

INTELLECTUAL PROPERTY CONSULTATIVE FRAMEWORK

SUBMISSION

by the

Innovative Pharmaceutical Association of South Africa (IPASA)

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INNOVATIVE PHARMACEUTICAL ASSOCIATION OF SOUTH AFRICA (IPASA)

EXECUTIVE SUMMARY

IPASA wishes to express its appreciation to **the dti** for the approach it is taking in preparation for a Draft IP Policy – the IP Consultative Framework. The Framework aims to inform stakeholders of the preliminary analyses conducted, in order to select the best way of introducing an IP Policy in South Africa so that the selected system will fit in with the policy and strategic objectives of the country. The IP Policy should be designed and implemented in a manner that promotes South Africa as a destination for innovation and technology, and not impede it.

IPASA supports the South African's government's goal to strengthen the local multinational and South African based pharmaceutical sector in order to accelerate the creation of manufacturing jobs, skills and technology transfer and to ensure a secure supply of medicines in the country.

In order to create an enabling environment for innovation and investment, IPASA believes that the following principles should underpin the IP policy:

- Equal treatment of local and foreign companies;
- Promoting conditions for enabling innovation—including a focus on strengthening scientific capabilities;
- Developing efficient and effective regulatory systems that are aligned with international best practice;
- Developing predictable and fair pricing, reimbursement and public procurement schemes;
- Ensuring effective implementation and administration of incentives for research and development.

The pharmaceutical industry is supportive of the proposed Substantive Search and Examination (SSE) system, provided this is appropriately resourced, patents can be examined within a reasonable timeframe, and it applies to patents for all categories of applications and is non-discriminatory by sector.

IPASA recommends that the introduction of an SSE for domestic filings be based on South Africa's technical capacity, starting in areas where this is strongest and then being expanded to other areas without any form of discriminatory treatment of one technology sector over others; and we urge the CIPC to clearly lay out the criteria for the selection of fields to be addressed.

IPASA does not support the introduction of a pre-grant opposition system in South Africa as this risks substantial delays and additional costs for patent applications, while potentially undermining the legitimate rights of patent applicants. We recommend that any procedures introduced for Post-grant opposition be robust, efficient and of high quality, with predefined timeframes and specified grounds upon which patentability can be challenged.

We also strongly recommend that opposition proceedings should be clearly and definitively established and that a legislated, expeditious, efficient internal appeal and review procedure be introduced.

Clarity and legal certainty is required as to the proposed Framework's view of TRIPS flexibilities, i.e. article 27's exclusions and the non-discrimination provision of article 27. TRIPS flexibilities do not provide any signatory with the possibility to develop different patentability criteria for medicines, or to create a separate system of patentability only applicable to medicines.

IPASA also recommends that South Africa follow the example of other patent office systems which evaluate any (whether incremental or not) advances through an SSE system on their own individual merits according to properly established principles of novelty, inventive step (non-obviousness) and utility (being capable of being applied in trade, etc.).

IPASA believes that the current provisions for parallel importation in the current legislative frameworks are adequate for South Africa and should therefore not be changed.

IPASA is unclear of the meaning of the "further exceptions" which are mentioned to be considered. Any additional or other exceptions must be consistent with South Africa's international obligations, the South African Constitution and supportive of the multiple stated objectives of the proposed IP Policy, as well as policies in science and technology and other policies of **the dti**.

IPASA recommends that compulsory licensing be considered only as a last resort and in truly exceptional circumstances, and in a manner consistent with WTO rules (i.e. in cases of health emergencies) and the Constitution. Case examples demonstrate that compulsory licensing is not the best policy option to promote access to medicines, and IPASA suggests that other options such as differential pricing, voluntary licensing and non-assert declarations should be considered before resorting to such a drastic measure as compulsory licensing. Such an approach would also align with the South African Constitution which requires minimally invasive limitations to rights.

1. PRELIMINARY REMARKS

IPASA is a trade association with 26 of some of the world's leading global pharmaceutical research and biotechnology companies devoted to inventing medicines that have and continue to contribute to patients living longer, healthier, and more productive lives. With nearly \$50 billion invested in R&D worldwide in 2013,¹ and more than 300 new medicines approved in the last decade, our

¹ Pharmaceutical Research and Manufacturers of America. "IPASA Annual Membership Survey" 1981–2013.

members are world leaders in medical research.²

Amendments proposed to intellectual property policy and law should afford the country the opportunity to strike a balance between incentives for investment and development, as manifestations of property rights and the realisation of the right of access to healthcare.

IPASA is appreciative that **the dti** acknowledges that Intellectual property (IP) is an important policy instrument in promoting innovation, technology transfer, research and development (R&D), industrial development and more broadly economic growth. We are encouraged that the Framework underscores the importance of respecting the South African Constitution and the international legal framework, in particular, *The World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS).

