international price fluctuations. Developing local content, and designing a policy, legal and regulatory framework to govern this, requires a good understanding of the dynamics of the industry and the capacity of large-scale mining and small-scale suppliers.

### **Horticulture**

The review specifically dealt with fruit and vegetables, focusing on the significant role agriculture plays and how sector development involves support for reforms that stimulate agri-business development. The following lessons were identified:

- National policy frameworks for horticulture development can help to establish the macro-conditions for improvement in the horticulture sector and can guide government interventions and private sector partnerships at national, regional and local levels. However, many national policies do not pay sufficient attention to the needs of private investors and the development of agri-businesses within the horticulture sector.
- National policies should address a 'critical triangle' of policy concerns: agricultural growth, poverty reduction and natural resource management.
- Other relevant policy issues include contract law, anti-trust law and the introduction of regulations relating to pesticide use, food standards, seed quality and provision of arrangements to certify quality and geographic origin, etc. Policies should seek to improve market linkages.
- Regional policy frameworks can be used to create new and expanded market opportunities for horticulture producers. These focus on improving cross-border trade in the supply of agricultural inputs and the export of horticulture products.
- While increasing attention of phyto-sanitary standards drive the demand for legal and regulatory reform, these reforms should not be used to isolate or protect local markets. Instead, these reforms should focus on increasing competitive pressures and integrating local and global markets.
- The major challenge for horticulture producers in developing economies is to meet the growing set of standards required to enter world markets. This requires significant improvements in the national policy, legal and regulatory framework as well as in national standard setting and testing. While lead firms, such as national exporters and multi-national enterprises, play an important role in helping local firms comply and link local producers to international markets, there is a high demand for public investment into improved standards, testing facilities and enforcement mechanisms.

- Regulatory mechanisms should be established to protect natural resources, worker's rights and food safety, as well as the rights of small producers and firms in contractual relationships with larger companies.
- Contract reform is a critical issue for business environment reform in horticulture. Legal and regulatory reforms are needed to improve commercial contract arrangements. Contracts should be clear, simple and enforceable. In some cases it may be necessary to develop a legal framework for contract farming, which defines roles and responsibilities of contracting parties.
- Land tenure is important for smallholder farmers, many of whom farm on communal or public land. Traditional land tenure systems in many countries provide little incentive for farmers to invest in the improvements necessary to fully exploit market opportunities. Thus, reform of property rights and land titling may be required.
- Small-scale farmers and agribusiness are generally poorly represented in policy development forums and public-private dialogue. Commercial success for these actors is often associated with linkages that are formed with large-scale exporters. However, government policy makers and programme managers need to be aware of the challenges faced by small-scale operators.

### **Common issues affecting vertical business environment reform**

The report identifies a number of common issues affecting sector-oriented business environment reform:

#### Policy frameworks and reform

- *A national policy framework is essential:* it guides reforms and can help coordinate the many government, private and civil society actors involved in sector reform and development.
- *The multi-dimensional nature of policy:* sector policy frameworks provide integrated, coherent and well-coordinated responses to the multi-dimensional needs of private firms.
- *Regional markets and reform policies:* sector markets typically extend beyond national boundaries and increasing attention is given to the harmonisation of regional trade regimes and the development of regional policy frameworks.
- *Policy implementation is a persistent challenge:* many governments lack the capacity to effectively coordinate a comprehensive and integrated set of strategies.
- *Political will and commitment:* high-level political is essential, but this should extend deeper into lower levels of government where resistance and intransigence can hinder reform.
- *Resistance to change:* this varies from a general reluctance to change to a deliberate undermining of reform efforts.

- *Connections between business environment reform and industrial policy:* the complimentary use of both instruments can enhance sector development opportunities.
- *Public procurement and subsidies:* can be used to create new market opportunities for local firms, provided they are consistent with and connected to national policies for sector development.

#### Legal and regulatory reform

- *Laws and regulations need to be consistent with national policies:* legal and regulatory frameworks need to be clear, coherent and consistent with the national policy guiding reform and development; too often this is not the case.
- *Coherence across national and sub-national laws and regulations:* in many cases there is a lack of coherence between laws and regulation at the national and local levels, causing confusion among businesspeople and investors, and raising costs.
- *Regional markets can drive increased investment:* the regulation of regional markets affects investor behaviour and increasingly regional reforms aim to harmonise and streamline regulations across regions.
- *Legal and regulatory instruments based on business models:* legal and regulatory instruments, such as tax incentives, have been designed to respond to the specific dynamics of targeted sectors.
- *Lack of awareness in government of private sector concerns:* poor legal and regulatory frameworks can be a result of government's lack of understanding of the practical problems or opportunities private firms face within a specific sector.
- *Common (persistent) challenges:* these include: the lack of investor clarity on government processes and procedures, as well as the length of time it takes investors to comply with legal and regulatory requirements.

#### Regulatory authorities

Industry regulation is a critical issue for all sectors. However, effective regulation is hampered by a lack of capacity (i.e., most regulatory authorities are understaffed and under-resourced), skills and autonomy from government. Sector-oriented business environment reform requires a sound understanding of the role of regulation and regulatory authorities.

#### Standards and quality assurance

Standards and quality assurance is a critical element of sector-oriented business environment reform. While few concerns about the process of standard setting were found, most concern was levelled at the systems and facilities required to effectively monitor standards, test products and prosecute those who are selling sub-standard or counterfeit products.

### Institutional arrangements

- *Beyond political will, institutional leadership is required*: successful reform requires senior-level leadership to guide institutional redesign and management in a coordinated, integrated and pragmatic manner.
- *Dealing with multiple stakeholders*: because of the integrated nature of development strategies and reforms many stakeholders are involved and need to be carefully managed.
- *Public-private dialogue*: government policies, laws, regulations, and institutions could be better informed if sector-based public-private dialogue was used more frequently and made much more inclusive (i.e., representing the full diversity of the sector business community).

### **Advice to donor supporting sector-oriented business environment reform**

When supporting business environment reform within specific industry sectors, donor and development agencies should, in partnership with developing-country governments and the private sector:

- Support national policy frameworks to strengthen coordination and integration within and across industry sectors and sub-sectors;
- Use regional policy frameworks to guide regional market reforms and harmonisation—donor and development agencies can provide support to regional policy frameworks, as well as to the assessment of policy, legal and regulatory barriers to regional trade;
- Address anti-competitive behaviour, while promoting open markets and responding to the political-economic obstacles to reform;
- Improve the quality of regulatory governance by building the capacity of regulators and strengthening accountability mechanisms;
- Strengthen industry representation and public-private dialogue by helping small-scale enterprises to become better organised and represented in industry associations and more engaged in dialogue structures;
- Support industrial policy interventions that improve access to finance and information to help small-scale enterprises obtain the resources they require to expand and exploit the opportunities created by business environment reform;
- Support the creation of new financing instruments designed to respond to the specific sectors and business models;
- Support the reform of sector-specific taxation instruments to influence business and investment decisions;
- Support commercial law and justice reforms relevant to the sector, such as contract law and land tenure;
- Help partner governments to develop a clear strategy around the use of intellectual property rights and the promotion of local industry;



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- Strengthen reforms for improving the registration of new products making it easier and cheaper for enterprises;
- Support the formulation of targets against which policy and reform outcomes can be monitored and refined;
- Build the capacity of partner governments to improve sanitary and phyto-sanitary standards, which can directly affect the competitiveness of new firms in global markets; and
- Support the improvement of standards testing facilities.

The report is a preliminary review of sector-oriented business environment reform. The Donor Committee for Enterprise Development will use these findings to determine if there is scope for further advice for donor and development agencies on how better to support reforms.

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## List of acronyms

|        |  |
|--------|--|
| ACP    | Africa, Caribbean and Pacific                                  |
| ACTESA | Alliance for Commodity Trade in Eastern and Southern Africa    |
| AMRH   | African Medicines Regulatory Harmonisation                     |
| ANDA   | Abbreviated New Drug Application                               |
| ANEEL  | Brazil National Energy Agency                                  |
| AU     | African Union  |
| BE     | Business environment   |
| BER    | Business environment reform                                    |
| CAADP  | Comprehensive Africa Agriculture Development Programme         |
| CIF    | Cost, insurance and freight                                    |
| COMESA | Common Market for Eastern and Southern Africa                  |
| CSR    | Corporate social responsibility                                |
| DCED   | Donor Committee for Enterprise Development                     |
| EAC    | East African Community   |
| ECOWAS | Economic Community of West African States                      |
| EITI   | Extractive Industries Transparency Initiative                  |
| EU     | European Union   |
| FDI    | Foreign direct investment                                      |
| FIT    | Feed-in Tariff   |
| GAP    | Good agricultural practices                                    |
| GDP    | Gross Domestic Product   |
| GFATAM | Global Fund to Fight AIDS, Tuberculosis and Malaria            |
| GIZ    | <i>Deutsche Gesellschaft für Internationale Zusammenarbeit</i> |
| GMO    | Genetically modified organism                                  |
| GMP    | Good manufacturing practice                                    |
| HDSA   | Historically disadvantaged South Africans                      |
| IFC    | International Finance Corporation                              |
| IP     | Industrial policy  |
| IPR    | Intellectual property rights                                   |
| ILO    | International Labour Organization                              |
| KNPP   | Kenya National Pharmaceutical Policy                           |
| KPSDS  | Kenya Pharmaceutical Sector Development Strategy               |

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|        |   |
|--------|---|
| MNE    | Multi-national enterprise                                 |
| NAIP   | National Agriculture Investment Plan                      |
| NEPAD  | New Partnership for Africa's Development                  |
| NGO    | Non-government organisation                               |
| NMRA   | National medicines regulatory agency/authority            |
| PEPFAR | President's Emergency Plan for AIDS Relief                |
| PPA    | Power Purchasing Agreement                                |
| PPD    | Public-private dialogue                                   |
| QI     | Quality infrastructure                                    |
| R&D    | Research and development                                  |
| RE     | Renewable energy  |
| REN21  | Renewable Energy Network for the 21 <sup>st</sup> Century |
| SPS    | Sanitary and phytosanitary                                |
| SSA    | Sub-Saharan Africa  |
| TNC    | Trans-national corporation                                |
| TRIPS  | Trade Related aspects of Intellectual Property Rights     |
| UNCTAD | United Nations Conference on Trade and Development        |
| UNEP   | United Nations Environment Programme                      |
| UNIDO  | United Nations Industrial Development Organization        |
| VAT    | Value-added tax   |
| WHO    | World Health Organization                                 |
| WTO    | World Trade Organization                                  |

# 1 Introduction and context

## 1.1 Background

The Donor Committee for Enterprise Development (DCED) is a membership organisation made up of donors and development agencies and private foundations that share the vision of making private sector development more effective.<sup>1</sup> The Business Environment Working Group (BEWG) of the DCED is a thematic group focusing on how donor and development agencies can support reform of the business environment in developing economies.<sup>2</sup>

In 2008, DCED published guidelines on business environment reform (BER), entitled *Supporting Business Environment Reforms*, which defines the business environment (BE) as a:

Complex of policy, legal, institutional, and regulatory conditions that govern business activities. It is a sub-set of the investment climate and includes the administration and enforcement mechanisms established to implement government policy, as well as the institutional arrangements that influence the way key actors operate (e.g., government agencies, regulatory authorities and business membership organisations, civil society organisations, trade unions, etc.).

Governments reform their BE, with the support of donor and development agencies, because of the significant influence this has on the development of the private sector and, as a result, on economic growth and the generation of livelihoods and jobs. Reforms to the BE endeavour to change the behaviour of private enterprises to increase levels of investment and innovation and the creation of more and better jobs. This is done by:

- Reducing business costs: by reducing business costs firms are able to increase profits so that these may be further invested to increase market share so that output and employment is increased;
- Reducing risks and uncertainty: the risks of doing business are reduced by improving the quality and stability of government policies, laws and regulations in order to reduce the cost of capital and increase the number of attractive investments in the market; and
- Increasing competitive pressures: firms become more competitive by making market entry easier and by stimulating the efficiency and innovating incentives of the market.

The Donor Guidance recognises a number of ‘functional areas’ of BER that donor and development agencies have typically focused on. While BER can focus on

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<sup>1</sup> See <https://www.enterprise-development.org/about-the-dced/>

<sup>2</sup> See <https://www.enterprise-development.org/organisational-structure/working-groups/overview-of-the-business-environment-working-group/>

general BE issues, most reforms are concentrated on one or more of the following:

- Simplifying business registration and licensing procedures;
- Improving tax policies and administration;
- Improving labour laws and administration;
- Improving the overall quality of regulatory governance;
- Improving land titles, registers and administration;
- Simplifying and speeding up access to commercial courts and to alternative dispute resolution mechanisms;
- Broadening public-private dialogue processes with a particular focus on including informal operators, especially women;
- Improving access to market information; and
- Enabling better access to finance.

In addition, it describes how BER can occur at a number of levels: regionally, nationally, sub-nationally, and within specific sectors. It is this latter level of reform that this report is focused on. Sector-specific BER seeks “to address policy, legal and regulatory requirements that unnecessarily raise the cost of doing business, increase risks or reduce competition within specific sector or industry categories”. This allows for “a deeper analysis within those sectors that are most strategic for national development or pro-poor economic growth” (DCED 2008).

There has been an observable trend in recent years where ‘horizontal reforms’ (i.e., those that affect all businesses) designed to stimulate private sector development in developing countries have been complemented by sector-based or ‘vertical reforms’ (i.e., those focused on a specific sector or sub-sector). The BEWG has commissioned this preliminary report to learn more about the approaches that have been directed at specific sectors. Many developing countries have identified priority sectors for development to realise economic and social development goals (i.e., employment creation, income generation, poverty alleviation, etc.). Consequently, to make progress requires attention is given to the critical constraints of targeted sectors.

This report is located within a collection of other related reports the BEWG has prepared. The BEWG’s work on industrial policy and quality infrastructure are particularly relevant in this regard.

In 2013, the DCED published an annex to its 2008 Donor Guidance entitled, *Complementing Business Environment Reform through Industrial Policy Support*. This guidance highlighted the complementary role played by industrial policy (IP) and BER. Both these approaches share a common objective: “to contribute to the development of the private sector in developing and transition economies in order to generate economic growth, increase livelihoods, create more and better jobs, and reduce poverty”. However, while BER aims to reduce business costs and risks, and promote competition, IP addresses market failures and supports the transformation of the economy. These approaches are particularly important when sector development strategies are considered. Thus, the current report is

focused on the BER aspects of sector development, while acknowledging the importance of IP.

Another annex to the 2008 Donor Guidance was published by the DCED in 2014, entitled, *Supporting Quality Infrastructure in Developing and Transitional Economies*. The term “quality infrastructure” (QI) refers to the policy and institutional framework that governments establish to provide evidence that products and services meet the requirements set by regulatory authorities and the market place. It consists of a number of institutions and service providers, and includes standardization, metrology and accreditation. Here again, BER and QI perform complementary roles. While BER promotes the development of vibrant and competitive markets in which private firms start-up and operate, QI focuses on the products and services these firms provide. Thus, QI is a significant feature in an analysis of sector-oriented BER and there are many references in the pages that follow on the importance of improved QI.

While this report was commissioned by the DCED Business Environment Working Group, three agencies sponsored it: the German development agency (*Deutsche Gesellschaft für Internationale Zusammenarbeit*, GIZ), the United Nations Conference on Trade and Development (UNCTAD), and United Nations Industrial Development Organization (UNIDO).

## 1.2 Purpose, approach and methodology

This review sought to learn more about the specific issues affecting sector-focused BER. Four sectors were examined, each with a particular perspective on the issues facing sector development and BER.

The sectors presented are:

- **Pharmaceuticals sector:** this case focuses on the local production of essential medicines. This is interesting because the pharmaceuticals sector presents the challenges faced by an industry sector in which there is strong international competition. While there is a significant market for pharmaceutical products in most developing economies, this market is often dominated by multinational enterprises that are able to produce and import products at low costs. However, the local market for these products also presents a considerable opportunity for boosting local production capacities.
- **Renewable energy sector:** this case specifically focuses on the generation and distribution of ‘on-grid’ renewable energy (e.g., solar, wind and tidal power). This case presents the challenges of an entirely new industrial sector. Governments and their development partners support IP and BER to encourage private investment into new technologies and business models. This requires a high degree of government coordination and integration across a range of policy portfolios.
- **Mining and small-scale suppliers:** this case focuses on the development of small-scale suppliers to mining activities (i.e., backward linkages). Here, the interest is on how developing country governments can maximise the



opportunities for local industry development through large-scale resource projects.

- **Horticulture**, specifically fruit and vegetables. This sector is of interest because of the significant role that agriculture plays in most developing economies. Sector development involves support and reforms to stimulate agri-business development, which includes building local capacity as well as improving the access local producers have to foreign markets.

As a preliminary exercise, this review seeks to better understand what facets of the BE have particular relevance to these sectors and how can they be worked on to stimulate sector development. There may be horizontal reforms, such as the functional areas described above, which are particularly relevant for these sectors, just as there are specific vertical BER elements that are identified as important.

Four key questions guided the review:

- What specific elements of the BE should be addressed to improve sector performance?
- How are these reforms pursued?
- Are there good examples of targeted BER in the selected sectors?
- What actions should key stakeholders (government, business, donors) take when promoting reforms that will improve sector performance?

This was largely a desktop review of documents and a survey of people who have experience in BER in the selected sectors and sub-sectors. Most respondents were identified by the sponsoring agencies. These people were a mix of specialists from development agencies, government policy makers and industry representatives. In some cases, respondents submitted a completed questionnaire; in other cases respondents were interviewed via telephone or Skype. Typically, these interviews ran for one hour each. The list of references at the end of this report presents the literature that was reviewed. Annex 1 contains a list of respondents.

The next four chapters present the findings of the sector reviews. These are followed by Chapter 6, which presents the common issues that were found to affect BER in the four sectors. Chapter 7 then concludes with a consideration of the ways in which these findings may affect the practices of donor and development agencies that support BER in these sectors in developing and transition economies.

## 2 Pharmaceuticals

This chapter presents the findings of the sector review into pharmaceuticals. It gives an introduction to the sector and sub-sector, and identifies the issues of major concern. It then presents the specific dimensions of BER and the experiences, practices and lessons that can be learnt. This review focuses on the promotion of local manufacturing of medicines. While pharmaceuticals in most developing countries are imported, there has been a growing interest in supporting local production.

The case of pharmaceutical production in developing economies reflects the challenges faced by an industry where there is strong international competition. While there is a significant pharmaceutical market in most developing economies, it is often dominated by multinational enterprises (MNEs), which are able to produce and supply foreign markets at low costs. However, the local market for these products also presents a considerable opportunity for boosting local production capacities.

### 2.1 Sector overview and characteristics

The World Health Organization (WHO) estimates that the global pharmaceuticals market is worth US\$300 billion a year and is expected to rise to US\$400 billion within three years. The ten largest drug companies control over one-third of the market, several with sales of more than US\$10 billion a year and profit margins of about 30 per cent. Six are based in the United States and four in Europe. It is predicted that North and South America, Europe and Japan will continue to account for 85 per cent of the global pharmaceuticals market well into the 21st century (WHO 2015a).

Most developing countries, with the exception of India and China, are dependent on imports for the supply of essential medicines. For example, in Africa, the WHO reported that half the population lack regular access to essential medicines and 90 per cent of medicines is imported (Chaudhuri & West 2014). While the overall pharmaceutical market in sub-Saharan Africa (SSA) is worth USD 3.8 billion annually, the pharmaceutical manufacturing sector in Africa contributes only 25-30 per cent of the continent's needs (UNIDO 2011).

There are increasing efforts to promote the development of a local pharmaceutical manufacturing base. From an industrial policy standpoint, local pharmaceutical manufacturing is typically justified on account of accruing benefits to the local economy, such as savings on foreign exchange, import substitution, employment creation, and export promotion. On the other hand, the rationale for local pharmaceutical manufacture from a health policy perspective is largely founded on increasing access to essential medicines.

A high proportion of the focus on local pharmaceutical production is on the manufacturing of essential medicines. The WHO defines essential medicines as "those drugs that satisfy the health care needs of the majority of the population". Essential medicines are selected based on disease prevalence, evidence on

efficacy and safety, and comparative cost-effectiveness. They are “intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford” (WHO 2015b). WHO publishes a model list of essential medicines and each country is encouraged to prepare their own list taking into consideration local priorities. Over 150 countries have published an official essential medicines list, which enables health authorities, especially in developing countries, to optimise pharmaceutical resources. The list forms the basis of a national health policy.

