



**Comments of the National Foreign Trade Council  
to the Office of the U.S. Trade Representative  
Concerning African Growth and Opportunity Act:  
Out-of-Cycle Review of South Africa Eligibility for Benefits  
August 5, 2015  
(Docket ID: USTR-2015-0009-0001)**

The National Foreign Trade Council (NFTC) is responding to a request for comments published in the Federal Register on September 21, 2015 by the Office of the U.S. Trade Representative concerning African Growth and Opportunity Act: Out-of-Cycle Review of South Africa Eligibility for Benefits. The NFTC, organized in 1914, is an association of several hundred U.S. businesses engaged in all aspects of international trade and investment. Comprised of companies representing a broad cross section that drives the U.S. economy, we are dedicated to an open rules-based international trading system.

Section 104 of AGOA requires that a country has established or is making continual progress toward establishing, *inter alia*: a market-based economy; the rule of law, political pluralism, and the right to due process; the elimination of barriers to U.S. trade and investment; economic policies to reduce poverty; a system to combat corruption and bribery; and the protection of internationally recognized worker rights.

We would like to offer comments with respect to South Africa's regulatory and intellectual property policy environments as they relate to South Africa's AGOA requirements on barriers to U.S. trade investment. Our focus is specifically on the pharmaceutical sector.

#### *Regulatory Barriers*

Modern and transparent regulatory systems aligned with international best practices can help advance the application of science to meet patient needs in South Africa. Lengthy regulatory review timelines results in *de facto* market access barriers to new and innovative medicines for South African patients.

The NFTC is concerned about the deteriorating regulatory environment governing the review and licensing of new medicines, which can now extend for up to 4 or 5 years or more. The pace of new medicines approvals represents one of the slowest on the African continent, where new medicines approvals can typically take 1-2 years following regulatory approval in the United States or Europe. In South Africa, this is now typically double the length of time.

These delays represent significant technical barriers to trade because South Africa requires innovative biopharmaceutical companies to obtain marketing authorization from the Medicines Control Council (MCC) prior to introducing those medicines into the market. In addition, although the South African government is taking steps to increase regulatory capacity, regulatory approval delays are further hampered by a lack of external evaluators due to a limited pool of qualified experts. More dedicated resources, including an expanded pool of qualified external evaluators, could help improve regulatory review timelines.

Lengthy delays in the new medicines review and registration process pose significant challenges for patients, physicians and care givers and impede access to promising new treatments and cures for both communicable and non-communicable diseases. Delays also pose hurdles for companies employing and operating in South Africa, as they cannot market new medicines. This acts to suppress investment, innovation and employment in the pharmaceutical sector. Competition and consumer choice are also harmed, as newer products are inhibited from entering and challenging established treatments.

Moreover, in the economic sphere, South Africa's aspirations to boost medical tourism are negatively impacted because the treatment standard of care in South Africa lags behind other countries—in our estimation, by five years or more. Finally, in terms of South Africa's industrial aspirations, unpredictable and delayed reviews act as a significant deterrent to new investment in manufacturing for domestic consumption and for exports.

Both the Department of Science and Technology and Department of Trade and Industry have expressed a keen interest in building up the competitiveness of the life sciences and innovative biopharmaceutical sector. Efforts to address lengthy regulatory review and approval can help provide regulatory predictability for innovative pharmaceutical companies and enhance efforts to increase access to medicines for South African patients.

### *Regulatory Impact Assessments*

Another area of concern is the RSA government practice of failing, in violation of its own prescript, to publish Regulatory Impact Assessments to accompany policy or legislative proposals.

One recent example pertains to amendments to the labor laws that have been published. In this example, the government performed and published an RIA, but the government did not consider the findings in the design of amendments to the labor laws.

The RIA provides one of the most important modes of consultation with the private sector, including American company affiliates operating in South Africa. Without publication of the RIAs, stakeholders cannot meaningfully participate in prescribed policy and legislative consultative processes. This adds a dimension of unpredictability for American companies operating, employing and investing in South Africa.

### *Intellectual Property Policy*

As a leading emerging economy, South Africa's internationally aligned IP standards have been an important element in encouraging biopharmaceutical company investments in South Africa. While the extent to which a country benefits from IP depends on the country's relative strengths and factors such as infrastructure, political stability, and respect for the rule of law, it is widely recognized that where countries have strong and effective IP protection regimes in place, there is a significant connection between increased incentives for local innovation and the transfer of technologies that foster local innovation and economic growth.

In September 2013, the RSA government made public its draft "National Policy on Intellectual Property," setting out numerous proposals to dramatically reshape existing IP protections. American companies are concerned about the draft policy, now under

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consideration by the government, because its overall intent appears to weaken current standards that are important to investors and innovators, including with respect to substantive search and examination, restrictions on patentable subject matter, and use of compulsory licensing as an industrial policy tool. Innovative biopharmaceutical companies support the South African government's overall objective to develop an IP policy grounded in the principle that strong IP would help spur useful innovation and socio-economic empowerment, but this draft proposal does not meet that standard.

While the draft policy raises concerns, the process of stakeholder engagement has also been less than transparent. Initially, the private sector was invited to provide comments, with the understanding that the Department of Trade and Industry would offer a meaningful consultation to discuss our concerns.

Unfortunately, since the draft policy was released in 2013, there has been little meaningful stakeholder consultation, and the process itself has been largely closed to public comment. American companies are concerned that the draft policy is about to be sent to the cabinet for approval without a thorough, in depth discussion of its impact on investors, employers and companies operating in South Africa. Instead, we would encourage open, meaningful consultation with the private sector to ensure that the perspectives of innovators developing and delivering treatments to South African patients receive due consideration.