IPASA also welcomes the news that the purpose of the Consultative Framework on IP is not to prescribe South Africa's IP policy position, but to put forward the perspective of **the dti** in a consultative instrument and to facilitate continuous engagement with governmental partners; the private sector and society at large. We agree that this coordinated and consultative approach is the best way to construct an IP Policy for South Africa.

IPASA acknowledges that **the dti** has an 'in-built agenda', with issues categorised as immediate, medium term and monitoring and evaluation. We also note that the intersection between IP and public health has been established as an immediate priority and an urgent and important reform area. We believe that this fresh approach to policy formulation will provide **the dti** with an opportunity to establish public confidence in the process being undertaken by the government, and in moving **the dti's** objectives forward.

We wish to draw your attention to the reference made in section 4.1 and its subsections to the National Drug Policy. This Policy has been up for review since the announcements made by the Minister of Health, Dr Aaron Motsoaledi, of the 10-point plan³ to overhaul the health sector; consideration must therefore be given to the important role that the National Drug Policy played in reforms such as that relating to generic substitution, and rational drug use, and the implementation of essential medicines lists.

However, as stated in the 10-point plan, the National Drug Policy is widely regarded as in need of important updates, and legislative reforms, such as the National Health Act, NHI medicines supply chain proposals and the 2008- and 2015 amendments to the Medicines Act have overtaken the initial drug policy of 1995.

The TRIPS Agreement establishes minimum standards of IP protection that a country must give to fellow WTO members. While TRIPS does not provide detail on how IP law is written or enforced, and while each country has "flexibility" in how they draft and enforce IP laws, the minimum standards, at

² Battelle Technology Partnership Practice. Growth Platform for Economies Around the World. Battelle Memorial Institute, May 2012. Prepared for the Pharmaceutical Research and Manufacturers of America (PhRMA).

³ <https://www.health-e.org.za/wp-content/uploads/2014/08/SA-DoH-Strategic-Plan-2014-to-2019.pdf>.

the very least, must be captured in the laws and in how they are enforced. Simply put, a country does not have the “flexibility” to not adhere to the minimum standards by which its other WTO members must abide.

Article 27 of TRIPS provides *“patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.... patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”*

This language in TRIPS indicates it would be unfair for a country to discriminate against a particular technology. Thus, trying to make it more difficult to obtain pharmaceutical patents would not be fair and would not abide by the minimum standards of TRIPS. However, creating an exception where patentability is regarded by law then as not possible, would be permissible under Article 27(2) – already in SA law as the Bolar or early workings provision and Article 27(3) (exclusion of diagnostic therapeutic and surgical methods for the treatment of humans or animals).⁴

The evaluation of the reasonability of measures, in this instance, IP measures, aimed at increasing access to healthcare, as is recognized in paragraph iii of Section 4, would, require a thorough analysis. The aspects that make up such a reasonability assessment, as set by the Constitutional Court in the various socio-economic rulings,⁵ are amongst others:

- Whether the measures are rational;
- Whether the measures would achieve the objective of increasing access to healthcare;
- Consideration of alternatives, and its level of appropriateness;
- Implication of a measure should the measure be required to be applied equally;
- Resource implications of the measures and the clear allocation of tasks and responsibilities, as well as capabilities and capacity;
- Whether the policy is flexible;
- Impact on vulnerable persons, such as children and the disabled.

The Constitution’s limitation clause would also find application in relation to the limitation of property rights in pursuit of the progressive realization of access to healthcare. The progressive nature of socio-economic rights (which also includes social security rights and therefore the manner in which healthcare is funded), signals the recognition that, these rights cannot always be immediately satisfied, and a rational programme of action is required to achieve that over time. Inasmuch as that applies to, for example, the National Health Insurance (NHI) plan, it applies to IP reforms aimed at giving effect to rights of access to healthcare.

IPASA is pleased that **the dti** recognises that the urgency to develop a new IP policy should not trump the need for an in-depth analysis of issues – and the evidence supporting various positions.

⁴ https://www.wto.org/english/tratop_e/trips_e/t_agm3c_e.htm#5.

⁵ The *Soobramoney* and *Grootboom* cases, amongst others.

We look forward to learning more about the medium term issues that will form part of the in-built agenda, which seem to be key areas that will require further in-depth study, with flexible timelines in accordance with international best practice’.

2. INTER-MINISTERIAL COMMITTEE (IMC) ON IP

IPASA supports the principle of setting up a structure for inter-governmental co-ordination of the policy formulation processes (i) and implementation (ii). IPASA agrees that the establishment of such a committee is urgent.

It is recommended that the IMC Terms of Reference be made available for public comment and that such Terms of Reference propose structured engagements on key policy issues with relevant stakeholders, including the private sector.