A key issue in the promotion of local pharmaceutical production is the role of good manufacturing practice (GMP). GMP ensures products are consistently controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation. GMP is aimed primarily at diminishing the risks inherent in any pharmaceutical production and ensuring that manufacturers do not place patients at risk due to inadequate safety, quality or efficacy.

The main risks associated with pharmaceutical production are:

- Unexpected contamination of products, causing damage to health or even death;
- Incorrect labels on containers, which could mean that patients receive the wrong medicine; and
- Insufficient or too much active ingredient, resulting in ineffective treatment or adverse effects.

GMP covers all aspects of pharmaceutical production: from the starting materials, premises and equipment to the training and personal hygiene of staff. Detailed, written procedures are essential for each process that could affect the quality of the finished product. There must be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process - every time a product is made. WHO has established detailed guidelines for good manufacturing practice. However, many countries have formulated their own requirements for GMP based on WHO GMP. Others have harmonised their requirements, for example in the Association of South-East Asian Nations, in the European Union and through the Pharmaceutical Inspection Convention (WHO 2015c).

## 2.2 The Business Environment for the Pharmaceuticals Sector

Four dimensions have emerged when examining the BE for the Pharmaceuticals Sector:

- Policy development and reform;
- Legal and regulatory framework;
- Regulation and quality assurance; and
- Institutional arrangements.

Each of these dimensions is presented in detail below.

### 2.2.1 Policy development and reform

National policies and strategies have been used to focus government efforts on local pharmaceutical production. Ministries of health or industry typically drive these documents. Examples include:

- Vietnam National Strategy for Pharmaceutical Sector Development (2000-2010 and 2010-2020), which is underpinned by the National Drug Policy (1996) and Vietnam’s Vision 2030;<sup>3</sup>
- Zimbabwe Agenda for Sustainable Socio-Economic Transformation — this is a five-year development plan, which identifies the need to “strengthen and promote the local production of pharmaceutical products”;
- Kenya Pharmaceutical Sector Development Strategy — with consideration for the Kenya Health Policy 2012-2030 and Kenya National Pharmaceutical Policy 2012;
- Rwanda’s Health Sector Policy;
- Tanzania’s Health Sector Strategic Plan III (2009–2015);
- Burundi’s National Health Policy (2005 – 2015) and National Health Development Plan (2006–2010); and
- Uganda’s Health Sector Strategic Plan (2005–2010).

The policy and strategy for pharmaceutical production in Kenya serves as a good example of the kind of focus these documents adopt. Here, the delivery of pharmaceutical services is part of the broad policy mechanisms as stipulated in the Kenya National Pharmaceutical Policy (KNPP). Pharmaceuticals are critical to the economic and social development of Kenya and are a core component of the right to health. One of the objectives of the policy is to “promote local production, research and innovations of essential health products and technologies”. The policy ideal of self-sufficiency in quality medicines requires an “enabling regulatory framework, which will facilitate recognition by stringent inspection agencies”.

The Kenya Pharmaceutical Sector Development Strategy (KPSDS) is the main vehicle for implementing the KNPP component concerned with local pharmaceutical production. This strategy, which the government adopted in 2012, was formulated with support from UNIDO and in collaboration with the Ministry of Industrialization, Ministry of Medical Services, the Pharmacy and Poisons Board, the National Quality Control Laboratory, and the Federation of Kenya Pharmaceutical Manufacturers.

In addition to the KPSDS, the Ministry of Industrialization and Enterprise Development developed the Sessional Paper No. 9 of 2012 of the National Industrialization Policy Framework for Kenya 2012–2030, whose theme is “Transforming Kenya into a globally competitive regional industrial hub”. This policy, amongst others, recognised the pharmaceutical sector as being vital to the industrial development of the country. In addition, the ministry launched the

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<sup>3</sup> Decision No. 68/QD-TTg dated January 10, 2014 of the Prime Minister approving the national strategy on development of Vietnam pharmaceutical industry up to 2020, with a vision toward 2030, 1/10/2014, No. 68/QD-TTg.

Kenya Industrialization Roadmap in 2013, which seeks to increase the contribution of manufacturing base to GDP.

The KPSDS has seven strategic components:

1. Setting out a roadmap for industry to achieve GMP Standards: To achieve WHO GMP in a stepwise manner;
2. Strengthening mechanisms for quality assurance of medicines in the distribution chain: To establish a national quality assurance system that will identify and remove from the market non-compliant products, and enhance the pharmacovigilance activities;
3. Strengthening regulatory capacity: To enhance regulatory oversight in tandem with industry growth and international trends;
4. Accessing required financing for investment in the sector: To facilitate access to affordable finance;
5. Devising time-limited incentives for industry: To assist the industry in remaining competitive whilst it is investing in quality infrastructure and products;
6. Developing necessary human resources: To enhance human capital with knowledge, skills, and competence, as required in the sector; and
7. Developing common support services for local pharmaceutical companies: To create a platform for pooling and sharing of technical resources.

Many respondents to this review describe how policies are important to focus reform efforts and promote coordination and coherence across government ministries, departments and agencies. However, there are few cases where successful coordination and coherence is found.

The role of political will in driving reforms in the pharmaceutical sector was found to be important. Without high-level political support, many of the reforms required cannot be successfully implemented. Indeed, this is the kind of will required to effectively formulate and adopt the requisite national policies and strategies. However, many respondents indicated that high-level political will, on its own, is not enough. Much more must be done to ensure the implementation of national policies and strategies.

The major challenges to implementation are:

- Lack of coordination and coherence across all government ministries, departments and agencies;
- Low levels of “buy-in” among senior and middle managers/officials, who are more comfortable with the status quo, than with change (i.e., lack of incentives to drive change) – high-level political will not filtering down;
- Lack of understanding of the real challenges faced by local pharmaceutical manufacturers; and
- Poor local industry representation and public-private dialogue.

In addition to the above, there are a number of issues found to affect the implementation of policy and the promotion of a more competitive pharmaceutical manufacturing sector. One of the most frequently raised issues concerned the impact of strong vested interests and market distortions.

Many local pharmaceutical manufacturers have reported facing obstacles that stem from the presence of MNEs. These firms have supplied the local market over many years and can inhibit the entry of new local firms. While MNEs typically have more market share and financial resources to draw from, they have also well-established ways of working with government. In many cases, governments feel more comfortable working with established MNE providers and importers than with new, local manufacturers that are smaller, younger and have a shorter track record.

There have also been examples of regional policies and strategies designed to promote pharmaceutical production. These include the African Union's Pharmaceutical Manufacturing Plan for Africa, launched in 2007, and its related Business Plan (2012), which aim to support local pharmaceutical manufacturing in order to contribute to "increased access to affordable quality medicines" and the "sustainable supply of essential medicines". This should improve public health outcomes and lead to industrial and economic development. UNIDO is working with the African Union Commission on the implementation of this plan under its Global Project on 'Strengthening the Local Production of Essential Medicines in Developing Countries'. This project endeavours to expand and upgrade small and medium-sized enterprises in selected developing countries, mainly in Africa, for the local manufacturing of essential generic drugs, with the objective of enhancing access of the poor to these drugs at affordable prices. This objective is pursued through a combination of advisory, promotional, institutional capacity-building and enterprise level activities to address the complex set of challenges that the local production of essential medicines in developing countries faces.

In West Africa, the Economic Community of West African States (ECOWAS) adopted a Regional Pharmaceutical Plan in April 2014. This plan envisions "a regional pharmaceutical sector, incorporating a vibrant manufacturing industry and a robust regulatory system that is enduring, sustainable, competitive and managed in an integrated manner to be able to provide quality, affordable, safe and efficacious essential medicines that meet the needs of the region and for exports by 2025". The goal of the plan is "to provide a strategic framework within which the pharmaceutical sector in the region will be managed and regulated to provide self-sufficiency in the production, access to and rational use of affordable essential medicines and other medical products of proven quality, safety and efficacy".

The objectives of the plan are:

- To improve and strengthen the governance of the pharmaceutical systems to ensure transparency, accountability as well as patronage of medicines produced in the ECOWAS region by the year 2020;
- To promote and support competitive and efficient regional pharmaceutical manufacturing to ensure the supply of essential medicines produced in the region from 30 to 60 per cent by the year 2020;
- To support pharmaceutical manufacturing in order to achieve international certification for ten pharmaceutical manufacturers by the year 2020;

- To strengthen the National Medicines Regulatory Authorities capacity and quality infrastructure in the ECOWAS region to achieve International Certification and designation as Regional Centres of Excellence by the year 2018;
- To reduce by 75 per cent the incidence of Substandard, Spurious Falsified and Falsely labelled Counterfeit medical products in the ECOWAS region;
- To establish a regional body for medicines regulation in line with the African Union's medicines harmonisation program by the year 2020;
- To facilitate the incorporation of ECOWAS policies on TRIPS flexibilities into national laws of a minimum of ten member states within the region by the year 2020; and
- To formulate and implement policies that will promote innovation, research and development into pharmaceuticals and medicinal products within the ECOWAS region as well as establish a competitive grant in the ECOWAS region by the year 2020.

In East Africa, the East African Community (EAC) Regional Pharmaceutical Manufacturing Plan of Action (2011-2016) recommends strategic interventions to be applied at firm, institutional, national and regional levels to improve the BE for pharmaceutical manufacturing, strengthen associated regulatory capacity and further develop human resource capacity development through a programmatic approach. Specifically, the plan has set out the following primary strategic objectives:

- Promotion of competitive and efficient pharmaceutical production regionally;
- Facilitation of increased investment in pharmaceutical production regionally;
- Strengthening of pharmaceutical regulatory capacity in the region;
- Development of appropriate skills and knowledge on pharmaceutical production in the region;
- Utilisation of TRIPS flexibilities (see discussion further below) towards improved local production of pharmaceuticals; and
- Mainstreaming innovation, research and development within regional pharmaceutical industry.

### 2.2.2 Legal and regulatory framework

While national and regional policies and strategies provide an overarching framework for guiding and coordinating reforms, which endeavour to promote a more competitive and diverse national pharmaceutical manufacturing sector, a legal and regulatory framework that is not fully aligned can undermine these efforts. Indeed, unclear and inconsistent laws and regulations can easily erode investor confidence. Within the pharmaceutical sector, there are a number of common legal and regulatory obstacles to address.

## Intellectual property rights

A key issue for reform in the BE for the pharmaceuticals sector concerns intellectual property rights (IPR). In their review of the literature on IPR in developing economies, Hassan, *et.al.*, (2010) outlines how IPRs in the pharmaceuticals sector affect public health in two ways. First, through their effect on access, where discussion focuses on the links between IPRs, the exclusion of competitors and the availability and pricing of new medicines. Second, by incentivising innovation in the pharmaceuticals sector, which includes expenditure on research and development (R&D).

Syam (2014) describes how MNEs use patents as a business strategy to restrain competition from local firms. To address this problem, the World Trade Organization (WTO) adopted an Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 2001, which aims to narrow the gaps in the way that IPRs are protected around the world and to bring them under common international rules. It establishes minimum levels of protection each WTO Member State must provide. According to a 2002 Decision of the TRIPS Council, least developed countries are exempted from implementing, applying or enforcing the TRIPS provisions on patents and the protection of undisclosed information with respect to pharmaceutical products.<sup>4</sup> Thus, these agreements, the duration of which was extended by the TRIPS Council to 1 January 2033 in November 2015, provide provisions for these countries to develop their local pharmaceutical production.<sup>5</sup> The World Intellectual Property Organization offers technical assistance to help countries become TRIPS-compliant.

Under the TRIPS agreement, developing-country governments are provided with tools, known as ‘flexibilities’, to promote access by local producers to patented pharmaceutical ingredients and also to the know-how and technology to produce patented pharmaceuticals. The importance of TRIPS flexibilities for investment in local pharmaceutical production is that they increase the amount of knowledge in the public domain, limit exclusive rights and promote competition. TRIPS flexibilities enable generic producers to not only access essential materials, but also knowledge (e.g., through re-engineering on a legal basis), which become crucial when entering these markets (GTZ 2007). However, while TRIPS offers safeguards to remedy the negative effects of patent protection or patent abuse, it is unclear whether and how countries can make use of these safeguards when patents increasingly present barriers to medicine access. Indeed, many developed countries and the international pharmaceutical industry pressure developing-country governments to implement patent legislation that goes beyond the obligations of TRIPS and to adopt “TRIPS plus” measures that extend patent life

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<sup>4</sup> WTO (2001): Declaration on the TRIPs Agreement and Public Health. Doha Declaration WT/MIN/(01)/DEC/W/2 of 14 November 2001, paragraph 7 [hereinafter Doha Declaration], and the implementing Decision by the TRIPs Council (2002): Extension of the Transition Period under Article 66.1 of the TRIPs Agreement for Least-Developed Country Members for Certain Obligations with respect to Pharmaceutical Products. WTO document IP/C/25, 27 June 2002.

<sup>5</sup> Syam (2014) indicates that many of the countries in East Africa have been slow to introduce these measures.



beyond the 20-year TRIPS minimum, tighten patent protection, limit compulsory licensing in ways not required by TRIPS, or limit exceptions which facilitate prompt introduction of generics (T'Hoën 2003).

From an industrial development perspective, Hassan, *et.al.*, (2010) describe how the strengthening of IPRs can boost investment in local technologies and manufacturing. However, Moser (2013) disputes this view and finds historical evidence to suggest that most innovations occur outside the patent system. This general analysis is supported by specific pharmaceutical studies showing how IPRs restrict market access, which has only been partially balanced by TRIPS. Indeed, more critical factors for increased investment in local medicine production are adequate infrastructure, qualified human resources in technical and managerial areas and production-distribution logistics systems (Santos Pinheiro 2014).

UNAIDS, WHO and UNDP (2011) recommend that developing-country governments consider revising national intellectual property legislation to ensure that TRIPS flexibilities are incorporated into national laws and regulations. Furthermore, least developed countries should consider taking the necessary legislative action to use the TRIPS transitional period and not to grant pharmaceutical patents until 2016 (as provided for in the Doha Declaration). Similarly, they recommend that governments encourage regional cooperation to develop intellectual property and trade policies that promote innovation, consistent with TRIPS, and that allow for the full use of flexibilities in order to promote access to affordable medicines. The capacity of national medicines regulatory authorities (NRMAs) should be strengthened to ensure the quality, safety and efficacy of health products and to fast track the registration of drugs that are prequalified by WHO. Finally and significantly, governments should “invest in regional and national production capacity in the pharmaceutical sector and in the development of local expertise”.

### **Public procurement**

A common instrument for promoting industrial development in developing economies is the use of public procurement. In many developing economies, government is the largest customer of pharmaceutical products and a number of countries apply a preference to local pharmaceutical supplies. For example, in Zimbabwe a price preference of up to ten per cent is offered. However, producers complain that this is not enough when local manufacturers are required to pay tax on imported raw materials while medicines can be imported without duty or VAT.

A number of respondents to this review also claimed that governments are ignorant of local purchasing capacities and the potential for local firms to provide the products governments require.

An additional factor affecting the procurement of medicines in many developing economies is the role of international agencies, such as the Clinton Foundation, the Bill and Melinda Gates Foundation, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATAM). These agencies and programmes bring vast sums of money to the sector and have a profound impact on the market for pharmaceutical products.

Many of these are more interested in purchasing the drugs required at the lowest possible price and have little interest in the development of local industry. Thus, procurement processes typically favour large MNE-providers.

### **Tariffs and taxes**

A common issue affecting pharmaceutical manufacturing is the tax regime, which is often skewed in favour of importing medicines. In Zimbabwe, for example, imported drugs are exempt from tariffs and value-added tax (VAT). However, the imported drug components (i.e., raw materials) required for medicine manufacturing are not. Furthermore, import permits and duties, including non-GMO (genetically modified organism) certification, are needed for raw materials for local produced medicines.

### **2.2.3 Regulation and quality assurance**

The need for good regulation and quality assurance in the production of medicines is obvious. As described earlier, pharmaceutical products must be of a standard and consistency that does not endanger patients.

The quality of pharmaceuticals is a function of many dimensions including:

- The level of active pharmaceutical ingredient (API) content;
- Appropriate formulation impacting on the pharmaco-kinetics of the drug (e.g., peak concentration, dissolution profile of drug);
- Degradation of the product due to many possible factors such as poor production or inappropriate storage and distribution;
- Contamination of the product with other drugs, with impurities, or following the degradation of the API, for example, during transport or once it has been formulated;
- Mislabelling of products; and
- Microbial contamination of product.

Respondents described the manner in which these regulations and standards are designed and enforced in developing countries as costly, inefficient and biased against local production.

### **Standards**

The process of standard setting in the pharmaceutical sector appears to be generally well regarded. A number of respondents indicated that there is sufficient industry involvement in these processes. However, the greater concern was with counterfeiting and sub-standard products being introduced into the market, which was seen as a result of porous borders and weak inspection. While this is often seen as a problem for African countries, Vietnam also identified the movement of counterfeit products through porous borders as a problem. As discussed below, many government agencies, such as the national medicines regulatory agency, are poorly equipped to deal with this problem, as are customs authorities.

## **Regulatory authorities**

While standard setting has not been raised as a concern, there is significant disquiet regarding the functioning of national regulatory authorities. IMS Health claims “weak regulatory mechanisms are more pronounced in Africa relative to other parts of the world” (IMS Health nd, p.13). The African Union (AU 2012) claims that the level of regulatory oversight across Africa “varies but in general it is insufficient to protect our citizens and to allow fair competition in our pharmaceutical markets”.

National medicines policies and laws establish a legal framework for the existence of a national medicines regulatory authority (NMRA). These agencies are typically responsible for the regulation and control of medical products such as medicines, vaccines, blood products and medical devices. They contribute to promoting and protecting public health by ensuring that (WHO 2015b):

- Medicines are of the required quality, safety and efficacy;
- Health professionals and patients have the necessary information to enable them to use medicines rationally;
- Medicines are appropriately manufactured, stored, distributed and dispensed;
- Illegal manufacturing and trade are detected and adequately sanctioned,
- Promotion and advertising is fair, balanced and aimed at rational drug use; and
- Access to medicines is not hindered by unjustified regulatory work.

Currently within the EAC, only three countries (Kenya, Uganda and Tanzania) have NMRAs that are operational while the other two countries (Burundi and Rwanda), carry out national medicines regulatory functions within the national ministries of health. These countries are currently in the process of establishing NMRAs. The regulatory regime of EAC countries in the region is characterised by a move towards creation of semi-autonomous government agencies to spearhead the national regulatory affairs. Across the EAC partner states, there is shortage of skilled human resource in NMRAs.

In West Africa, there are two different NMRA systems regulating health-related products. English-speaking countries have a system in which the regulatory functions are centralised in a semi-autonomous or autonomous body. The French and Portuguese-speaking system has regulatory functions shared between several bodies under the authority of the ministry of health. ECOWAS (2014) indicates there is a need to improve regulations, which include “the restructuring or establishment of NMRAs to enable them to undertake their regulatory activities more effectively, developing and implementing comprehensive guidelines and procedures for drug registration and strengthening human capacity at NMRAs in Partner States”.

Some respondents raised important concerns regarding the independence of regulators. They referred loosely to instances where regulators had not taken action against uncompetitive activities by entrenched MNE suppliers; activities that undermined the potential for new entrants in the market.

As indicated above, there is also wide spread concern regarding the capacity and competency of regulators. Many complained that the regulators are under-staffed and under-resourced.

IMS Health argues that the key to improving regulatory services is to “strengthen the regulatory and approval process by engaging local stakeholders to gain clarity on the application process, participating in regional harmonisation efforts such as those led by the World Bank, and sharing expertise with government stakeholders. Such efforts will streamline the registration process within and across countries, particularly those aiming for regional harmonisation” (IMS Health nd, p.21).

### **Testing facilities**

A major weakness faced by regulators in developing countries is the lack of accredited testing facilities. Testing laboratories are expensive to set up, run and maintain because of equipment costs, cost of chemicals, reagents and reference standards, retention of qualified human resource personnel, provision of constant supply of electricity, running water, etc.

In the ECOWAS region, the sale of medicines on the open unregulated market makes the region particularly susceptible to the circulation of substandard and counterfeit medicines. The situation is further compounded by poor quality assurance infrastructure for testing suspected products. A survey conducted under the auspices of WHO in 2011, showed that 17 national testing laboratories were in existence in the ECOWAS region providing support to the NMRAs in regulatory assurance of the quality of medicines.

In the EAC there are only three drug quality control laboratories. One, in Kenya, is pre-qualified by the WHO. The two others, one in Uganda the other in Tanzania, are in the process of prequalification and accreditation to meet international standards.

In Vietnam there are two national institutes of drug quality control, one in Hanoi, the other in Ho Chi Min City. In addition, there are 52 provincial drug quality controls centres.

### **New product registration**

Typically, there are few ‘new’ products brought for registration in most developing countries. Instead, well-known generic drugs are imported, which local manufacturers wish to produce. Many pharmaceutical manufacturers complain that the processes for new product registration are costly and time-consuming.

IMS Health has identified the following common hurdles in bringing new products to market (IMS nd, p. 13):

- **Registration processes:** The lack of available dossier standards and poor delineation of decision makers leads to lengthy and often very disparate timeframes for registration. For example, the regulations for registering a drug across SSA vary significantly, but in some cases are time consuming,

opaque and open to corruption.<sup>6</sup> Weak regulations and their enforcement increase both costs and risks.

- **Pricing and reimbursement:** Within the public sector, barriers include non-transparent tendering and procurement processes, the absence of pricing strategy, limited opportunity for reimbursement and lack of tiered pricing levels. In the private market, companies face the challenge of fragmented payer channels between donors, private insurers and employers, as well as high out-of-pocket expenditure imposing access limitations.
- **Distribution:** Inadequate regulatory oversight, risking the entry of substandard and counterfeit medicines, as well as weak infrastructure in cold chain, ordering and transport can be key challenges for distribution in the public sector. Lack of expertise in stock management, poor education and irregular energy supply are major contributors. Challenges in the private sector include fragmented wholesaler and distributor channels, expensive credit and variable quality among local distributors.
- **Marketing and sales:** Efforts to reach out to the public market can be hindered by limited knowledge among physicians regarding disease states and medicine needs. This is due to weak education and insufficient numbers of pharmacies and clinics to distribute medicines to those who need them. Barriers to marketing in the private sector include limited business experience among staff and talent retention among staff. Additionally, specialised and innovative medicines may be challenging to promote due to inadequate knowledge of the related disease among sales staff and physicians.
- **Pharmacovigilance:**<sup>7</sup> Although some MNCs conduct their own pharmacovigilance surveillance in Africa, much of the data is not centralised or examined at the national level. In reality, governments have limited to no means of monitoring medicine use in a target population or sufficient human resources and informatics capabilities at clinics. Clinicians in turn are unfamiliar with the practice and wary of admitting liability. The private market also lacks treatment guidelines and/or the incentives to adhere to them.

The use of an Abbreviated New Drug Application (ANDA) can be an efficient means of introducing a new product. An ANDA is an application for a generic drug approval for an existing licensed medication or approved drug. The ANDA is submitted to the regulator, which provides for the review and ultimate approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the public. A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. Generic drug applications are

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<sup>6</sup> These variations are endemic: according to interviews, in Rwanda it can take only two weeks to register a product; in South Africa, 3-4 years.

<sup>7</sup> For the uninitiated, 'pharmacovigilance', also known as 'drug safety', is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products.

termed 'abbreviated' because they are generally not required to include preclinical (i.e., animal and in vitro) and clinical (i.e., human) trial data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product is bio-equivalent (i.e., performs in the same manner as the innovator drug).

### **Regional harmonisation of regulations**

Some of the problems of new product registration are exacerbated when access to regional markets are considered. In many countries in Africa, for example, new product registration must be repeated in every country of the region. This is a burdensome process of applying multiple times across many neighbouring countries. Thus, there is a need for regional harmonisation and mutual recognition of product registrations and approvals.

Both ECOWAS and the EAC have somewhat similar plans for the regional harmonisation of pharmaceutical regulations. Each of these was presented above: the ECOWAS Regional Pharmaceutical Plan and the EAC Regional Pharmaceutical Manufacturing Plan of Action. It is interesting to note the focus these plans have on regulatory issues and, in particular, the harmonisation of regulatory frameworks across their respective regions. The ECOWAS Regional Pharmaceutical Plan's objectives in this regard deal with improving and strengthening "the governance of the pharmaceutical systems to ensure transparency, accountability as well as patronage of medicines produced" in the region; strengthening the NRMAs' capacity and quality infrastructure to achieve International Certification and designation as Regional Centres of Excellence; significantly reduce the incidence of substandard, spurious falsified and falsely labelled counterfeit medicines; the establishment of a regional body for medicines regulation; and the incorporation of ECOWAS policies on TRIPS flexibilities into national laws of a minimum of ten member states. The EAC Regional Pharmaceutical Manufacturing Plan of Action contains a number of regulatory issues, such as the strengthening of pharmaceutical regulatory capacity in the region; the utilisation of TRIPS flexibilities.

In addition, the African Medicines Regulatory Harmonisation (AMRH) Initiative has been developed as a programme of the African Union's Pharmaceutical Manufacturing Plan for Africa. The New Partnership for Africa's Development (NEPAD), the World Bank, WHO, and the Bill and Melinda Gates Foundation support the initiative, which aims to improve public health by increasing access to good quality, safe and effective medicines through the harmonisation of medicines regulations. This includes the reduction of the time taken to register essential medicines for the treatment of diseases. In harmonising medicines regulations, it is anticipated that a positive impact will be made on:

- Access: communities get quicker, greater access to priority essential medicines of good quality;
- Availability: the availability of affordable essential medicines can be improved through simplified, harmonised, efficient and transparent regulatory approval processes; and

- **Affordability:** with more generics (lower priced) on the market, patients can achieve greater savings, and governments and donors can enjoy cost savings from subsequent downward pressure on prices through enhanced competition and pooled (shared) procurement.

## Institutional arrangements

### **Government oversight and coordination**

Addressing the challenges faced by local pharmaceutical manufacturers and effectively implementing the integrated and multi-faceted elements of a pharmaceutical development policy or strategy requires high-level government coordination. As indicated above, many respondents were not convinced their governments were achieving this.

In the case of Kenya, the government implements the KPSDS through the Ministry of Industrialization—dealing with industry development matters—and the Ministry of Medical Services—dealing with medicines and health. The KPSDS recommends the establishment of a Steering Committee to guide its implementation, led by the Permanent Secretary of the Ministry of Industrialization and the Permanent Secretary of the Ministry of Medical Services. The committee would make the overall policy decisions and monitor implementation, while a working group would be responsible for the actual implementation activities and would make progress reports to the Steering Committee. For efficacy of implementation, the KPSDS could be made part of the performance contracts of the government departments and officials involved.

### **Industry representation**

In general, there are national organisations representing pharmaceutical manufacturers. In Vietnam, the Vietnam Pharmaceutical Companies Association was established in 2000 and represents all pharmaceutical manufacturers. It is a member of the Vietnam Chamber of Commerce and Industry.

In Zimbabwe, the Pharmaceutical Manufacturers' Association is an affiliate of the Confederation of Zimbabwe Industries, which is the umbrella body representing all manufacturing companies in the country. To that extent the industry is well represented. However, the capacity of the association is constrained by limited resources and a small membership: it does not have a fully-fledged secretariat or administration offices. It is also unable to fund the research to garner the required evidence to inform policy reform it will be advocating for. The Pharmaceutical Manufacturers' Association is also an employment council and represents the industry in wage negotiations for the sector. It is also represented in the boards' of regulatory bodies such the Pharmacists Council of Zimbabwe and Medicines Control Authority of Zimbabwe. In its advocacy mandate it constantly engages the government through its relevant ministries that include Ministries of: Health and Child Care; Industry and Commerce and Finance among others.

There are industry associations at sub-regional level in Africa, such as the Southern African Generic Medicines Association, the Federation of East African Manufacturers Pharmaceutical Manufacturers, and the West African

Pharmaceutical Manufacturers Association. Across the continent, there is the Federation of African Pharmaceutical Manufacturers Associations. More broadly, there is a range of international associations, including the International Federation of Pharmaceutical Manufacturers and Associations, and the International Pharmaceutical Congress Advisory Association.

### **Public-private dialogue**

In general, there appears to be very little evidence of regular and effective public-private dialogue (PPD) in the local pharmaceutical manufacturing sector. While some countries have established PPD mechanisms involving a broader business body, such as chambers of commerce and industry, there was little evidence found where this occurs specifically among emerging local pharmaceutical manufacturers.

### **Other factors affecting the development of the pharmaceutical sector**

In addition to the above BE concerns, there are other factors that appear to affect pharmaceutical production in many developing countries.

#### **Good Manufacturing Practices**

As described earlier in this chapter, WHO and UNIDO are working in various developing countries to support improved compliance with GMP in the pharmaceutical sector. This is largely because of the significant deficits that have been found in manufacturing practices. This support has largely focused on regular, standardised assessments and diagnosis of manufacturing facilities and the provision of technical assistance to firms, along with other support for plant upgrading, such as solutions for increasing access to finance.<sup>8</sup>

#### **Access to finance**

Many local pharmaceutical production facilities require funds to introduce GMP as well as to expand. However, access to finance in developing economies can be very difficult to obtain.

#### **Infrastructure and logistics**

Unreliable supporting infrastructure such as electricity, water and transport creates additional costs to pharmaceutical manufacturing. Similarly, market logistics can be difficult to deal with. Many market systems in developing countries are still structured along colonial lines (e.g., Francophone countries in Africa are often supplied by firms based in France or Belgium), while local and regional markets do not operate effectively.

#### **Cost structure**

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<sup>8</sup> In Kenya, UNIDO and the Government of the Republic of Kenya have established a 'GMP Roadmap', described as a "stepwise approach for the pharmaceutical industry to attain WHO GMP standards". The Kenya GMP Roadmap document covers fundamental principles in line with WHO GMP and presents a two-phased approach. The first phase focuses on the establishment of WHO GMP compliant manufacturing sites. The second phase focuses on the establishment of a comprehensive Quality Management System.



The EAC Secretariat (2011) describes how pharmaceutical manufacturers operating from within the EAC region and SSA generally produce at a cost disadvantage to larger generic product manufacturers internationally. This is due to a variety of reasons, including scale, expensive asset-bases, coupled with older technology, higher financing costs as well as a lack of integration with active pharmaceutical ingredients suppliers. However, Chudhuri and West (2014) describe how higher costs are an issue for African manufacturers: “higher costs need not necessarily lead to higher prices”. They argue that to enable local companies to access the required market, what is required is the active intervention of the government, including initiatives for the regional economic communities. One option is to enlarge the “list of products which should not be imported into the national or regional markets subject to the condition that the prices must not be above the international reference prices”. Other options include restricting public procurement or reimbursement under the national insurance to locally manufactured products again subject to the price restriction and quality considerations.

### **Skill deficits**

The EAC Secretariat (2011) suggests that the local pharmaceutical production industry in East Africa faces shortages of skilled professional personnel. Skills deficits were also raised as a problem in Kenya. In general, respondents to this review indicated that there are few trained and experienced *industrial* pharmacists (as opposed to retail pharmacists), microbiologists and operations managers.

### **Research and development**

Very limited public or private investments are made in R&D in Africa. While many pharmaceutical companies invest in R&D, this is often done in facilities located in advanced economies. Both the ECOWAS Regional Pharmaceutical Plan and the EAC Regional Pharmaceutical Manufacturing Plan of Action support the formulation and implementation of policies that will promote innovation, research and development into pharmaceuticals and medicinal products.

### **Limited data**

Many respondents referred to the lack of sufficient data on pharmaceutical markets in developing countries. This makes planning and policy development and reform difficult.

## **2.3 Lessons learned**

The following lessons from BER practices in the pharmaceuticals sector have been identified:

- Political will at the highest level is required to drive reform. However, there is also a need for this commitment to permeate the lower levels of the government bureaucracy so reforms can be understood and adopted by those who are directly affected.

- Good coordination across a range of government ministerial portfolios and sector agencies is required. Reforms in this sector affect health, industry, commerce, and trade portfolios, among others. If there is a lack of coordination, then reforms are unlikely to succeed.
- A “step-wise” approach is needed in which reforms and capacity building efforts designed to boost local manufacturing capacity go hand-in-hand.
- Government policy makers, regulators and programme managers must develop a clear understanding of the practical challenges faced by local manufacturers. This requires regular consultation and public-private dialogue, involving large and small-scale manufacturers.
- There is a need for better market information to accurately assess the market dynamics, including information on the importation of medicines.
- Laws and regulations can be used in an anti-competitive manner. There should be a consistent commitment to promoting competition within local markets and to ensuring present incumbents, whether they are multi-national enterprises or large national companies, are not allowed to unfairly protect their position in the market.
- Because local markets may be small, there is a need to support the regional harmonisation of policies, laws and regulations to promote great cross-border trade in pharmaceutical products.
- Many regulations and standards in this sector were found to be unnecessarily costly, inefficient and biased against local producers.
- Programmes are required to build the capacity and autonomy of regulators in this sector so that they are able to fulfil their mandates effectively.

## 3 Renewable Energy

This chapter presents the findings of the sector review into renewable energy (RE) focussing on the issues affecting the promotion of on-grid energy production. This is where RE production is fed into the existing power grid, rather than through a local, off-grid system or a hybrid system. This case presents the challenges of an entirely new industrial sector. Governments and their development partners support investment promotion, IP and BER efforts to encourage private investment into new technologies and business models. This requires a high degree of government coordination and integration across a range of policy portfolios.

While on-grid RE production and distribution typically involves large-scale enterprises, there are growing opportunities for medium-sized firms. Where possible, this chapter highlights the BER affecting firms of this size.

### 3.1 Sector overview and characteristics

The International Energy Agency (2008) has defined RE as “derived from natural processes that are replenished constantly. In its various forms, it derives directly or indirectly from the sun, or from heat generated deep within the earth. Included in the definition is energy generated from solar, wind, biomass, geothermal, hydropower and ocean resources, and biofuels and hydrogen derived from renewable resources”. The development of RE systems requires a range of mechanisms that encourage private investors to invest in new technologies. The United Nations Environment Programme (UNEP 2011, p. 22) suggests that the transition to a green economy requires specific enabling conditions: national regulations, policies, subsidies and incentives, as well as international market and legal infrastructure, trade and technical assistance. “Currently, enabling conditions are heavily weighted towards, and encourage, the prevailing brown economy, which depends excessively on fossil fuels, resource depletion and environmental degradation”.

RE represents promising responses to energy security and energy mix diversification of all countries whilst responding to their sustainability ambition. For developing countries, scale is needed in the supply of RE to provide access to modern energy services. Currently, 80 per cent of global energy needs or 66 per cent of power supply are fossil fuel-based, and global energy systems currently represent some 60 per cent of total current greenhouse gas emissions. In a business-as-usual scenario, the world’s energy needs will increase by almost 60 per cent in 2030. All climate mitigation scenarios comprise an increase in renewables, and all underscore that policies are needed to accelerate RE capacity installations by helping to overcome various barriers. This is closely linked to the decoupling of traditional growth patterns from energy use (Rickerson, *et.al.*, 2012).

The Renewable Energy Network for the 21<sup>st</sup> Century (REN21, 2014) estimate that RE provided 19 per cent of global final energy consumption in 2012. Of this,

modern renewables accounted for approximately ten per cent, with the remainder, estimated at just over nine per cent, coming from traditional biomass.

### 3.2 The business environment for on-grid renewable energy production

There is a significant body of literature dealing with the BE for RE production. Much of this responds to the specific concerns private investors face when entering, or being encouraged to enter, the RE market. The European Union Energy Initiative Partnership Dialogue Facility describes the components of an energy market system as “the entire system delivering energy services, including all its component parts, subdivided into three functional levels: the energy market chain, the required inputs, services and finance, and the enabling environment factors”. The BE is located above the market chain and covers the diverse set of factors that act as the ‘rules of the game’, shaping how the market chain and inputs, services and finance operate. This environment is often generated by institutions (i.e., national and local authorities and research agencies) and comprises policies, regulations and cultural practices. Three types of BE factors are identified (European Union Energy Initiative Partnership 2015):

- Factor 1: Political and regulatory factors:** these include the specific political and regulatory factors which affect the energy market chain and inputs and services (e.g., national rural electrification plans, forestry and agricultural development plans, energy tariff and electricity concession regulations, quality control regulations, regulatory permits and licences, fiscal regulations, economic regulations, including subsidies on fuels and appliances, and trade regulations, including import taxes on energy goods such as solar PV equipment, batteries and imported improved cook stoves).
- Factor 2: Social and cultural factors:** these include the social and cultural factors that affect the effective exploitation of particular energy services and appliances as well as their demand by the end users (e.g., lack of awareness and specific knowledge about the benefits or negative impacts of energy use, informal community ownership rules of resources such as rivers and forests, social norms concerning cooking habits, misconceptions around the performance of energy technologies, such as the level of lighting from solar PV systems),
- Factor 3: Financial and economic factors:** this includes the financial and economic factors that influence the delivery and affordability of a range of energy products and appliances (e.g., income levels and livelihood strategies of end users, end users’ ability to pay, formality of payment systems, level of local economic activity).

In addition to the three factors identified above, there are ‘wider aspects’ typically associated with the market’s environment, but which typically go beyond the scope of energy sector reforms and market development (European Union Energy Initiative Partnership Dialogue Facility 2015):

- **Global market trends:** global technology development trends as well as the demand for, and costs of, materials and energy goods that affect the availability and affordability of energy services.
- **Macroeconomics:** political and economic stability and levels of macro-economic indicators (e.g., growth, inflation and exchange rates) affect the willingness of potential market actors to engage in specific energy market systems.
- **Social and cultural norms:** the collective beliefs of consumer groups within urban or rural settings of developing countries shape decisions with respect to the consumption of a range of energy services.
- **Major infrastructure:** this includes infrastructure that is beyond the scope of a particular energy sector (e.g., roads, telecommunications, aqueducts).
- **Environmental and ecosystem factors:** this includes rain regimes, quality of soil, presence or absence of minerals or plants for fuel, etc.
- **Legal system and enforcement:** the robustness of the legal system, confidence in contractual enforcement, clarity in relation to issues such as land ownership, and a business-friendly environment in relation to factors such as repatriation of earnings, are all considerations for investment decisions by prospective market actors.

As with the other sectors reviewed in this report, the key dimensions of the BE, as defined by the DCED (2008), are applied to the assessment of on-grid RE production:

- Policy development and reform;
- Legal and regulatory framework; and
- Institutional arrangements.

Each of these dimensions is presented in detail below.

### 3.2.1 Policy development and reform

All respondents to this review were unanimously in favour of the need for a comprehensive and integrated policy framework that establishes a long-term vision for the development of RE and a coherent set of strategies that outline the manner in which this vision will be realised. Indeed, a wide range of literature on this topic also supports this view. For example, Couture, *et.al.*, (2015, p. 1) indicate that growth in the RE market has been driven by a combination of factors, including government policy, rising energy prices, and rapidly declining RE costs.

REN21 (2014) report that by early 2014, at least 144 countries had RE targets and 138 countries had RE support policies in place, up from the 138 and 127 countries, respectively. Developing and emerging economies have led this expansion in recent years and account for 95 of the countries with support policies, up from 15 in 2005.

National policies and strategies are needed to integrate a range of ministerial portfolios. These include, for example, ministries of energy, industry and the environment. In addition, national policies and strategies must incorporate the

roles of different levels of government, from national to local, recognising their differing mandates and powers, and integrating these into a coherent approach.

REN21 (2014) report that governments are increasingly aware of renewable energy's potential role in advancing national development. "While the primary objective of developing a RE sector is often to maintain or expand energy services, the far-reaching impact of these technologies adds several co-benefits including: reducing the health and environmental impacts associated with the use of fossil and nuclear fuels, improving educational opportunities, creating jobs, reducing poverty, and increasing gender equality".

### **Functions of a policy and strategy**

A key function of national policies and strategies is to establish a long-term set of visions and goals that the government and private sector aspire to. Investments in RE typically take a long time before they can generate a return—up to 15 or 20 years—and this requires a stable and consistent policy framework.