It is further recommended that the IMC also include representation from statutory bodies such as the Medicines Control Council (MCC) or its successor in title, SAHPRA, as well as quality control- and licensing bodies, such as the South African Pharmacy Council and the Office of Health Standards Compliance to ensure comprehensive regulatory impact assessments of key policy proposals.

The involvement of the Department of Science and Technology would also be important. In its **Ten-Year Innovation Plan**, the government outlines its vision to “become one of the top three emerging economies in the global pharmaceutical sector by 2018.” We applaud this goal and believe, as is envisaged with the proposed IMC, that takes a holistic and long-term view of the role of IP for development; one that strikes the right balance to ensure an innovative culture where local inventors can develop, bring to market and export new products and technologies knowing that their inventions and creativity are secure; one where branded and generics producers can manufacture their products locally; and one where multinational companies have the confidence to invest in the health of all South Africans for the long-term.

3. IMMEDIATE ISSUES IDENTIFIED IN THE FRAMEWORK

3.1 LOCAL MANUFACTURE AND EXPORT IN LINE WITH INDUSTRIAL POLICY (SECTION 4.1.1)

It is not clear from the Framework’s statement in paragraph (v) on page 6⁶ exactly how it is proposed that the IP regime could support local manufacturing. Various studies by industry, and entities such as Nedlac, have investigated this matter and provide useful information as to the barriers and enablers required in this regard.⁷

⁶ South Africa’s IP regime should complement the country’s industrial development ambitions...pharmaceuticals”.

⁷ Genesis 2007 *The Growth Potential of the Pharmaceuticals Sector in South Africa* available at [http://ipasa.co.za/Downloads/IPASA%20and%20Pharmaceutical%20Industry%20Profile/GENESIS%20Pharmaceuticals%20Report%20070529%20\(2\).pdf](http://ipasa.co.za/Downloads/IPASA%20and%20Pharmaceutical%20Industry%20Profile/GENESIS%20Pharmaceuticals%20Report%20070529%20(2).pdf); Nedlac FRIDGE report 2000 *Pharmaceutical Manufacturing Sector Study*.

We support the South African's government's goal to strengthen the local pharmaceutical sector. When positive incentives for local manufacture (localization) are introduced in a market, the country is more likely to succeed in securing investment to build a competitive and innovative domestic biopharmaceutical sector. A positive investment environment would include, amongst others, systems that reward voluntary skills and technology transfer, expeditious and efficient regulatory frameworks, a consistent and aligned policy environment across government departments.

Research shows that localization barriers, defined as punitive incentives and mandatory requirements for investment, do not have a positive impact on economic activity or innovation.⁸ Countries like China, Vietnam, Algeria, Turkey and Indonesia, which have set up localization barriers, have seen limited growth in knowledge-intensive employment as a percentage of their total workforce.⁹ In addition, studies examining the impact of trade barriers introduced during the recent financial crisis found that trade flows affected by restrictive policies dropped by an average of 5-8% compared to flows not affected by such policies.¹⁰

There might also be unintended consequences in localization requirements. In some countries local innovative sectors remain largely dormant or non-existent. Instead, generic and/or basic manufacturing operations continue to dominate the sector, and targets aimed at growth of innovative products are unmet.¹¹

In line with South Africa's constitutional imperative that changes in policy and law should lead to an actual increase in access to healthcare, South Africa can also learn from countries such as Indonesia, Algeria, China and Vietnam.

In *Indonesia* where localization is required, essential medicines are not readily available; only half of the drugs on the WHO-recommended Essential Drug List (EDL) are supplied in the local market, and a survey of 9,000 health centres in the country found that 85% had less than 80% of the medicines on the country's EDL in stock. In *Algeria*, import bans on over 300 medicines, combined with inadequate resources and infrastructure to produce a number of these products locally, have resulted in drug shortages in key areas. Shortages of over 320 mainly chronic disease treatments (including cardiovascular and cancer drugs as well as insulin) were reported in 2015, with many of these recently added to the list of banned imports but not yet supplied by local manufacturers.¹²

⁸ Pugatch Consilium, "Separating Fact from Fiction – How Localization Barriers Fail Where Positive Non-Discriminatory Incentives Succeed: A Global Assessment of Localization Policies and Incentivizing" Life Science Investment and Innovation" PhRMA publication, p8.

⁹ Pugatch Consilium, PhRMA publication, p9.

¹⁰ Henn, C. & McDonald, B. (2011) "Protectionist Responses to the Crisis: Damage Observed in Product-Level Trade," IMF Working Paper WP/11/139, Washington, DC.

¹¹ Pugatch Consilium, PhRMA publication, p46.