Policy coherence and coordination is also required because of the nature of RE, which is typically a fluctuating power source. As a result, RE requires a mechanism that responds to these fluctuations and accommodates energy from other sources, including other RE sources.

Thus, a national RE policy or strategy fulfils a number of functions:<sup>9</sup>

- Outlines the vision and rationale for RE;
- Defines a set of strategies and approaches to realise the vision and goal;
- Sets targets for RE production as a proportion of total energy production;
- Establishes clear rules of the game for public and private actors within a given market system;
- Balances economic, social and environment concerns;
- Defines risks and revenues, and establishes instruments to respond to these;
- Determines the viability of relevant business models;
- Creates mechanisms for unlocking financing opportunities;
- Coordinates government ministries, departments and agencies.

Ashden and Christian Aid (2014) make two broad recommendations to policy makers regarding the creation of an enabling environment for RE. First, put in place policies and support mechanisms for energy enterprises that create a conducive operating environment, which help RE energy enterprises access finance. Second, develop proactive national strategies for energy access, which include "positive mechanisms that enable energy enterprises to thrive, and the responsible phasing out of policies that encourage unsustainable energy usage", such as kerosene subsidies.

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<sup>9</sup> Adapted from European Union Energy Initiative Partnership Dialogue Facility (2014).

Presenting the findings of a survey of business people and non-government organisations (NGOs) involved in enhancing energy access in developing economies, Bellanca and Wilson (2012) identified a series of policy issues:

- High import duties and taxes;
- Subsidies for fossil fuel, but fewer policy incentives for RE;
- The monopolisation of electricity provision with a lack of support for decentralised power generation;
- The need for better co-ordination of aid programmes and a better understanding of markets on the part of aid agencies;
- The need for non-traditional forms of up-front investment for testing new technologies, building infrastructure and creating markets;
- A lack of business support services or existing infrastructure;
- Developing payment models that address end user finance (i.e., to allow low-income users to obtain access to energy avoiding unaffordable up-front costs);
- Lack of quality standards, certification and guarantee is undermining consumers' trust in technology, making market expansion slower.

One key feature of a national RE policy or strategy is the use of targets for the production of RE. These are presented in terms of the proportion of RE production compared with the total energy consumption. Some respondents to this review suggested that while a common approach was to present RE targets in terms of volume, a better approach is to formulate targets in percentage terms. Thus, the aim would be to see an increase over time in the percentage of RE contributing to the overall energy mix. This, it is argued, would improve policy coherence.

The table below presents an outline of the levels of RE policy.

**Figure 1: Levels of RE policy**

| <b>Level</b>   | <b>Relevance</b>  |
|--|---|
| <b>Global</b>  | National level policies, e.g., fiscal, employment, development agendas etc. |
| <b>Sector-specific</b>   | Energy policy<br>Energy strategy  |
| <b>Sub-sector specific</b><br>(i.e., primary regulation)       | Petroleum policy/law<br>Electricity policy/law<br>Cooking energy policy/law |
| <b>Market-segment specific</b><br>(i.e., secondary regulation) | Specific policy issues relevant to market actors                            |

SOURCE: Franz (2014)

## **Some examples of national policies and strategies**

### Indonesia

In recent years, Indonesia has introduced several initiatives and regulations to shift away from the dependence on fossil fuel and moving towards RE. The *Presidential Regulation No.5/2006* has established a national target for RE generation to be achieved by 2025. This was eventually translated into the *2007 Energy Law*. According to this policy, the share of RE will be 17 per cent of total primary energy consumption in 2025. In this context liquefied coal is also considered as a renewable source which is expected to contribute two per cent of the RE share. In order to achieve this target, the Ministry of Energy and Mineral Resources has proposed the plan to increase the capacity of RE from 2012 until 2015. Around 15 GW of accumulated RE capacity is expected in 2015. Large hydropower will be a dominant source of RE.

In 2011, Indonesia announced the *Vision25/25*. According to this, the share of RE will increase to 25.9 per cent in 2025, 30.9 per cent in 2030, and 39.5 per cent in 2050. These targets have not yet been finalised and adopted as a regulation or law. However, it shows a tendency to replace the old targets set by the *Presidential Regulation No.5/2006* in the near future.

The Government of Indonesia and Asian Development Bank (2015, p. xviii) claim that universal electricity access is “a matter of policy, not a consequence of wealth or settlement patterns... Government policy and commitment determines whether universal access can be achieved. Electrification is a necessary (but not sufficient) driver of economic growth rather than a consequence of economic growth”.

### Kenya

The Sessional Paper No 4 of 2004 identified the need to integrate energy planning with the national economic, social and environmental policies. At the sector level, there are close linkages between the various forms of energy and this requires integrated energy planning to improve coordination. The Energy Act, No 12 of 2006 assigned the responsibility for development of indicative national energy plans to the Energy Regulatory Commission (ERC). To fulfil this mandate, ERC has established a committee with responsibility for preparing and updating the Least Cost Power Development Plan (LCPDP). The Ministry of Energy and Petroleum has drafted documents that set out the national policies and strategies for Kenya's energy and petroleum sector in line with the new 2010 Constitution and in tandem with Vision 2030.

The law encourages the development and use of RE in the following fields:

- Formulating a national strategy for coordinating research in RE;
- Providing an enabling framework for the efficient and sustainable production, distribution and marketing of biomass, solar, wind, small hydro, municipal waste, geothermal and charcoal;



- Promoting the use of fast maturing trees for energy production including biofuels and the establishment of commercial woodlots including peri-urban plantations;
- Promoting the use of municipal waste for energy promoting the development of appropriate local capacity for the manufacture, installation, maintenance and operation of basic renewable technologies such as bio-digesters, solar systems and hydro turbines;
- Promoting international co-operation on programmes focusing on RE sources;
- Harnessing opportunities offered under the clean development mechanism and other mechanisms including, but not limited to, carbon credit trading to promote the development and exploitation of RE sources;
- Promoting the utilisation of RE sources for either power generation or transportation;
- Promoting co-generation of electric power by sugar millers and sale of such electric power through the national grid directly to the consumers; and
- Promoting the production and use of gasohol and biodiesel.

### **Evolving trends in national policy**

As the RE industry evolves, so too are the policy instruments that are designed to foster growth in this sector. UNEP (2011) argues that government policy to support increased investment in RE needs to be carefully designed in an integrated manner; there is no one-size-fits-all approach:

The range of regulatory policies, fiscal incentives and public financing mechanisms to support renewable energy is broad and can be complemented with support to R&D as well as other measures, such as those to stimulate investments in adapting grid infrastructure. The diversity of circumstances among countries, including existing energy systems and potential renewable development, requires that policy frameworks be carefully designed and tailored to specific situations (UNEP 2011, p. 203).

In their review of RE policy frameworks, Couture, *et.al.*, (2015) identify three emerging RE policy trends. First is the desire to support a diversity of investors and project sizes across the RE sector. Second is the need to design new policy approaches to deal with markets that have reached, or surpassed, socket parity. Third is the push to integrate non-hydro renewable electricity technologies into wholesale spot markets. They find that distinctions between conventional policy labels are transforming as policymakers adapt policy frameworks to new RE market realities.

“These innovations have been driven by a number of factors, including the decreasing costs of renewable energy technologies, the difficulty in adjusting policies to rapidly changing market conditions, and the growing share of renewable electricity in some countries’ overall electricity mix. Collectively, these factors are leading policymakers to develop new

frameworks that are better adapted to changing market circumstances. In some cases, this has meant creating new policies that lie somewhere between traditional FITs and net metering or auctions, while in others, it has meant exposing renewable electricity producers to spot market signals while attempting to retain some minimum level of revenue certainty by adopting so-called premium FITs (Couture, *et.al.*, 2015, p. 31).

This view is supported by Rickerson, *et.al.*, (2012) who suggest that policymaking involves inherent trade-offs and is dynamic involving new and innovative ways. The continual evolution of RE policies has led increasingly to “blended policies that share many of the same design elements”. Different countries have implemented the same policies in different ways and most countries have updated their policies over time.

UNEP (2011) suggests that national level reforms should include:

- Changes to fiscal policy, reform and reduction of environmentally harmful subsidies;
- Employing new market-based instruments;
- Targeting public investments to green key sectors;
- Greening public procurement; and
- Improving environmental rules and regulations, as well as their enforcement.

### **Policy and business environment reform**

RE policy is required to deal with a wide range of BE issues, including the legal, regulatory, administrative, and institutional arrangements, discussed in the sections that follow. Mani (2012) has identified a series of general, crosscutting factors, the ‘Ten Cs’, found to affect the BE for RE production and distribution:

- **Clarity and coherence:** policies and laws on clean energy should be very clear and transparent as well as coherent. They should send a strong signal about the country’s intention to move toward cleaner or low carbon energy options.
- **Consistency:** policies have to be consistently implemented across sectors and regions of a country. In a federal structure, for example, the national standard should guarantee a minimum level of RE development, with states being allowed to set more aggressive targets if needed.
- **Commitment and credibility:** for policies to be credible, governments should signal a long-term commitment to the RE sector, backed by a comprehensive and transparent regulatory and tariff structure.
- **Clearances:** investors are often discouraged by the number of clearances required to set up, for example, a wind or solar farm; the approval process can be eased considerably by setting up a single-window clearance system or a no-objection based approval process for specific sectors.
- **Capacity:** as countries ambitiously expand their clean energy portfolios, the capacity of agencies should be enhanced to ensure compliance with targets, policies and regulations.

- **Compliance:** investors often are concerned about utilities' commitment to comply with Power Purchasing Agreements (PPAs). It is therefore important to establish transparent cost recovery rules and prudency tests for utility compliance with policies and contractual arrangements. It is also necessary to ensure utilities' compliance with any obligations they may have to purchase RE or RE certificates.
- **Coordination:** coordination across the multitude of agencies involved in the clean energy sector (regulatory agencies, implementing agencies, utilities, distribution companies, etc.) is critical to ensure that clean energy policies are implemented consistently and efficiently.
- **Collateral:** banks are often reluctant to finance clean energy projects because of concerns about the bankability of the PPAs, which are often related to utilities' compliance. Until clean energy becomes as competitive as conventional energy, countries should consider specialised vehicles or institutions that could ensure adequate clean energy financing and help to mitigate risk.
- **Connectivity:** access to the grid is an important criterion for investment in the renewable energy sector. Investors look for transparent rules, procedures and standards for grid connectivity for the energy they produce.
- **Cartography:** since the quality and availability of RE (i.e., wind, solar, hydro, biomass) varies across locations, the accurate mapping of potential sites will have a bearing on returns to investment.

Mani (2012) proposes a Climate Investment Readiness Index to determine the extent to which countries have addressed the full range of policy-related factors that affect private investment in RE. See the table on the following page.

Finally, REN21 propose the following recommendations to policy makers:

- Facilitating more-rigorous adaptation of the energy system to increase shares of renewable energy;
- Creating a level playing field for the entire energy sector;
- Securing stable policy frameworks for renewables;
- Harnessing local action to ensure global renewable energy uptake;
- Ensuring long-term and differentiated policies to sustain and increase investment levels;
- Paying greater attention to the heating and cooling and the transport sectors; and
- Improving energy data to monitor advancements in achieving a renewable energy transition.

**Figure 2: Key Indicators for Climate Investment Readiness Index**

| <b>Cross-cutting indicators</b>   |   |
|---|---|
| 1   | Existence of RE policy and law (i.e., RE policy, RE law)  |
| 2   | Existence of RE targets   |
| 3   | RE purchase or off-take obligations   |
| 4   | Availability of tradable instruments for RE   |
| <b>Sector specific indicators for solar PV, wind, biomass and small hydro</b> |   |
| 1   | Preferential tariffs for solar/wind/biomass/small hydro   |
| 2   | Grants/subsidies/incentives related to capital/investment tax credits                           |
| 3   | Incentives linked to generation/production tax-credits  |
| 4   | Income tax holidays/exemptions  |
| 5   | Trade-related incentives (e.g., customs duty exemptions, absence of local content requirements) |
| 6   | Other tax exemptions (VAT, excise, etc.)  |

SOURCE: Mani (2012)

### 3.2.2 Legal and regulatory framework

As with other sectors reviewed in this report, the aspirations of national policy and strategy are often undermined by barriers that are found in the legal and regulatory framework. However, when considering this framework there are two categories of issues that can be considered. The first concerns the laws and regulations that have been introduced to encourage private investment in the RE sector. The second concerns the common constraints found that in some way contradict or compete with the first category.

#### Enabling laws and regulations

As discussed above, national policies and strategies are formulated to guide government and the private sector in the pursuit of an agreed vision for RE. Once this is in place, new laws and regulations are formulated to ensure the implementation. One of the first efforts this involves is the creation of an energy law.

#### Energy law

Energy, electricity or RE laws or acts establish the legal and institutional framework for public planning and the implementation and enforcement of regulations for rural electrification in general and mini-grids in particular, usually through an act of parliament. They lay down the responsibilities of important actors and provide the basis for any specific regulations or promotion instruments. All the instruments presented below need this legal foundation, as well as public institutions to implement the energy and electricity laws, and design and enforce energy regulation (European Union Energy Initiative Partnership Dialogue Facility 2014).

## Financing instruments

A major focus in the RE sector is the development of instruments that are typically tailored to suit the business model that underpins RE. There are a number of these instruments and with experience, these are being refined and adapted to suit specific kinds of RE sources. The instruments are used to stimulate private investment in RE. Generally, the aim of these instruments is to reduce investor costs, guarantee returns of the long-term and crowding in new private investors. In addition, energy laws and regulations must make provisions for the production and distribution of energy.

Examples include:

### Feed-in-Tariffs

Feed-in-Tariffs (FIT) offer long-term contracts to RE producers, typically based on the cost of generation of each technology. However, rather than paying an equal amount for energy generated, technologies such as wind power are awarded a lower per-kWh price, while technologies such as solar and tidal power are offered a higher price, reflecting costs that are higher at the moment. To produce the desired results, FIT must be consistent. They are typically designed to span some 15 to 20 years and changes within this period can easily un-nerve investors and reduce the effectiveness of these instruments. There was some concern expressed by respondents that not all FIT address all RE sources equally. The table below presents the use of FIT in Indonesia and shows how these vary to suit the RE source.

**Table 1: Indonesia's Feed-in Tariff Scheme**

| Sources  | Feed-in-Tariff (per kWh)                      |                              |
|--|---|------------------------------|
|  | Medium-Voltage                                | Low-Voltage                  |
| <b>Hydro (less than 10MW)</b>                                    | 656 IDR<br>(6.8 cent USD)                     | 1,004 IDR<br>(10.3 cent USD) |
| <b>Biomass and biogas</b>  | 975 IDR<br>(10.0 cent USD)                    | 1,325 IDR<br>(13.6 cent USD) |
| <b>Municipal solid waste (with sanitary landfill technology)</b> | 850 IDR<br>(8.8 cent USD)                     | 1,198 IDR<br>(12.3 cent USD) |
| <b>Geothermal</b>  | <b>High-Voltage</b><br>950 IDR (9.7 cent USD) |                              |

SOURCE: Indonesian Ministry of Energy and Mineral Resources (2013)

### Power purchase agreement

A power purchase agreement (PPA) is a contract between government and the energy provider, which defines the commercial terms for the sale of electricity,

including when the project will begin commercial operation, schedule for delivery of electricity, penalties for under delivery, payment terms, and termination. A PPA is the principal agreement that defines the revenue and credit quality of a generating project and is a key instrument of project finance. The PPA clearly defines the output of the generating assets and the credit of its associated revenue streams, and can be used by the RE provider to raise finance from a bank or other source.

#### Net metering

Net metering is a service to an electric consumer. Electric energy generated by the consumer from an eligible on-site generating facility and delivered to the local distribution facilities may be used to offset electric energy provided by the electric utility to the electric consumer during the applicable billing period. In Brazil, the net metering system is favoured over a FIT and was recently established by the national energy agency ANEEL.

#### Energy auctions

In 2004, the Brazilian government established energy auctions as the main procurement mechanism for distribution companies to acquire energy to serve their consumers. This initiative introduces competition in the power sector. Under this system, auctions of capacity from new generation projects are held three to five years in advance of delivery dates. The Ministry of Mines and Energy aims to ensure that the totality of future expansion needs is met and that plants are only built once they have won bids through these auctions and are guaranteed long-term contracts.

#### Wheeling

Wheeling is the transportation of electric power over transmission lines. In South Africa, energy provider Eskom allows wheeling by non-Eskom generators and Eskom generators, which are treated equally regarding access. However, generators have to be licensed to generate and trade before access can be provided. The National Energy Regulator of South Africa issues licenses to generators to allow for the third party transportation of energy under the requirements of the Electricity Regulation Act (Eskom 2011).

#### Duty free imports and VAT exemption

Some governments have removed duty on all equipment required for RE production. However, in other countries, duties and taxes on RE equipment are considered to be a barrier to investment. Similarly, in an effort to stimulate RE investment, some countries offer exemption from VAT in the purchasing of RE equipment. For example, the Government of Kenya has zero-rated the import duty and removed VAT on RE equipment, which has resulted in the development of solar RE projects. In Morocco, the importation and installation of Solar Water heaters is tax reduced.

### Income tax holidays

In recognition of the high-upfront costs and time required for new RE ventures to generate a profit, government can provide income tax holidays for the early years of an RE operation.

### Concessional loans and financing guarantees

While legal or regulatory instruments do not typically create concessional loans and financing guarantees, new RE production plants have a specific set of financial requirements. Set-up costs are high and only recoverable over a considerable period of time. Thus, governments may consider specialised credits for these ventures.

### Legal and regulatory barriers

Despite the introduction of laws and regulations that encourage private investment in the RE sector, there are many instances where existing laws and regulations present barriers to new investment. These barriers typically arise because of a lack of understanding of what RE investors require, a lack of transparency around what investors are required to do, or a lack of coordination among government ministries, departments and agencies.

As with any new business, RE producers are required to meet a range of legal and regulatory obligations when they are starting up. These may include, for example, a number of the issues outlined in the World Bank Group's annual *Doing Business* reports. However, the RE sector brings with it a number of added complexities that can make the legal and regulatory regime more difficult to navigate. In the Philippines, for example, a new RE plant requires some 165 signatures before it can be approved. Each government ministry, department and agency has its own mandate to fulfil and set of legal and regulatory obligations. These are also spread across national and local levels of government.

The range of licences and permits required by new RE plants can vary according to the type of RE that is produced. For example, wind projects are likely to require approval from the civil aviation authority, hydro projects from the relevant water authorities, and biogas project require special land use licenses.

Local governments often require many permits and licenses for new RE plant developments. There have been many complaints regarding the highly bureaucratic nature of these authorities.

In Kenya, there are also many laws and regulations to comply with when establishing a new plant. Here, investors complain that regulations and procedures are very unclear. The basic administrative procedures for on-grid RE power plants are:

- Approval of Expression of Interest by the Ministry of Energy and Petroleum;
- Acquisition of Environmental Impact Assessment License; and
- Approval of PPA.

However, different RE power plants may have additional requirements depending on the technology and capacity.<sup>10</sup>

According to many project developers, the major hurdle is the lack of clarity on PPA negotiating procedures; some also state that there are few FITs for technologies other than hydro, which make it difficult for project developers to secure project financing. Given the fluctuating nature of renewable energies like solar and wind, other projects may be given priority and less burdensome processes in order to avoid potential grid instabilities.

Grid barriers are among the administrative barriers faced by new RE projects. They can be an important obstacle especially in the case of large-scale RE projects and variable sources like wind. These non-economic barriers need to be addressed in order to enable support schemes to be effective. De Jager, *et.al.*, (2008) suggest that the following potential approaches can be used for reducing these barriers:

- **One-stop authorisation:** Poor coordination between authorities (i.e., national, regional and municipal) often leads to delays, investment uncertainty and a multiplication of necessary efforts. A single authorisation agency can drastically reduce the administrative burden for the developer related to the authorisation of new projects.
- **Response periods and approval rates:** The time required to obtain all necessary permits for the construction of a RE plant can take many years. Clear guidelines for authorisation procedures are needed to provide for obligatory response periods for the authorities involved. Setting approval rates can be a tool for checking the streamlining of authorisation procedures.
- **Pre-planning:** Pre-planned areas for RE production can speed-up the processes for permits.
- **Increase grid capacity:** Because many national grids have little capacity available for the connection of large-scale RE power plants, grid expansion and reinforcement are necessary to ensure the future realisation of RE power production.
- **Transparent grid connection procedures:** Procedures related to grid connection and accounting rules for the grid costs are not always transparent to the developers and many countries have not yet formulated transparent and non-discriminatory rules for bearing and sharing the necessary grid investment costs.

A number of respondents interviewed for this review spoke of the concerns regarding the role of so-called 'vested interests' in inhibiting reforms of the legal and regulatory framework. Many large energy producers that have been established for many years were initially dismissive of RE, but are now becoming concerned about the ability of these new disruptive technologies to compete for

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<sup>10</sup> A detailed flow chart on each of these requirements can be found here <https://renewableenergy.go.ke/licensing/clearances-flow-chart/>



their market share. Government may indeed, wholly or partly own some of these producers.

An interesting example of this has been reported in South Africa, where the government-owned power generation and distribution company, Eskom, which provides 95 per cent of the country's energy, has been accused of 'malicious compliance'. A recent paper by Professor Anton Eberhard at the Graduate School of Business at the University of Cape Town illustrates this point:

In 2008, Eskom initiated the Medium Term Power Purchase Programme for projects that could supply a total of 3,000MW of electricity to the grid by 2012. However, decisions on preferred bidders were delayed repeatedly, and by 2011 only 373MW had been contracted.

Eskom also called for an expression of interest in April 2008 for potential base-load projects, to which 76 companies responded. The utility then issued a request for qualification in August 2008 under which 23 local and international developers prequalified. However, by 2009, the base-load programme, along with the Pilot National Co-generation Programme and Medium Term Power Purchase Programme, had all been suspended by Eskom.

Some have described Eskom's actions as malicious compliance: The company has accepted the government policy to introduce IPPs [independent power plants] and initiated relevant steps, but in each case the initiatives have yielded nothing. Others have suggested that it is unfair to blame Eskom managers, who depend on the political directions of its shareholder, the Department of Public Enterprises. The real battle, they argue, is who controls big investment decisions (Eberhard 2014).

South Africa is not alone in experiencing a contest between incumbent power producers and emerging RE producers. In some cases there is directly lobbying against reforms by these incumbents, in others, reforms are simply seen as being too difficult.

The Government of Indonesia and Asian Development Bank (2015, p. xxi) argue that "a comprehensive and conducive institutional and regulatory framework, with accountability for results, is required to ensure efficient and effective investment, management and operation of the sector".

### 3.2.3 Institutional arrangements

#### **Key stakeholders**

Because of its multi-dimensional nature and demand for integrated action, there is a wide range of stakeholders involved in the promotion of RE systems. The table below identifies five major stakeholder groups and the kinds of problems they may experience.

**Table 2: Five key stakeholder groups for a renewable energy barrier assessment**

| <b>STAKEHOLDER GROUP</b>                | <b>DESCRIPTION/EXAMPLE BARRIERS</b>  |
|---|--|
| <b>Project developers and investors</b> | Project developers and investors (i.e., equity and debt) in renewable energy may encounter barriers such as a lack of track record on the performance of renewable energy technologies, uncertainties on the outlook for the local energy market, and uncertainties related to political instability   |
| <b>Consumers and end-users</b>          | Consumers encounter a range of barriers associated with the consumption of renewable energy, including a lack of awareness about renewable energy and the potential for alternatives, uncertainties that come from black-outs or brown-outs for mismanaged grids, or a lack of funds to afford cleaner energy technologies   |
| <b> Policymakers</b>                    | This may include individuals charged with creating the rules and regulations that govern the energy industry, such as legislators and regulators. Policymakers may encounter barriers such as a lack of political or institutional incentives to support renewable energy, limited knowledge about the range of potential policies and their trade-offs, and the prospect of prohibitively high policy costs |
| <b>Utilities</b>                        | Utilities include the entities that generate, transmit and/or distribute electricity. Utilities may encounter barriers such as a lack of experience in planning and managing intermittent renewable energy generation, a lack of knowledge about renewable energy technologies and their track record, and economic conflicts of interest (depending on the ownership model)                                 |
| <b>Supply chain</b>                     | This includes companies that manufacture, distribute, install and maintain renewable energy technologies. Supply chain stakeholders may encounter barriers such as a lack of expertise in sustainable energy technologies, the availability of more profitable business opportunities in which to invest, and a lack of demand for renewable energy equipment  |

SOURCE: UNDP 2012, p. 25.

All stakeholders in the energy enterprise sector can play a role in encouraging policies and practices that enable energy enterprises to grow. For example policy influencers can advocate a conducive operating environment and investors can showcase how they have successfully managed the risks of their energy enterprise investment, opening the space up to new investors (Ashden and Christian Aid 2014).

### **Government oversight and coordination**

Typically, the energy ministry provides government oversight and coordination.

In Brazil, the National Council of Energy Policy works at a macro level and advises the president. The Ministry of Mines and Energy is responsible for planning, monitoring and implementing policies, being the competent authority to set guidelines and grant concessions in the energy sector. Working closely with the

ministry, the Monitoring Committee of the Electricity Sector, the National Energy Agency (ANEEL), and the Energy Research Company play important roles in the energy sector. The Monitoring Committee of the Electricity Sector monitors the continuity and security of electricity supply, ANEEL is a federal agency regulating and supervising activities in the electricity sector and in charge of promoting the energy auctions whereas EPE supports the government with planning.

### **Industry representation**

Industry representation is important to ensure that private actors in the RE sector are able to present their demands for reform. In Kenya there is the Kenya RE Association, which is made up of private sector actors. This association is a member of the broader Kenya Private Sector Alliance. In Brazil RE associations are very new. The *Associação Brasileira de Energia Solar Fotovoltaica*, known as 'ABSOLAR', represents the interests of private firms in the solar PV sector.

### **Public-private dialogue**

Regular and structured PPD is important so that government and the private actors in the RE sector can discuss the issues affecting the sector and develop an agreed programme of reform. Most respondents indicated that the level of PPD in the RE sector is reasonably good. However, there are still calls for more and better PPD. In Kenya, for example, there are a number of donor and development organisations as well as international private event organising companies involved in organising PPD platforms, but there is still need for more. In Morocco, dialog mechanisms exist in the form of the federation for RE, known as 'AMISOLE', a Solar Cluster, Energy Efficiency Cluster, conferences and other dialogue mechanisms.

### **Other factors affecting the development of the renewable energy sector**

In addition to the above BE concerns, there are other factors that appear to affect the development of on-grid RE systems in many developing countries.

### **Access to finance**

Ashden and Christian Aid (2014, p. 24) suggest there is a need for changes in the operating environment to allow energy enterprises more opportunities to access finance for working capital, for example, by building confidence in these enterprises among local financial institutions.

Bellanca and Wilson (2012) indicate that most energy access investment opportunities in developing economies offer a bad combination of high risk and low returns: "Private sector investors want to share the risk with governments and donors". In addition, impact investors could be a potential source of finance, "if they are willing to accept higher risk and lower rates of return than private equity investment or venture capitalists, which is sometimes not the case. Carbon finance could play a role though this is complicated to set up and price volatility undermines its reliability".

In Brazil, national development bank, known as 'BNDES', ANEEL and the Financier of Studies and Projects (known as 'FINEP') are collaborating to support *Inova Energia* to develop Brazilian companies and technology in the production chain of smart grids, solar energy and wind power, hybrid vehicles and vehicle energy efficiency.

### **Need for demonstration projects and domestic and regional markets**

Huenteler and Schmidt (2015, p. 31) suggest that progress in the development of RE technologies “will need domestic demonstration projects and the creation of domestic and regional markets”. In order to capture part of the value creation, local suppliers will need to establish “innovation networks including users, developers and manufacturers”. Thus, donor and development agencies can support the development and diffusion of new RE technologies through demonstration projects and market-based networks.

## **3.3 Lessons learned**

The following lessons from BER practices in the RE sector have been identified:

- The development of the renewable energy sector requires an integrated, multi-sector policy framework with many elements. This can be very difficult to design, as well as to implement and monitor. Not only do such policies affect a wide range of national government ministries, departments and agencies, they also require careful coordination and integration with sub-national government authorities. Furthermore, because of the relatively new nature of the sector (i.e., dealing with emerging technologies) the issues affecting policy frameworks are changing rapidly. Thus, new policies and practices are evolving and there is a constant need to review and revise policy directions and instruments.
- Industrial policy dominates development in this sector. It is important business environment reforms occur in tandem with these interventions and provide a supportive, complementary function. However, this appears to be difficult. There is evidence to suggest that many legal and regulatory barriers undermine government's broader development efforts in this sector.
- Sector-specialist agencies have an important role to play in advising, guiding and supporting business environment reform in this sector. These agencies have an understanding of international developments and best practices and can work with a wide range of local actors, public and private, to identify and facilitate reform efforts.
- It is important to be pragmatic when responding to business environment barriers. For example, while the unbundling of state-owned non-renewable energy production and distribution enterprises may be a typical first step in business environment reform, it may be more practical to simply create financial incentives that encourage utilities to be more open to purchasing renewable energy.

- There is clear evidence of anti-competitive behaviour in this sector, where well-established incumbents actively resist the introduction of new technologies and new actors. Business environment reform should be underpinned by a clear political-economic analysis of the power structure of the market.

## 4 Mining and small-scale suppliers

This chapter presents the findings of the sector review into mining. It gives a brief introduction to the sector, and identifies the issues of major concern. It then presents the specific dimensions of BER and the experiences, practices and lessons that can be learnt. This review focused on the issues affecting the promotion of local content to the mining sector, specifically the development of small-scale suppliers. Here, the interest is on how developing-country governments can maximise the opportunities for local industry development that stems from large-scale resource projects.

Across the mining sector, there are a number of stages of development and operation that create opportunities for the development small-scale suppliers. These include:<sup>11</sup>

- Advice and support in obtaining an exploration licence;
- Exploration activities;
- Reserve calculations, financial calculations and metallurgical test work;
- Market studies;
- Preparation of the bankable feasibility study and environmental impact assessment and management plan;
- Environmental services;
- Advice and support in obtaining a mining licence;
- Equipment ordering and delivery;
- Mine and plant construction;
- Building up to full production;
- Catering, laundry, security, and general operational services;
- Mine closure; and
- Mine site rehabilitation.

As this chapter demonstrates, many programmes have been introduced to support the development of supply firms in the mining sector. However, there is growing interest among developing-country governments in the use of legal and regulatory instruments for this purpose, not least because there has tended to be a general lack of success in encouraging local content through voluntary methods.

### 4.1 Sector overview and characteristics

The UNCTAD (2007) *World Investment Report*, which focuses on extractable industries, describes how global mineral markets are characterised by an uneven geographical distribution of reserves, production and consumption. Some developing and transition economies are among the main producers and net exporters of various minerals, while developed countries and fast-growing emerging economies are the major consumers and importers. “For countries that lack the necessary indigenous capabilities for transforming their natural resources

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<sup>11</sup> Adapted from Cole Baker Associates (2013).

into commercial goods, trans-national corporations (TNCs) can bring the needed capital, knowledge and access to markets” (p. xxi).

Besada and Martin (2014) describe how, at the community level, the promised benefits and linkages of resource exploitation have often failed to materialise. They cite an African Development Bank study that shows few of the inputs into capital-intensive mining activities in Africa over the last decade have been sourced locally. Rather, equipment, machinery and consumables are most often imported. Employment generation is also limited by the capital-intensive nature of mining operations. In Mali, for example, although the mining industry accounts for up to 17 per cent of national GDP and 70 per cent of exports, it generates direct employment for only 13,000 people in mining communities. Similarly, in Ghana, between 2000 and 2007 the minerals sector employed approximately 0.2 per cent of the non-agricultural labour force, despite contributing 5.5 per cent of Ghana’s GDP and 40 per cent of its exports.

Supplier inputs and linkages can occur along and beyond the mining value chain. Backward linkages occur when foreign affiliates acquire inputs (i.e., goods or services) from local suppliers. Forward linkages occur when foreign affiliates sell outputs (i.e., minerals) to domestic buyers. Linkages can be developed with domestic firms or with other foreign affiliates in the host country. Hanlin (2011) identifies three phases in a mine’s lifecycle that influence procurement decisions: Design, Construction and Operational. Within each of these phases, critical decisions are made that impact and influence procurement decisions during that phase and subsequently throughout the life cycle of the mine.

## 4.2 The Business Environment for the Mining Sector

The following dimensions have emerged when examining the BE for small-scale suppliers in the mining sector:

- Policy development and reform;
- Legal and regulatory framework; and
- Institutional arrangements.

Each of these dimensions is presented in detail below.

### 4.2.1 Policy development and reform

At the regional level, the AU’s (2009) *African Mining Vision* presents a holistic framework for improving Africa’s mining regimes, focused on balancing the requirements of transparency and accountability with the need to integrate mining into Africa’s long-term development at the local, national and regional level. It has become, in Besada and Martin’s (2014) words, “among the most important frameworks for developing mineral resources in Africa”. The African Mining Vision calls for “more fiscal space and responsive taxation to allow host countries to better capture windfall gains and to encourage the use of revenues for value addition...[including] employment generation, local procurement of goods and services, entrepreneurial development, skills and knowledge creation,

technology transfer, infrastructure expansion and above all linkages” (Pedro 2012). See Box 1.

**Box 1: Africa Mining Vision**

- A knowledge-driven African mining sector that catalyses & contributes to the broad-based growth & development of, and is fully integrated into, a single African market through:
  - Down-stream linkages into mineral beneficiation and manufacturing;
  - Up-stream linkages into mining capital goods, consumables & services industries;
  - Side-stream linkages into infrastructure (power, logistics; communications, water) and skills & technology development (HRD and R&D);
  - Mutually beneficial partnerships between the state, the private sector, civil society, local communities and other stakeholders; and
  - A comprehensive knowledge of its mineral endowment.
- A sustainable and well-governed mining sector that effectively garners and deploys resource rents and that is safe, healthy, gender & ethnically inclusive, environmentally friendly, socially responsible and appreciated by surrounding communities;
- A mining sector that has become a key component of a diversified, vibrant and globally competitive industrialising African economy;
- A mining sector that has helped establish a competitive African infrastructure platform, through the maximisation of its propulsive local & regional economic linkages;
- A mining sector that optimises and husbands Africa’s finite mineral resource endowments and that is diversified, incorporating both high value metals and lower value industrial minerals at both commercial and small-scale levels;
- A mining sector that harnesses the potential of artisanal and small-scale mining to stimulate local/national entrepreneurship, improve livelihoods and advance integrated rural social and economic development; and
- A mining sector that is a major player in vibrant and competitive national, continental and international capital and commodity markets.

SOURCE: African Union (2009)

The AU (2009, p. 23) claims that many African governments now agree: “most of what they wish to achieve through ownership in mining projects can be achieved through the regulatory and fiscal instruments”. This view is based on the assumption that the state is more able to attract private investors than it is to raise the funds and skills to directly undertake mining activities.

Ernst & Young (2014) describe how governments are imposing new steep export levies or complete export bans on unrefined ores in order to ensure in-country beneficiation, “it is questionable whether new jobs are indeed created, given technological advancements in downstream processing”. They cite the example of Indonesia, which has proposed a new export levy of 25 per cent on mining exports (increasing annually) in the belief it will become a producer of higher-value finished goods from an exporter of raw materials.

The policy instruments for local content vary. They include:



- Policy documents that are largely aspirational, but non-binding;
- Laws and regulations, which are binding;
- Mining agreements which are framed by government policy or law, and in some cases legislated in their own right;
- Mining codes, charters and scorecards that establish targets for local content, among other things (e.g., South Africa’s Mining Charter, 2004, see below).

Most countries have comprehensive policies for the development of mineral resources. In recent years the requirement for ‘local content’ or ‘beneficiation’ has become more prominent.<sup>12</sup> Many countries now have policy provisions that require companies to sub-contract to local companies subject to equal quality and price. Some of these are reviewed below.

### **Nigeria**

Local content in the Nigerian oil and gas sector is estimated to be around 40 per cent. Foreign workers and overseas suppliers provide most white-collar jobs, engineering, materials and maintenance work (Fabi 2009). The Nigerian Content Development Bill of 2003 set a target of 45 per cent local content by 2006 and 70 per cent by 2010. It defined Nigerian content as “the quantum of composite value added to, or created in, the Nigerian economy through the deliberate utilization of Nigerian human and material resources and services in the Upstream Sector of the Nigerian Petroleum Industry. It includes all activities connected with the exploration, development, exploitation, transportation and sale of Nigeria Crude Oil and Gas Resources, without compromising quality, health, safety and environmental standards”. The president signed a local content bill for the oil industry on 22 April 2010 that gives local firms priority in awarding oil concessions and requires foreign companies to employ more local staff.

The Nigerian Oil and Gas Industry Content Development Act 2010 contains provisions to enhance local participation in all aspects of oil operations. These include specifying minimum amounts of local materials and personnel used by oil and gas operators in the country. It is claimed that this law enjoys general acceptability in the industry. This act, which is modelled on Norwegian legislation, makes it imperative that exclusive consideration be given to Nigerian indigenous service companies that demonstrate ownership of equipment, Nigerian personnel and the capacity to execute jobs in the Nigerian oil and gas industry. It presents a template for companies’ classification and a value matrix to measure local input,

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<sup>12</sup> The Government of South Africa describes ‘beneficiation’ as value-added processing, which involves the transformation of a primary material, produced by mining and extraction processes, to a more finished product, which has a higher export sales value. Beneficiation involves a range of different activities including: large-scale, capital-intensive activities, such as smelting, sophisticated refining plants, and labour-intensive processes, such as craft jewellery, metal fabrication and ceramic pottery. Each successive level of processing permits the product to be sold at a higher price than the previous intermediate product or original raw material and adds value at each stage. Ref: Government of South Africa, Department of Mineral Resources, <https://www.dmr.gov.za/mineral-policy-promotion/beneficiation-economics>

while spelling out the responsibility of the respective institutions charged with the effective delivery of the Nigerian content (Gbegi & Adebisi 2013).

The Nigerian Content Division has been quite successful in ensuring compliance with local content regulation, providing financial support to help local companies bid for contracts and coordinating local capacities. However, limited infrastructure, a small industrial base, high project costs, a high interest rate, and skills shortages constrain local content levels. Gbegi and Adebisi (2013) argue that having “a few companies committed to Nigerian content and pursuing local content programmes is not enough. Support for local content policies must be nation-wide. It must be accepted by all and should become embedded in every operator’s business philosophy”.

### **South Africa**

In South Africa, the *Beneficiation Strategy for the Minerals Industry* seeks to advance development through “the optimisation of linkages in the mineral value chain” and to “facilitate” economic diversification, job creation and industrialisation. It also aims to expedite progress towards a knowledge-based economy and contribute to incremental GDP growth in mineral value addition per capita in line with other government plans. The purpose of the strategy is to provide a “framework that will enable an orderly development of the country’s mineral value chains, thus ensuring South Africa’s mineral wealth is developed to its full potential and to the benefit of the entire population” (Republic of South Africa 2011, p. v). The concept of beneficiation is articulated within the Minerals and Mining Policy of 1998, which identified the need to adopt a policy that will create an enabling environment for the development of the country’s mineral wealth.

In addition, the Broad Based Socio-Economic Empowerment Charter for the South African Mining Industry, established in 2004, aims to (Republic of South Africa 2004):

- Promote equitable access to the nation's mineral resources to all the people of South Africa;
- Substantially and meaningfully expand opportunities for HDSAs (historically disadvantaged South Africans) including women, to enter the mining and minerals industry and to benefit from the exploitation of the nation's mineral resources;
- Utilise the existing skills base for the empowerment of HDSAs;
- Expand the skills base of HDSAs in order to serve the community;
- Promote employment and advance the social and economic welfare of mining communities and the major labour sending areas; and
- Promote beneficiation of South Africa’s mineral commodities.

### **Mozambique**

There is no policy framework that guides local content requirements in Mozambique. However, there are important policy and legal structures that support local content development. These form the broader development context in which local content initiatives can be framed. They include the Poverty

Reduction Action Plan (2011-2014), which outlines the government's vision for economic development and poverty reduction. This plan explicitly indicates pursuing a policy that promotes "broad-based" growth, diversifying the economy, and creating jobs and linkages between foreign investment and the local economy. In addition, the Government Five-year Plan, 2010-2014, speaks of crowding-in foreign direct investment to stimulate local economic growth.

Kaplan (2013) examines the policy framework for local content in Mozambique and identifies the following weaknesses:

- Conflicting definitions and requirements that create confusion and sometimes legally conflicting guidance;
- Insufficient dissemination and education on existing laws with key stakeholders, both public and private; and
- Poor levels of consistent and fair enforcement.

This, says Kaplan, has resulted in "confusion in the marketplace as to what rules firms are expected to follow and what the penalties are for non-compliance". Small and medium-sized firms are largely unaware of these existing requirements and instead are frustrated with government for not doing anything to protect and help local suppliers.

UNCTAD is supporting the Government of Mozambique in the Business Linkages Programme, which is an essential component of the promotion of equitable and sustainable business linkages in Mozambique. The project is designed to create an environment conducive to sustainable business linkages between local producers and larger corporations. The overall objective of the project is to promote equitable and sustainable businesses linkages in Mozambique, thereby enhancing the local productive capacity and the efficiency of the domestic small and medium enterprise (SME) sector. The government has also requested UNCTAD to assist in matching the potential demand of MNEs in the mining industry with the potential supply of Mozambican producers (Cole Baker Associates 2013).

In 2006, the International Finance Corporation (IFC) launched Mozlink II, the Mozambique SME Linkage Development Programme, which aims to help SMEs gain the skills and technical capabilities they need to compete effectively, and in a sustainable way, for large contracts in a number of important industries. The programme taps into high-capital industrial projects in Mozambique that have committed to a long-term presence (i.e., 8-20 years) in various sectors, including mining and natural gas. It helps SMEs improve in areas of safety, quality, maintenance and management, identifies common products and services required by industry and local procurement, increases access to finance by participating SMEs, and links SMEs to larger firms (IFC 2010).

## **Ghana**

Ghana began by developing a Local Content and Local Participation in Petroleum Activities Policy Framework in 2010. This Framework defines 'local' as "the level of use of Ghanaian local expertise, goods and services, people, businesses and financing in oil and gas activities". The policy framework sets out the obstacles in the sector, the vision, objective and goal of local content and how local content

fits into the larger economic development agenda for the country. It requires an Annual Local Content Plan and an Annual Recruitment and Training Program and creates the National Local Content Committee to oversee the implementation of the Policy Framework. It also establishes an Oil and Gas Business Development and Local Content Fund to support the capacity development of local suppliers in the oil and gas industry (Kaplan 2013).

### **The challenges to local supplier policies and programmes**

A number of respondents expressed agreement with the need for national policy frameworks to promote local content, but also have reservations regarding the ways these policies and their accompanying laws are designed and implemented. These include the following issues.

#### Monitoring local content agreements

A number of respondents described scenarios in which mining agreements have been formed between miners and host-country governments that contain local content provisions. At the signing stage, miners are eager to agree to these provisions, just as they are eager to begin their operations. However, once the agreement has been reached, the desire to track local content performance declines. The price and quality criteria for local suppliers are often used to argue that no local suppliers were able to meet these criteria. Increasingly, NGOs are becoming involved in scrutinising and monitoring mining agreements and bringing these issues to public attention.

#### Carrots versus sticks

A number of respondents questioned the value of policy or legal provisions for local content. While on the one hand it is generally agreed that without policy or legal imperatives mining companies would have little regard for local content, on the other hand, the quality and price provisions contained in most policies and laws provide an excuse for non-compliance and render many local content provisions meaningless. Too many constraints to mining activities can scare investors away, especially when there are other countries competing for investment. Many agree that using local suppliers can make good business sense and this, rather than policy or legal compliance, is a more sustainable rationale for the development of the supplier industry. In the end, success in achieving local content aspirations is likely to involve a careful balancing of policy and legal prescripts, industrial development programmes and services, and close interaction between governments, miners and potential and current local suppliers.

#### Company programmes

Many large mining companies have established local supplier development programmes, often in response to government policy. For example, Vale and Rio Tinto have good programmes in Mozambique to encourage local procurement, by helping to develop local competencies. They have internal targets to achieve certain levels of local supply. Vale's global *Inove* programme is a supplier development programme that "aims to contribute to the sustainable development of [its] suppliers and build a positive legacy in the regions where

Vale operate". In line with Vale's business strategy, *Inove* acts in three fronts: training, business fostering and competitiveness. These activities are developed in partnership with national, regional and local institutions. Since its creation in 2010, *Inove* has trained about 700 companies and 4,000 users, and there has been more than US\$186 million in transactions of materials and supplier kit services. The programme has financed more than US\$800 million through its partners (Vale 2015).

In Chile, BHP Billiton has established a local supplier development programme to create lasting business and technological capabilities and increase suppliers' economic value. The Cluster Program was launched in 2009 with funding from the Chilean Government, BHP Billiton and participating suppliers. It aims to develop 250 Chilean-based resource industry suppliers into 'world-class' global resource industry suppliers by 2020. BHP Billiton define world-class suppliers as those that sell more than 30 per cent of their product internationally, have standards equal to the industry leader and add a high level of value to their customers. The program engages local suppliers to develop innovative solutions to manage at least one aspect of mining identified as critical by BHP Billiton operations, such as water, energy, human capital, maintenance, air quality, acid mist control or leaching. The programme was born out of a broader initiative by the Chilean Government to improve local economic development and BHP Billiton was one of two resource companies to undertake the initiative (BHP Billiton 2012).

#### Capacity development

UNCTAD (2007, p. 39) argues that BER is not enough to attract greater foreign direct investment (FDI) into manufacturing to benefit from such investments. As a consequence, "it is important for host countries to adopt policies that help improve their local capacities, and in particular their labour skills and technological capacities".

#### Coordinating and integrating local content programmes

Beyond policy itself, governments are required to coordinate a range of industry development programmes and services. A good, but sadly unique, example of this comes from Botswana where the government established two sector specific institutions to promote forward linkages in the diamond sector: the Diamond Office and Diamond Hub. The Diamond Hub is the sector executive agency tasked with the practical implementation of policy. The Diamond Hub implemented five policies designed to provide a favourable BE for the industry (Morris, *et.al.*, 2012):

- Reduced corporate tax rate (15 per cent rather than 25 per cent) for the cutting and polishing firms;
- Fast tracking of Work Permit applications for skilled labour used to train locals and for labour visiting to maintain and repair their equipment;
- An exemption from paying the economy wide training levy if firms have their own training programmes;
- An exemption from paying taxes on polished diamonds exports; and
- Cutting and polishing firms do not have to pay import duties on their technology imports.

Morris, *et.al.*, (2012) suggest that if government policy is to promote linkages it needs to address the development of linkages from the commodities sector and those that have an indirect effect on linkage development. This involves:

- Initiate and sustain a process of strategic visioning and policy development drawing in a range of relevant stakeholders;
- Develop a local content policy;
- Support the development of local supplier firms and processors, particularly second and third tier firms;
- Develop appropriate local capabilities—this involves investments in all levels of skill development as well as skills development institutions that can support both the lead commodity firms and particularly their suppliers and customers; and
- Develop infrastructure—hard infrastructure (e.g., roads, telecoms and utilities) and soft infrastructure (e.g., support businesses such as customs clearance and ease of entry and exit for firms).

Underwriting each of these elements, say Morris, *et.al.*, (2012, p. 212) “is the capacity which government has to develop and effectively implement its policy towards linkage development”. Doepel and Bolton (2013) present the case for a closely integrated mining sector:

When mining is fully integrated into an economy and a skilled workforce is sourced locally with goods and services largely procured from within the jurisdiction, then the economic multipliers are very significant. By contrast, if the majority of support services and goods are procured internationally and the labour workforce is also imported (except for local unskilled labour), then the potential returns to a national economy are greatly diminished.

#### 4.2.2 Legal and regulatory framework

The legal and regulatory framework provides a means through which local content policies are implemented. Many features of a ‘good’ legal and regulatory framework become apparent when examining local content in the mining sector. The *African Mining Vision*, for example, highlights the importance of good governance: “good governance is critical in ensuring local content minimums in the resource contracts/licenses and investing in the appropriate human resource development and technology development” (AU 2009, p. 21).

Ovadia (2014) argues that strong state governance is required to promote local content because the higher costs associated with local procurement and the time and money spent on training and skills development may seem too burdensome for international companies involved in mineral extraction. Despite the long-term benefits, many MNEs will not act to develop local content without strong regulation. This view is supported by Archine (2013) who says the two major issues impeding the maximisation of benefits from natural resources for the sustained development of natural resource-rich developing countries are “the lack of transparency in contracts and the harmful effects of corruption”.

Besada and Martin (2014) suggest:

[R]egulatory frameworks should establish spending and investment requirements that direct a minimum portion of resource revenues towards domestic assets that offset resource depletion, diversify the national economy and explicitly target job creation. This may take the form of direct equity holding by the state (including joint ventures with the private sector), or by directing favourable loans to the private sector to help foster linkages in the commodity value chain. The goal of governments should be to promote strong and transparent fiscal linkages between the extractive sector and the broader economy, by using taxes and royalties collected from extractive industries to promote economic development in sectors unrelated to commodities.

In Angola, legal and regulatory provisions for the promotion and enforcement of local content in the extractives sector include the adoption of tax incentives for Angolan oil exploration and production companies: the adoption of regulations requiring the use of Angolan banks and local currency; the coordination and promotion of investments in manufacturing and oil services; and efforts to build human capacity for the oil and oil services sectors (Ovadia 2014).

### **Duties and taxes**

Graham (2013) describe how a “policy of allowing duty free importation of mining inputs provides little incentive for firms to buy locally and places potential local producers and suppliers of such inputs at a disadvantage”. This, he says, blunts the development of backward linkages and local procurement. He cites the example of Ghana to illustrate the perverse effects of duty free importation by mining firms. Because firms that supply things to the mines do not enjoy the waiver, but pay duties the mines can import supplies at a lower cost and therefore have no incentive to buy locally.

In Tanzania, Curtin and Lissu (2008, p. 42) describe how mining companies enjoy special VAT relief on imports and local supplies of goods and services to mining companies and their subcontractors. On this basis, they propose a “number of new tax laws must be considered, such as the introduction of windfall taxes, allowing the state, district councils and village governments to control a percentage of equity in the mines, and requiring a certain proportion of royalties to go directly to the mine areas”. In contrast, Ernst & Young (2014) argue mining investors look for stability: “Any government promoting tax policy stability will be favoured as miners seek low-risk investments with minimal political uncertainty”.

Land (2008) says it is important for governments to set up suitable arrangements if they are to maximise the benefits of mining for economic and social development. This requires particular attention is paid to the fiscal arena:

- There has to be an appreciation of the characteristics of the extractive industry and the government’s bargaining strength;
- There must be fiscal policy coherence between government institutions to underpin suitable fiscal arrangements;
- It is necessary to ensure the availability of skills necessary to formulate fiscal policies and appropriate negotiating strategies; and

- Governments must have the capacity to administer and enforce more sophisticated forms of taxation and contractual arrangements.

It is the view of some respondents that taxes and royalties are, in fact, a better way to promote local content when compared to other policy and legal instruments. Mining companies understand and respond to tax. It would be better for governments to use tax and royalty revenues to finance supplier development programmes.

### Standards

Typically, there are few standards that specifically focus on suppliers to the mining industry. However, across the mining sector, including the extractive industry sector, there has been a major international push for improved transparency and governance. The Extractive Industries Transparency Initiative (EITI) is an international initiative designed to improve the governance of the extractive industry sector within the public and private sectors, including supplier contractors. See Box 2. EITI helps countries in which extractive industries are based to improve their BE by providing a clear signal to investors and international financial institutions that the government is committed to greater transparency.

#### **Box 2: Extractive Industries Transparency Initiative**

The EITI is a global standard that promotes open and accountable management of natural resources. It seeks to strengthen government and company systems, inform public debate, and enhance trust. Countries implementing the EITI disclose information on tax payments, licenses, contracts, production and other key elements around resource extraction. This information is disclosed in an annual EITI Report, which allows citizens to see for themselves how their country's natural resources are being managed and how much revenue they are generating. The EITI Standard requires that EITI Reports are comprehensible, actively promoted and contribute to public debate.

The EITI Principles provide the cornerstone of the initiative:

- We share a belief that the prudent use of natural resource wealth should be an important engine for sustainable economic growth that contributes to sustainable development and poverty reduction, but if not managed properly, can create negative economic and social impacts.
- We affirm that management of natural resource wealth for the benefit of a country's citizens is in the domain of sovereign governments to be exercised in the interests of their national development.
- We recognise that the benefits of resource extraction occur as revenue streams over many years and can be highly price dependent.
- We recognise that a public understanding of government revenues and expenditure over time could help public debate and inform choice of appropriate and realistic options for sustainable development.
- We underline the importance of transparency by governments and companies in the extractive industries and the need to enhance public financial management and accountability.
- We recognise that achievement of greater transparency must be set in the context of respect for contracts and laws.
- We recognise the enhanced environment for domestic and foreign direct investment



that financial transparency may bring.

- We believe in the principle and practice of accountability by government to all citizens for the stewardship of revenue streams and public expenditure.
- We are committed to encouraging high standards of transparency and accountability in public life, government operations and in business.
- We believe that a broadly consistent and workable approach to the disclosure of payments and revenues is required, which is simple to undertake and to use.
- We believe that payments' disclosure in a given country should involve all extractive industry companies operating in that country.
- In seeking solutions, we believe that all stakeholders have important and relevant contributions to make – including governments and their agencies, extractive industry companies, service companies, multilateral organisations, financial organisations, investors, and non-governmental organisations.

SOURCE: EITI [www.eiti.org](http://www.eiti.org)

### 4.2.3 Institutional arrangements

#### **Government oversight and coordination**

Coordination between ministries is a problem in many countries. Typically, the national ministry of minerals or mines is the ministry responsible. Other ministries have their priorities and there has been limited success in coordinating policy and programme initiatives across national government portfolios and the different levels of government. Local supplier development requires close cooperation and integration between the mining ministry and the industrial development ministry.

#### **Industry representation**

While mining representation is typically strong and well organised, such as through a national chamber of mines, the same cannot be said for small-scale suppliers. While these firms may form part of a supplier network, they are not necessarily represented effectively or able to successfully advocate to government for reform.

#### **Public-private dialogue**

In many cases, mining companies take the lead in PPD through their representative organisations, such as chambers of mines. Big miners often have direct access to ministers and senior government officials. There is very little evidence found of local suppliers engaging in PPD with government.

The AU recommends that active participation of small-scale miners in the planning, designing, implementation and evaluation of policy is a crucial element for success. "It is also important to identify and empower leaders in the mining communities who can be agents of the change process" (AU 2009, p. 29). However, Morris, *et.al.*, (2012, p. 207) argue that one of the failings in government efforts to promote linkages in the mining sector has been "the pervasive failure of private and public sector stakeholders to work together in the development of a collective vision, and mutually reinforcing and implemented

policies. In most cases, we observed an absence of dialogue on the specifics of linkage development”.

Ernst & Young present the case for ‘multi-stakeholder approach’:

There needs to be a multi-stakeholder approach to sharing the benefits, and companies should tailor their approach depending on the group. Companies need to ensure that governments, communities, shareholders, employees and suppliers have a common understanding of the challenges their projects face. By forming strong partnerships with each of these groups, they are better able to communicate their long-term value to shareholders as well as integrate themselves into the local and regional communities (Ernst & Young 2014, p. 35).

### **Corporate social responsibility**

Corporate social responsibility (CSR) can be a useful mechanism for mining companies to begin their outreach to local suppliers and to develop local supply networks and capacities. While some have argued CSR is typically removed from the core commercial operations of a mine, and CSR initiatives are trivialised in terms of the essential interests of the mine, others suggest it can be a good start. Indeed, companies that are well established at a site over many years can build long-term relationships with local communities and potential suppliers. CSR is often used to promote local social and economic reforms in response to modern mining codes, rather than to promote small-scale suppliers to the industry. For example, in Mali, AngloGold Ashanti had a policy to encourage local agricultural developments because they specifically did not want communities to become fully dependent on the mine.<sup>13</sup>

On a more positive note, CSR initiatives have often been used to establish local supplier development funds, where one or more companies contribute to a basket of funds that are used to develop local supplier skills and capacities. In Peru, Ernst & Young (2015, p.36) suggest the “major mining and metals organisations are trying to implement systems to share and measure the benefit of their operations, demonstrating that they not only make communities wealthier but healthier”. This, says Ernst & Young, involves “working with local communities to create shared value, listening to what they want, rather than just coming up with initiatives that are not tailored to their needs. Community support for a project is partly dependent on its economic participation and local employment is an important element of that”.

## **4.3 Lessons learned**

The following lessons from BER practices in the mining sector have been identified:

- While policies set governments’ intention in terms of the development of local content, these are far from binding. The national policy framework requires a realistic and implementable legal and regulatory framework to ensure the

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<sup>13</sup> For a further discussion on the links between mining and agriculture development see McHenry & Persley (2015).

aspirations and goals (and possibly the targets) of government in this sector are achieved.

- Supplier development programmes help local firms respond more successfully to the opportunities presented by local content provisions. This illustrates the combined use of industrial policy and business environment reform to achieve the desired development goals. However, it appears the capacity constraints of local firms are significant.
- Coordination across government ministries, departments and agencies is important. Success requires good communication and coordination across the government portfolios associated with minerals, energy, industry, commerce, labour, and the environment.
- In all aspects of this work, careful attention should be given to the economic imperatives of the sector. Mining is a long-term, high-cost business, which is typically vulnerable to international price fluctuations. Developing local content, and designing a policy, legal and regulatory framework to govern this, requires a good understanding of the dynamics of the industry and the capacity of large-scale mining and small-scale suppliers.

## 5 Horticulture

This chapter presents the findings of the review into the horticulture sector focusing on fruits and vegetables. It presents the specific dimensions of BER and the experiences, practices and lessons that can be learnt. While this review focuses on specifically the fruit and vegetables sub-sector it also recognises that horticulture is part of a broader agriculture sector with its own sector-specific concerns.

This sector is of interest because of the significant role that agriculture plays in most developing economies. Sector development involves support and reforms to stimulate agri-business development, which includes building local capacity as well as improving the access local producers have to foreign markets.

### 5.1 Sector overview and characteristics

The Chartered Institute of Horticulture in the United Kingdom defines horticulture as:

The art, science, technology and business of intensive plant cultivation for human use. It is practised from the individual level in a garden up to the activities of a multinational corporation. It is very diverse in its activities, incorporating plants for food (fruits, vegetables, mushrooms, culinary herbs) and non-food crops (flowers, trees and shrubs, turf-grass, hops, grapes, medicinal herbs). It also includes related services in plant conservation, landscape restoration, landscape and garden design/construction/ maintenance, horticultural therapy, and much more. This wide range of food, medicinal, environmental, and social products and services are all fundamental to developing and maintaining human health and well-being (Chartered Institute of Horticulture 2015).

The horticulture industry is one of the most significant sectors in the world. The production of fruits and vegetables has acquired much importance in recent times due to their increasing demand. Global fruit production was reported at 548 million tonnes and vegetable production at 990 million tonnes in 2011. The size of the global floriculture industry stood at around US\$109 billion, while the demand for fruits, vegetables and flowers has been constantly on the rise (Research and Markets 2015).

By 2050, the world population will exceed nine billion people of which more than 68 per cent will be living in cities. To feed this growing population, FAO estimates that an average annual increase in production of 44 million metric tons per year to be sustained for 40 years must be attained. The situation may be further compounded by the scarcity of natural resources required for agriculture and the impact of climate change.

In 2008, the *World Development Report; Agriculture for Development* described the global performance of agriculture as “impressive”: from 1980 to 2004, the GDP of agriculture expanded globally by an average of two per cent a year, more than the population growth of 1.6 per cent a year. This growth, driven by

increasing productivity, pushed down the real price of grains in world markets by about 1.8 per cent a year over the same period. Developing countries achieved much faster agricultural growth (2.6% a year) than industrial countries (0.9% a year) in 1980–2004. Indeed, developing countries accounted for almost 80 per cent of overall agricultural growth during this period; their share of world agricultural GDP rose from 56 per cent in 1980 to 65 per cent in 2004 (World Bank 2008, p. 50).

Within the agriculture sector, horticultural development has been described as “a revolution”. Fruits and vegetables are one of the fastest growing agricultural markets in developing countries, with production increasing by 3.6 per cent a year for fruits and 5.5 per cent for vegetables over 1980–2004. During this period, 58 per cent of the increase in worldwide horticulture production came from China, 38 per cent from all other developing countries, and the remaining four per cent from developed countries, suggesting that the boom in horticulture is mainly benefiting developing countries (World Bank 2008, p. 58).

In Pakistan, one of the countries identified for this review, agriculture contributes 25 per cent to the GDP, employs 44 per cent of country's workforce while it substantially contributes to export earnings. This is mainly due to the presence of vast agricultural resources, which is a result of geography, landscape, soil and climate. In addition the country has a well-established irrigation system with the result that all types of agriculture produce are grown depending upon the climate and soil quality conditions.

Within Pakistan's agriculture sector, horticulture plays an important role. Approximate yearly production of fruits, vegetables and spices is 12 million tons. The important fruits include citrus (2 million tons), mangoes (1 million tons), dates (0.63 million tons), and apples (0.4 million tons). In addition, there are a large variety of other fruits that are harvested around the year. Important vegetables and spices include potato, onion, tomato, chillies, garlic and a large variety of leafy, root and other crops. In recent years, the floriculture industry has significantly emerged as a viable non-traditional produce, particularly, in the urban centres of the country. A large number of flowers and foliage plants are now being grown for ornamental purposes. Horticulture produce in Pakistan also holds a huge market for exports. The relative importance of this sector can be gauged with high growth rate of exports of fruits and vegetables from Pakistan due to ever increasing demand in the existing and new international markets. Some of the fruits grown have great potential for exports, which are available in volumes, varieties and are of rich flavour (Pakistan Horticulture Development and Export Company 2013).

In Africa, agriculture creates most of the jobs. The agricultural population in Africa stands at 530 million people, and is expected to exceed 580 million by 2020. The population relying on agriculture accounts for 48 per cent of the total African population. A special feature of African agriculture in comparison to the rest of the world over the last 30 years is that the sector has continued to absorb a large proportion of the working population; half of all new entrants to Africa's working population have turned to agriculture (NEPAD 2013, p. 15).

## 5.2 The Business Environment for the Horticulture Sector

The following dimensions have emerged when examining the BE for the horticulture sector:

- Policy development and reform;
- Legal and regulatory framework;
- Regulation and quality assurance; and
- Institutional arrangements.

Each of these dimensions is presented in detail below.

### 5.2.1 Policy development and reform

Policy development and reform in this sector can be found at national and regional levels.

#### **National policy frameworks**

The University of California (2005) argues that the prerequisites for a thriving horticultural industry include secure systems of land tenure, reliable credit markets geared towards resource limited producers and firms, equal opportunities for education, and adequate infrastructure.

Effective policy frameworks aimed at improving agricultural production and poverty alleviation will also take into account the ‘critical triangle’ of how agricultural growth and poverty affect natural resources. Regulatory mechanisms for protecting natural resources, worker and food safety, and the rights of small producers and firms in contractual relationships with larger companies will promote a sustainable and just horticultural sector (University of California 2005 p. 53).

NEPAD (2013, p. 11) recommends that national policies for agriculture development focus on five priority areas:

- Increasing production more sustainably, while absorbing a growing labour force;
- Promoting diversification based on high quality processed products by offering more standardised products in terms of taste, shelf life and, increasingly compliance with health and environmental standards;
- Promoting efficient and more equitable value chain development by encouraging intra-branch approaches;
- Making farms and agricultural systems more resilient to a changing environment; and
- Developing regional markets and controlling international integration.

Shepherd (2007) suggests that while governments should concentrate on developing an environment that can enable the private sector to function in a competitive way, they “often seek to move beyond facilitation towards direction, by taking over decisions about areas in which investments are made”. This leads to interventions that act as a disincentive for purely commercial investment and, “if misguided investments promote market surpluses, can also increase the risks that both the ‘beneficiaries’ and other farmers face”.

Cooksey (2007) asks whether the policy environment matters for horticulture investors. His interviews with investors suggest they are “more concerned with what the government does than with what it says”. They worry that government actions often contradict policy commitments and investment conditions, for example, over the imposition of VAT on imports and exports. Lack of coordination between government departments and rent-seeking practices increase uncertainties and the cost to doing business. “Information on these and other (un)official practices filtering back along the information grapevine is likely to discourage potential investors, however rosy the formal policy environment may be” (Cooksey 2007, p. 14).

Effective policy must, says NEPAD (2013, p. 11), exhibit a multi-sector character: effective agricultural policy must be comprehensive and based on actions in different areas such as infrastructure investment, and economic policy measures, for instance on trade, taxation, social sectors, regulations, training and the effectiveness of institutions”. Ministries of agriculture cannot address all these components alone. Thus, agricultural policy must be defined as an overall priority, and allocated to various administrations and stakeholders according to responsibilities, and to constituencies at different geographical levels according to their competencies under the principle of subsidiarity.

In Pakistan, Raja (2013) says there is a need to formulate a comprehensive horticultural policy which should “indicate the broad direction, create institutions and define their respective roles, make rules for coordination, set safety standards and provide an incentive and rewards system for various stake holders”. Within this framework the government’s role “should be confined to policy formulation, regulation, capacity building and facilitation, while the private sector will take the lead in investment and value chain development, on its own or on public-private partnership basis”. The policy should:

- Ensure sustainability by promoting environment friendly good horticultural practices through incentives and rewards, awareness campaigns and promulgation of appropriate legal framework;
- Ensure equitable distribution of gains from enhanced productivity by making available public sector goods and services to all stakeholders without distinction;
- Accelerate the national economic growth by increasing the rate of growth of this important subsector of the economy;
- Reduce unemployment by creating jobs in horticulture sector;
- Increase Pakistan's foreign exchange earnings by increasing quantity, quality and variety of horticultural exports;
- Ensure food security and nutritional balance of the people’s food intake by providing them vitamin rich horticultural products;
- Help the state in its poverty alleviation efforts by providing them a labour intensive, low capital intensive investment; and
- Improve the condition and status of women by providing them opportunities to own resources.

In its global assessment of horticulture, the University of California (2005) argues for policy considerations to be given to:

- Regulatory systems for horticultural standards;
- Clarification and application of intellectual property rights agreements;
- Secure land tenure and credit markets for small producers and agribusinesses;
- Water use systems; and
- Postharvest and food safety protocols.

Some of these issues are examined further in the sections that follow.

There are a number of critical areas in national policy that deserve particular attention within the context of agriculture and horticulture development. These are discussed below.

### **Trade agreements**

Trade agreements, such as the North American Free Trade Agreement, other treaties within the Pacific Rim region (e.g., Chile and Singapore), and African, Caribbean, and Pacific (ACP) economic partnerships with the European Union (EU), have unfolded within and across regions with a distinctive set of opportunities and challenges to nations, markets and producers. This includes the US African Growth and Opportunity Act. However, trade agreements do not necessarily ensure equity or growth and there is evidence to suggest that treaties such as the EU-ACP treaty favour developed nations as opposed to developing nations and in the short and medium term, are harmful towards smaller producers and subsistence farmers. Shepherd (2007, p. 14) argues that “successful export market development usually owes more to an active private sector working within a supportive policy and institutional environment than it does to donor intervention”.

### **Subsidies**

In SSA four specific interventions have been used in the recent past that can be considered to be “market-smart” subsidies and provide assistance to the poor while not interfering with markets (Kelly and Crawford 2007, p 67):

- Input vouchers—redeemable by commercial suppliers or credit institutions;
- Demonstration packs—even if very small in size and designed to stimulate demand;
- Matching grants—farmers or farmer groups invest an equal amount to the grant in some activity that is related to fertiliser use; and
- Credit guarantees—used to encourage input importers to offer credit to distributors further down the value chain.

### **Regional policy frameworks**

Regional policy frameworks have been developed in recognition of the regional character of agriculture markets. In the case of Africa, many regional economic



communities have focused on ways to improve cross-border trade in the supply of agricultural inputs and the export of agricultural products.

The Comprehensive Africa Agriculture Development Programme (CAADP) is a framework that reflects the recognition that agriculture is central to the alleviation of poverty and hunger in Africa. The AU and NEPAD launched CAADP in 2003 in an effort to accelerate agricultural growth in the region. CAADP provides a vision for African agriculture that would achieve food security, and improve productivity so as to reach an annual growth rate of six per cent, create dynamic agricultural markets, integrate farmers into the market economy, achieve more equitable distribution of wealth, be a strategic player in science and technology development, and practice environmentally sound production methods. See Box 3.

The AU Heads of State and Government summit in Maputo embraced CAADP as the investment framework for sustained agricultural development in Africa. The vision urges Member States to invest at least ten per cent of their country's national budgets in agriculture.

In June 2014, the African Heads of States adopted the Malabo Declaration, which reaffirmed the principles and values of the CAADP process. This includes “the pursuit of agriculture-led growth as a main strategy to achieve targets on food and nutrition security and shared prosperity”, as well as “support implementation at countries levels, and regional coordination and harmonization”. The Heads of State expressed their commitment to enhancing investment finance, both public and private, to agriculture and “to create and enhance necessary appropriate policy and institutional conditions and support systems for facilitation of private investment in agriculture, agri-business and agro-industries, by giving priority to local investors”.

**Box 3: CAADP Pillars**

CAADP focuses its interventions in four key pillars to achieve measurable outcomes:

**Pillar 1: Extending the area under sustainable land management and reliable water control systems**

The application of water and its managed use has been an essential factor in raising the productivity of agriculture and ensuring predictability in outputs. Water is essential to realise the potential of the land and to enable improved varieties of both plants and animals to make full use of other yield-enhancing production factors. By raising productivity, water management helps to ensure better production both for direct consumption and for commercial disposal, thereby enhancing the generation of economic surpluses necessary for uplifting rural economies.

**Pillar 2: Improving rural infrastructure and trade-related capacities for market access**

This pillar deals with complementary investments in rural infrastructure, particularly rural roads, storage, processing and market facilities, that are required to support the anticipated growth in agricultural production and improve the competitiveness of production, processing and trade in the crop, livestock, forestry or fishery sub-sectors.

**Pillar 3: Increasing food supply, reducing hunger, and improving responses to food emergency crises**

Hunger remains a major peril for far too many people in Africa, with many adverse

consequences for health and productivity. In Africa as elsewhere, the poorest and the most hungry tend to be one and the same people, living on the margin of survival and highly vulnerable to any shock. There is no doubt that eventually Africa will develop a diversified agricultural sector with commercial as well as smallholder farming. However, in the short term, the need is for an immediate impact on the livelihoods and food security of the rural poor through raising their own production.

**Pillar 4: Improving agriculture research, technology dissemination and adoption**

Agricultural research, technology dissemination and adoption present an area of intervention for long-term gain. In Africa as elsewhere in the world, agriculture will need a scientific and technological underpinning if it is to have sustained productivity gains necessary to remain competitive.

The CAADP provides a framework for the preparation of a National Agriculture Investment Plan (NAIP). These plans identify and prioritise key national investment and policy changes required to enhance agricultural productivity growth. Within this context, a NAIP provides a national implementation strategy for achieving the CAADP targets of annual agricultural growth rate of at least six per cent and an annual national budgetary allocation of at least ten per cent.

Within east and southern Africa, COMESA has recognised the significant role agriculture plays in regional integration. To this end, Chapter 18 of the COMESA Treaty details areas of cooperation in agriculture, which include, among others, the supply of staple foods, trade facilitation, research and extension and strengthening farmers' capacity to participate in agricultural development. Thus, under article 182 of the Treaty COMESA established the Alliance for Commodity Trade in Eastern and Southern Africa (ACTESA) as its specialised agency to handle agricultural commodity trade and production.

### 5.2.2 Legal and regulatory framework

The legal and regulatory framework typically presents a number of challenges to developments in the horticulture sector. In part, increasing concerns over phytosanitary standards drive the demand for reform, particularly as developing economies become more integrated into world markets. However, there are also numerous examples of legal and regulatory instruments that are used to protect local markets as well as laws and regulations that are old and out of date. In some countries that have shifted from a socialist state to a more liberal, market-based system, the old laws and regulations have not been changed and continue to be a barrier to increased private investment.

In Pakistan, UNIDO and the EU through the Trade-Related Technical Assistance (2013) program published a research report into the BE reforms required to enhance competitiveness and exports in the horticulture sector, focusing on mangos and kinnow mandarins.<sup>14</sup> Key concerns identified include:

- Lack of a clear government policy and strategy for the export of horticultural products;

<sup>14</sup> Trade Related Technical Assistance (2013) Policy Reforms Required to Enhance Competitiveness and Exports of Horticulture (mangos and kinnow), December, TRTA-II, Islamabad

- Lack of regulatory oversight in the wholesale auction market, which distorts product pricing and standards;
- Fill the gaps in the regulatory framework governing the quality of exported products;
- Improve border processing of exported goods;
- Better regulation of nurseries providing plant materials; and
- Develop legal framework for contract farming — currently there is no formal legal framework defining roles and responsibilities of contracting parties and there is an urgent need to bring this form of trade under regulatory framework.

In Tanzania, Cooksey (2007, p. 19) describes how “weaknesses in the business environment add an estimated twenty per cent to the cost of doing business”. One investor-respondent indicated that ‘bureaucracy’ and lack of coordination between government departments costs his business hundreds of thousands of dollars.

Shepherd (2007) suggests there are many legal issues that governments should address in order to promote agribusiness development. Companies are unlikely to invest in countries where there is general political uncertainty. An environment where corruption is prevalent is not conducive to investment in any sector, and particularly in agriculture, which even in the best policy environment is always fraught with risk. These issues include contract law, anti-trust law and the introduction of regulations relating to pesticide use, food standards, seed quality and provision of arrangements to certify quality, geographic origin, etc. “The emphasis should be on enabling successful market linkages rather than on trying to control those involved in production and marketing”.

### **Taxation**

Taxation is a powerful tool for providing incentives and disincentives to investors and financiers. Flexible tax regimes can help industries deal with external shocks. However, tax regimes require consistency, particularly where sizeable investments are made on the basis of policy changes.

Shepard (2007) presents the case of Mozambique, which reduced export taxes on raw cashews, leading to a surge in exports of raw nuts and hard times for domestic processors. From 2001 the policy was changed, giving renewed encouragement to processors and the establishment of village-based primary processing with donor and NGO support. Considerable progress has been made but this could be jeopardised if there were further changes in the export tax policy.

In Tanzania, in the early 2000s the Tanzanian Investment Centre offered a package of attractive incentives to horticulture investors. However, implementation was poor. Imported inputs were frequently held up at the border point until duties were paid. Claiming back duty paid was a long and often futile task. These tax issues constituted a major disincentive to investors, especially

when compared to Ethiopia where investors get considerable help (Cooksey 2007).

### **Contract reform**

Kelly and Crawford (2007, p. 48) suggest there is general consensus that legal and regulatory reforms are needed improve commercial contract arrangements. Contracts need to be “clarified, simplified, and enforced through a legal and judiciary system that can make decisions quickly and is not subject to corruption”.

### **Land tenure**

Land tenure is a critical issue for many smallholder farmers, many of whom farm on communal or public-owned land. Traditional land tenure systems in many countries provide little incentive for farmers to invest in the improvements necessary to fully exploit market opportunities. Such improvements can include irrigation equipment, soil improvement and infrastructure required to comply with international standards such as EuropGAP.

The lack of secure property rights also makes it difficult to obtain loans for inputs, as these usually require collateral. Where irrigation is required a related issue is that of water rights and the management of water allocation (Shepherd 2007).

### **5.2.3 Standards and quality assurance**

Horticulture exporters are required to comply with international phyto-sanitary standards. All these incur significance compliance costs in the interest of minimising ‘reputational risk.’ However, in his investor survey Cooksey (2007) complained that compliance costs are excessive or prohibitive. Others suggest that the standards imposed by the private sector and governments, certification requirements, and the growing need for traceability all impose high costs that are difficult for small farmers to absorb. “Even before these new developments, exporting was a difficult and risky business and best undertaken by private companies with the necessary skills and resources, rather than by small groups of farmers” (Shepherd 2007, p. 41).

Exports to sophisticated markets can involve farmers in considerable complexity and risk. The high quality, safety and logistical standards demanded by importers (e.g. for organic certification, for EuropGAP or for the purposes of traceability) can be expensive and difficult, although not impossible, to achieve by smallholders (Shepherd 2007).

The Agreement on the Application of Sanitary and Phytosanitary Measures, also known as the “SPS Agreement”, is an international treaty of the WTO. It was negotiated during the Uruguay Round of the General Agreement on Tariffs and Trade, and entered into force with the establishment of the WTO at the beginning of 1995. Sanitary and phytosanitary (SPS) measures covered by the agreement are those aimed at the protection of human, animal or plant life or health from certain risks.

Under the SPS Agreement, the WTO sets constraints on member-states’ policies relating to food safety (i.e., bacterial contaminants, pesticides, inspection, and

labelling) as well as animal and plant health (i.e., phyto-sanitation) with respect to imported pests and diseases. There are three standards organizations that set standards that WTO members should base their SPS methodologies on: the Codex Alimentarius Commission, the World Organization for Animal Health and the Secretariat of the International Plant Protection Convention.

In Pakistan, Raja (2013) argues horticulture production and export promotion should be based on quality. Testing laboratories must be established to certify quality of the produce for exports and in the domestic market. A coherent sanitary and phyto-sanitary management system for strong coordination and effective interaction between various departments involved in inspection, testing and other related activities should be facilitated. The regulations and procedures of export and import of horticulture industry commodities should be reformed to reduce compliance and transaction costs as part of achieving efficiency gains.

Investors in the Pakistan mango sector have complained about the gap between government policy and other services. For example, in response to a fruit fly infestation the Department of Plant Protection now requires exporters to treat mangos with hot water prior to shipments to EU. In 2014, there was only one facility available capable of the “hot water treatment”. Many planned shipments had to forgo their deliveries. Farms need to be certified by the department on fruit fly management to qualify for EU exportation. The Department of Plant Protection technical staff are responsible for certification. The large farms may possibly undergo such certification, but small farms have no capacity to qualify. These small farms need technical support and training on fruit fly management.<sup>15</sup>

In another example of pesticides registration: the number of registered pesticides for use in Pakistan is limited. This limits the access of more effective and new pesticide products to the farmers, particularly to GlobalGAP farmers who abide by the compliance of using locally registered pesticides on their crops and for post-harvest treatment. The National PakistanGAP Scheme covers the Good Practices of Farm cultivation, hygiene practices, pesticide safe application and safe food practices for the farmers and processors. Private farms and processors undertake certification on these standards. Local authorities are not participating in these activities in Pakistan.

In Pakistan’s Punjab Province, global priorities to produce safe food and the demand for Maximum Residual Levels are becoming critical and may create barriers as the government has no policy reforms so far.

#### 5.2.4 Institutional arrangements

Governments and donors have for many years tried to establish market information services but these have often suffered from problems of both

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<sup>15</sup> In Pakistan’s Punjab state, USAID is supporting the Punjab Enabling Environment Project (PEEP-Project) with the Government of Punjab. The project is coordinating with different stakeholders of the mango industry (i.e., Mango Growers Association, academia, research organisations, processors, middlemen, exporters and the Department of Plant Protection) to deal the policy issues creating hindrance in export. The Government of Punjab is promoting mango export to high-end markets.

sustainability and data accuracy. Moreover, such services usually address only basic agricultural commodities and may be ill equipped to provide information on export markets or on markets for processed products.

### **Industry representation**

NEPAD (2013, p. 45) describes how agricultural producers have had to organise themselves in order to take over the roles states had formerly played before markets were liberalised. These roles included the supply of inputs, support and advice, the grouping of supply, storage and marketing. Other organisations have positioned themselves in the trade union sphere. “With very few exceptions, producer organisations have a limited economic impact and are highly dependent on external funding. A number of cash crop sectors such as cotton and coffee or a powerful trade sector (e.g., Zimbabwe, South Africa) have also formed the basis of agricultural organisations that influence economic strategies and political life. They are universally recognised by the public authorities as stakeholders in negotiating agricultural policies and programmes”.

Farmer organisations are of different sizes in terms of membership, outreach, resource endowment (i.e., human, financial and assets), with the majority being small. While some organisations are well established, many have only been formed in recent years and are still small in capacity.

Producer organisations have also been formed at the regional level in Africa. This includes, for example, the Pan-African Farmers’ Organisation, which brings together two types of regional networks: those made up of national platforms of smallholder organisations and those that are direct members of producer organisations in the countries concerned. Another example is the Southern African Confederation of Agricultural Union. These organisations have become active partners of regional economic communities, the AU and NEPAD. However, NEPAD (2013, p. 45) claims that these networks “remain fragile due to their members’ vulnerability, their difficulties in becoming more professional and, sometimes, their insufficiently representative nature”.

In Pakistan, trade associations such as the Kinnow Growers, Processors, Exporter and Cooperative Association and the Kinnow Growers Association are advocates for reform in the horticulture sector. However, many trade associations are run and managed by the more influential members. Smaller sized members are often excluded from the decision-making processes. These associations should be extended to more of the medium and small farmers, farmers’ groups and market intermediaries. The benefits and interactions of the agencies and ministries have always been focused on the few and influential members of the fraternity. Field trips, overseas trips have often included the same people in the industry. The selection criteria of who can qualify for the sponsored trips need to be changed.

### **Public private dialogue**

Because governments need to consult to ensure the right enabling environment, Shepherd (2007, p. 43) recommends that governments organise regular consultations with the private sector and with “linking organisations” to identify and address concerns about policy and the legal and institutional frameworks.” He

proposes the creation of “inter-professional commodity or industry associations” that can liaise with government on policy issues. He cites the Sugar Board of Tanzania, which has membership drawn from both sugar millers and out growers and arbitrates on behalf of all. Relationships between out growers and millers are said to have improved considerably now that there is an effective mechanism to resolve issues related to breach of contract and allegations of inaccurate grading and weighing.

Tanzanian policymakers, says Cooksey (2007, p. 35), “easily forget that ultimately external markets determine the nature of Tanzania’s insertion in global value chains, horticultural included, not the implementation of a national strategic blueprint. Yet the revised horticulture strategy proposes just such a blueprint”.

### **Research and development**

The University of California (2005) suggests that significant research is required to determine:

- The effects of intellectual property rights on production choices;
- The consequences of trade liberalisation and market aggregation for small producers and households;
- Credit markets; and
- Operation of up-to-date phytosanitary monitoring systems.

### **5.3 Lessons learned**

The following lessons from BER practices in the horticulture sector have been identified in this preliminary review:

- National policy frameworks for horticulture development can help to establish the macro-conditions for improvement in the horticulture sector and can guide government interventions and private sector partnerships at national, regional and local levels. However, many national policies do not pay sufficient attention to the needs of private investors and the development of agri-businesses within the horticulture sector.
- National policies should address a ‘critical triangle’ of policy concerns: agricultural growth, poverty reduction and natural resource management.
- Other relevant policy issues include contract law, anti-trust law and the introduction of regulations relating to pesticide use, food standards, seed quality and provision of arrangements to certify quality and geographic origin, etc. Policies should seek to improve market linkages.
- Regional policy frameworks can be used to create new and expanded market opportunities for horticulture producers. These focus on improving cross-border trade in the supply of agricultural inputs and the export of horticulture products.
- While increasing attention of phyto-sanitary standards drive the demand for legal and regulatory reform, these reforms should not be used to

isolate or protect local markets. Instead, these reforms should focus on increasing competitive pressures and integrating local and global markets.

- The major challenge for horticulture producers in developing economies is to meet the growing set of standards required to enter world markets. This requires significant improvements in the national policy, legal and regulatory framework as well as in national standard setting and testing. While lead firms, such as national exporters and multi-national enterprises, play an important role in helping local firms comply and link local producers to international markets, there is a high demand for public investment into improved standards, testing facilities and enforcement mechanisms.
- Regulatory mechanisms should be established to protect natural resources, worker's rights and food safety, as well as the rights of small producers and firms in contractual relationships with larger companies.
- Contract reform is a critical issue for business environment reform in horticulture. Legal and regulatory reforms are needed to improve commercial contract arrangements. Contracts should be clear, simple and enforceable. In some cases it may be necessary to develop a legal framework for contract farming, which defines roles and responsibilities of contracting parties.
- Land tenure is important for smallholder farmers, many of whom farm on communal or public land. Traditional land tenure systems in many countries provide little incentive for farmers to invest in the improvements necessary to fully exploit market opportunities. Thus, reform of property rights and land titling may be required.
- Small-scale farmers and agribusiness are generally poorly represented in policy development forums and public-private dialogue. Commercial success for these actors is often associated with linkages that are formed with large-scale exporters. However, government policy makers and programme managers need to be aware of the challenges faced by small-scale operators.



## 6 Common issues affecting vertical business environment reform

Drawing from the findings in the four preceding chapters, this chapter identifies some of the common issues affecting sector-oriented BER.

### 6.1 Policy frameworks and reform

#### **A national policy framework is essential**

National policy frameworks provide a guide for reforms and the coordination of many actors. In some cases, sector development is embedded in broader policies, such as local content provisions in national mining policy or pharmaceutical production within a national health policy or industry policy. However, there are clear advantages in specific policies and strategies that address the concerns of targeted sectors or sub-sectors and connect industry development and reform interventions across a range of government portfolios. National policy frameworks can focus reform efforts and provide an opportunity for government and the private sector to come together around a common vision, goal and set of strategies. The review shows a high-degree of evolution in the use of policy and policy instruments (e.g., RE).

#### **The multi-dimensional nature of policy**

All the sectors reviewed demonstrated the need for policy frameworks to provide integrated, coherent and well-coordinated responses to the multi-dimensional needs of private firms. While one ministry would typically lead the development and implementation of the policy or strategy, many others are closely connected. However, each of these has a mandate, powers and interests, which can create challenges to effective coordination and collaboration.

#### **Regional markets and reform policies**

In all sectors reviewed, the sector markets extend beyond national boundaries. Whether through the importation of inputs for local production (e.g., agricultural produce) or the sale of local goods (e.g., medicines, agricultural produce), business is increasingly required to deal with the business environments of neighbouring countries. In a number of sectors reviewed (e.g., pharmaceuticals, agriculture), increasing attention is being given to the development of regional policy frameworks, including industrialisation policies and programmes.

#### **Policy implementation is a persistent challenge**

In all the sectors reviewed, concern has been expressed regarding the ability of governments to successfully implement national policies and strategies. Policies and strategies are, by nature, ambitious documents that present long-term goals, along with more immediate milestones. However, the ambition, scope and integrated nature of modern-day policies and strategies create a substantial challenge. Many governments lack the capacity to effectively coordinate a comprehensive and integrated set of strategies. On the other hand,

implementation also requires commitment and a way of overcoming the resistance that some entrenched interests will provide.

### **Political will and commitment**

It is clear that political will and commitment is required to create an agenda for reform and to ensure a reform programme is adopted and implemented. This was clearly expressed in the reforms found in the pharmaceutical and RE sectors. However, while high-level political will may exist, even at the highest levels of government, more is required to infuse this desire for and commitment to change at lower levels and equally across ministries. Often, political-will appears aspirational rather than pragmatic. The true test is to follow through with a reform programme over the long term and to squarely face the intended and unintended resistance to change that emerges.

### **Resistance to change**

Because reform is about change, many actors that are content with the current arrangements are likely to resist it. This resistance may take the form of a general reluctance to change (e.g., to deal with small pharmaceutical producers, instead of the established, large-scale providers) or it may be a deliberate undermining of reform efforts (e.g., as reported in the RE sector). MNEs and traditional (fossil fuel) energy providers can be threatened by reforms that open up the market and potentially challenge their dominant position. Similarly, national enterprises that have benefited from protection may resist change. Thus, balancing interests and powers of MNEs and local firms is a major challenge. Reformers should understand the political economy of the country and the processes of change.

### **Connections between BER and industrial policy**

Many of the sectors reviewed here involve a combination of BER and industrial policy. Support for GMP and GAP reflect these interests. Sometimes, the line between the two is difficult to distinguish. However, what is clear is the need for consistency across these efforts. The DCED Annex on Industrial Policy is a relevant resource in this regard.

### **Public procurement and subsidies**

In many developing economies, government is a major market actor. This is particularly pronounced in the pharmaceutical and RE sectors. This is also the case in relation to the fertiliser sector. Public procurement policies and programmes, including government subsidy schemes, can have a dramatic effect on these sectors. There is a need to ensure these policies and programmes are consistent with and connected to national policies for sector development.

## **6.2 Legal and regulatory reform**

### **Laws and regulations need to be consistent with national policies**

In many ways, policy is easy to change. What is more difficult, as identified above, is the implementation of policy. Part of this challenge is to reform the legal and regulatory framework through which policy objectives are realised. A clear,

coherent and consistent legal and regulatory framework has many moving parts and takes time to create. While policy is aspirational—desiring change—legal and regulatory instruments are typically conservative and can be used to resist change and innovation.

This review has identified a number of cases in which the legal and policy framework contradicts, competes with, or undermines national policies. This includes tax exemptions on imported medicines and not raw materials, which is inconsistent with policies that seek to boost local pharmaceutical production. Similarly, exempting mining companies from VAT on imports can undercut that goods and services are provided by local suppliers.

### **Coherence across national and sub-national laws and regulations**

In all the sectors reviewed in this report, private firms are required to deal with national and sub-national (e.g., local government) laws and regulations. In many cases there is a lack of coherence between these levels of government, making the process of compliance more difficult. Taxes, duties and royalties can be used to influence firm behaviour and promote investor confidence. They are also useful instruments when promoting strong and transparent fiscal linkages between strategic industry sectors and the broader economy.

### **Regional markets can drive increased investment**

In a globalised economy, regional markets play an increasingly important role. The regulation of regional markets is becoming an important element in BER at the sector level. This report has identified a number of regional reforms that attempt to harmonise and streamline regulations across regions.

### **Legal and regulatory instruments based on business models**

In a number of sectors examples have been found of legal and regulatory instruments that have been designed around specially defined business models. Here, legal and regulatory instruments, such as tax incentives, have been designed to respond to the long time frames required from initial investment to first profits (e.g., RE supply) or to encourage local supply and purchasing practices.

### **Lack of awareness in government of private sector concerns**

Poor legal and regulatory frameworks have often been created or enforced when government lacks understanding of the practical problems or opportunities private firms face within the specific sector or sub-sector. Many respondents to this review, from a variety of sectors, have complained that their governments do not sufficiently understand the capacity of the firms in the sector, their challenges or the ways government could more effectively stimulate demand. Governments need to engage more closely with private investors and understand their challenges.

### **Common (persistent) challenges**

Across the sectors reviewed in this report there are a number of challenges that are experienced in the legal and regulatory framework. These include:

- Lack of clarity on processes and procedures: many examples have been found of the problems investors face because the steps required to comply with the relevant laws and regulations are unclear;
- Length of time taken to comply: it often takes a significant period of time to comply with the legal and regulatory framework, usually because of the multiple steps involved and the number of ministries, departments and agencies, across different levels of government, which investors must deal with.

There appears to be some scope for considering one-stop facilities within targeted sectors to facilitate compliance.

### 6.3 Regulatory authorities

Industry regulation and the role of regulatory authorities is a critical issue across all sectors. Many sector regulators considered in this report exhibit common problems:

- Lack of capacity (i.e., under-staffed, under-resourced);
- Lack of skills needed to fulfil their responsibilities;
- Lack of autonomy from government with industry involvement.

Sector-focused BER requires a sound understanding of the role of regulation and regulatory authorities.

### 6.4 Standards and quality assurance

The role of standards and quality assurance is particularly pronounced when sector-focused BER is considered. Increasingly, products and services are required to meet clearly defined national and international standards. In the sectors reviewed there has been little concern expressed about the standard-setting processes. Most concern has been levelled at the systems and facilities required to effectively monitor standards, test products and prosecute those who are selling sub-standard or counterfeit products. The DCED Annex on Quality Infrastructure is relevant in this context.

### 6.5 Institutional arrangements

#### **Beyond political will, institutional leadership is required**

Successful BER requires senior-level leadership that guides institutional arrangements in order to achieve a coordinated, integrated and pragmatic response to the problems faced by private firms while pursuing the government's reform agenda. All the sectors reviewed here highlight the importance of the institutional framework.

#### **Dealing with multiple stakeholders**

Because of the integrated nature of development strategies and reforms surrounding these sectors, it is clear that there are many stakeholders involved and that these need to be managed carefully.

### **Public-private dialogue**

PPD mechanisms were found in most, if not all, the sectors reviewed. While some sectors were better served than others by these mechanisms, in general, large industry actors, including MNEs, dominated PPD processes. Many respondents indicated that there should be more PPD and that government policies, laws, regulations, and institutions could be better informed if PPD was used more frequently and made much more inclusive.

## 7 Donor support for sector-specific BER

This chapter briefly considers the findings of this report in terms of its implications for donor and development agencies, often known as ‘development partners’ in developing countries. As described in Chapter 1, donor and development agencies work with developing-country governments, and the private sector, to support BER because of the significant influence the BE has on the development of the private sector and therefore on economic growth and the generation of livelihoods and jobs. BER endeavours to change the behaviour of private enterprises in ways that lead to increased levels of investment and innovation and the creation of more and better jobs.

This review has revealed a number of areas where donor and development agencies are working with government and sector actors to improve the BE at the sector level.

When supporting business environment reform within specific industry sectors, donor and development agencies should, in partnership with developing-country governments and the private sector, consider the following practices.

### **Support national policy frameworks to strengthen coordination and integration within and across industry sectors and sub-sectors.**

In all four sectors reviewed, new national policy frameworks were being used to drive and guide the reform process. In all cases, national policy frameworks sought to keep up-to-date with international trends and national realities. All policy frameworks spanned a range of government ministries, departments and agencies, as well as all levels of government. Thus, increasingly, policy development and implementation adopts a multifaceted and integrated character, which can be extremely challenging.

Donor and development agencies provide support to these policy frameworks, as well as to policy implementation and monitoring mechanisms.

### **Use regional policy frameworks to guide regional market reforms and harmonisation—donor and development agencies can provide support to regional policy frameworks, as well as to the assessment of policy, legal and regulatory barriers to regional trade.**

There have been examples presented where the development of regional policy frameworks have been used to guide reform and harmonisation across a number of states. This was particularly apparent in the pharmaceuticals and horticulture sectors where access to neighbouring markets by local producers is important. Regional harmonisation aims to reduce non-tariff barriers to regional trade and enhance regional trade opportunities, in order to expand the size of markets local producers have access to. While the substance of regional harmonisation deals with the sector-specific realities of non-tariff barriers, the use of a regional policy mechanism to do this makes it a general BER issue.

Donor and development agencies provide support to regional policy frameworks, as well as in the assessment of policy, legal and regulatory barriers to regional trade. Donors can support the design, management and monitoring of regional harmonisation and trade reform programmes.

**Address anti-competitive behaviour, while promoting open markets and responding to the political-economic obstacles to reform.**

In a number of the cases reviewed, a resistance to increased local competition was found. While one of the key objectives of BER is to increase local competitive pressures, such as by increasing the number of new entrants, there are many firms with significant economic and political power that resist these changes. This issue was particularly noticeable in the RE sector where incumbent firms actively sought to use legal and regulatory instruments to prevent new firms from entering the market.

Competition laws and institutions are considered to be a general BER domain. However, this issue (i.e., competitiveness) is particularly relevant when specific industry sectors are investigated. Donor and development agencies should apply a political-economic analysis to identify the roots of anti-competitive behaviour and work with governments and other programme partners to develop a practical response.

**Improve the quality of regulatory governance by building the capacity of regulators and strengthening accountability mechanisms.**

In all four sectors reviewed, the need to improve the quality of regulatory governance is recognized. In some sectors (e.g., pharmaceuticals, horticulture), there is a specific need to improve the effectiveness, autonomy and capacity of regulatory authorities. However overall, the demand for a more rule-based, transparent and accountable regulatory regime was documented. Thus, donor and development agencies can work with national regulatory authorities to build their capacity and to improve their governance and accountability mechanisms.

**Strengthen industry representation and public-private dialogue by helping small-scale enterprises to become better organised and represented in industry associations and more engaged in dialogue structures.**

Across all four sectors larger firms dominated most industry representative structures. Small-scale enterprises, including small-scale farmers, are typically under-represented in these structures and have a weaker, less organised “voice”. Similarly, many PPD structures were found to be weak and inadequate.

While many donor and development agencies support PPD across the general business community, there is clearly a need to support industry-oriented membership and representative organisations and to support improvements in sector-specific PPD.

**Support industrial policy interventions that improve access to finance and information to help small-scale enterprises obtain the resources they require to expand and exploit the opportunities created by business environment reform.**

Many firms operating in the four sectors reviewed face the problem of access to finance. This is common in all four sectors. Thus, while this review found examples of programmes dealing with this issue (e.g., finance for RE producers, capacity building programmes in the pharmaceutical and mining supply sector), improving the access to finance for firms is a general BER issue relevant to all sectors.

Similarly, access to information is critical at many levels. Firstly, government policy makers require information that can be used to inform the policy making process. Donor and development agencies can support the generation and distribution of relevant, up-to-date data and information on the sector that can be used by governments and sector actors to inform government policies and programmes, and business advocacy. Secondly, many private sector firms require better market information that can be used to inform their investment decisions. Donor and development agencies can work with sector associations to improve the access local firms have to market information.

**Support the creation of new financing instruments designed to respond to the specific sectors and business models.**

A major focus in the RE sector is the development of instruments that are typically tailored to suit the business model that underpins RE. The aim of these instruments is to reduce investor costs, guarantee returns of the long-term and crowding in new private investors. In addition, energy laws and regulations must make provisions for the production and distribution of energy. They include purchase price agreements, feed-in-tariffs and net metering.

**Support the reform of sector-specific taxation instruments to influence business and investment decisions.**

Taxation is a common BER concern at the horizontal level. However, within the specific sectors, taxation plays a specific role. In the case of the pharmaceutical sector, we have seen that the application of VAT on raw materials can provide an unfair advantage to drug importers over local producers. Similarly, we have seen how tax concessions can boost investments into RE and how VAT on imports can affect opportunities in the mining supply sector. Thus, taxation advice can be general in nature, but is often associated with the specific dynamics of industry sectors.



**Support commercial law and justice reforms relevant to the sector, such as contract law and land tenure.**

Improved commercial law and justice can underpin the development of new commercial opportunities. This was found to particularly be the case in the horticulture sector. Donor and development agencies can support efforts to make contract laws clearer, simpler and more enforceable. Similarly, land tenure can increase the incentives for businesspeople to invest in the infrastructure and facilities required to improve productivity and competitiveness.

**Help partner governments to develop a clear strategy around the use of intellectual property rights and the promotion of local industry.**

IPR plays an important role in the local production of medicines and the access local producers have to markets. There are a number of specific instruments that have been developed to address this issue, including the TRIPS Flexibilities. Donor and development agencies can work with governments and their partners to develop a clear strategy around IPRs in order to support local industry development and to enhance the access local firms have to broader markets.

**Strengthen reforms for improving the registration of new products making it easier and cheaper for enterprises.**

All medicine producers face a specific set of regulatory procedures they must comply with to gain permission to produce a new product (i.e., market authorization). There is international technical assistance available to support this process and new instruments (e.g. ANDA) have been developed for this purpose.

**Support the formulation of targets against which policy and reform outcomes can be monitored and refined.**

In the mining sector, particular attention is given to the ways in which local content provisions can be mandated by policy or law. Increasingly, national mining policies include provisions for local content, but because this is not always considered enough, individual mining agreements are also being used to stipulate targets for local content.

**Build the capacity of partner governments to improve sanitary and phytosanitary standards, which can directly affect the competitiveness of new firms in global markets.**

In the horticulture sector, SPS measures play an important role. There are a number of important technical issues in this field that affect the development of the sector, including food safety and plant health.

**Support the improvement of standards testing facilities.**

The lack of access to internationally accredited testing facilities can undermine the authority of national regulators. This is a persistent problem in many sectors under review and donor and development agencies can provide critical support to these facilities either at national or regional levels.

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## Appendix 1: Respondents

### RESPONDENTS

#### Pharmaceuticals Sector

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#### Renewable Energy Sector

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#### Horticulture Sector

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