¹² Le Soir d'Algerie. "Drug Shortages" 18 August 2015 (translated), www.lesoirdalgerie.com/articles/2015/08/18/print-2-182951.php; Jeunesse d'Algerie (2015), "More than 200 Drugs are Missing from the Algerian Market" (translated), <http://jeunessedalgerie.com/article.php?id=1266>; Tout Sur l'Algerie (2015), "How Do Patients and Pharmacists Cope with Drug Shortages" (translated), 30 June 2015, www.tsa-algerie.com/20150630/comment-lesmalades-et-les-pharmaciens-se-debrouillent-face-a-la-penurie-de-medicaments/.

In *China*, new and advanced medicines are not being made available to Chinese patients - in 2014, close to 60% of sales involving multinational pharmaceutical companies in China consisted of products launched more than ten years ago.¹³ In addition, only 21% of all new molecular entities registered globally between 2009 and 2012 were available to Chinese patients in 2013.¹⁴ In spite of the strong emphasis on locally produced generic drugs in *Vietnam* pervasive gaps in access to medicines exist; in 2014 the social health insurance formulary was reduced by around 100 products to just 57, and in turn, a rising number of complaints of lack of access to cancer treatments have been reported.¹⁵ Access to healthcare, and in particular access to medicines, should remain the ultimate yardstick for any proposed reforms.

It is argued by some that local manufacturing would necessarily lead to lower healthcare- and medicines costs. In *Brazil* for instance, average patient drug expenditure in Brazil as a percentage of total healthcare spending has not fallen, but rather grown by about 5% over the past 5-8 years according to the most recently available figures.¹⁶ Under *Vietnam's* local production requirements, drug prices on the lowest-priced generics are still more than 10 times higher than modelling by the WHO would suggest and are reportedly increasing at an average rate of nearly 8% per year.^{17 18} Moreover, government data from Vietnam indicates that some winning local bids in public tenders can in some cases bring prices 150-250% higher than that of imported products.¹⁹

International Best Practice: Best practices for non-discriminatory incentive-based policies can be found in countries like **Denmark, Ireland, Singapore and the United States**. *Denmark* has excelled at creating a local biopharmaceutical environment, earning the title of one of Europe's "Innovation Leaders".²⁰ It has done so by providing companies with access to an educated workforce, tax credits for R&D, government funding for biotechnology companies and strong intellectual property

¹³ McKinsey and Company, (2014), "China's drug industry must innovate" Retrieved from www.mckinseychina.com/chinas-drugindustry-must-innovate.

McKinsey and Company, (2014), "China's drug industry must innovate" Retrieved from www.mckinseychina.com/chinas-drugindustry-must-innovate.

¹³ IMS Institute for Healthcare Informatics (2014), "Global Outlook for Medicines Through 2018" November 2014, p24.

¹⁴ IMS Institute for Healthcare Informatics (2014), "Global Outlook for Medicines Through 2018" November 2014, p24.

¹⁵ Than Nien News (2014), "Cancer Patients Face Double Whammy as Vietnam Slashes Pharma Subsidies" 29 December 2014, www.thanhniennews.com/health/cancer-patients-face-doublewhammy-as-vietnam-slashes-pharma-subsidies-36861.html.

¹⁶ Bertoldi et al. (2012), "Is the Brazilian pharmaceutical policy ensuring population access to essential medicines" Health Policy, March 2012.

¹⁷ Supply Chain (2015), "Vietnam Supply Chain Pharma" p21. http://vietnamsupplychain.com/assets/files/54fd289fd5177VSC_Pharma_Supply_Chain_Booklet_2015.pdf.

¹⁸ Decision Resources, (2014), "Vietnam's Pharmaceutical Market is Among the Fastest Growing in Southeast Asia," Retrieved from <http://decisionresources.com/News-and-Events/Press-Releases/Vietnam-Market-Access-Tracker-042114>.

¹⁹ PharmaForum (2013), "Vietnam Market Update 2013" Retrieved from www.pharmaphorum.com/articles/vietnam-pharmaceuticalmarket-update-2013.

²⁰ European Commission. (2014). "Innovation Union Scoreboard 2014," p4.

protections. Similarly, to attract global pharmaceutical companies, *Ireland* has implemented various business friendly policies. These include low tax rates and substantial tax credits for R&D, government backed funding initiatives and strong intellectual property protections.²¹ *Singapore* has developed world-class R&D and manufacturing capabilities and has seen tremendous growth in investment by multinational research-based companies. Manufacturing today alone is estimated at SGD23 billion, a value close to 5 times higher than in 2000.²² Finally, the innovation strategy²³ that the *US* adopted in the last 40-50 years has helped make the country a leader in biopharmaceutical investment and innovation. Although South Africa places emphasis on skills development, and R&D tax incentives exist, investigating the differences and permutations of such policy interventions may benefit the South African IP policy process.

The pharmaceutical industry in South Africa therefore stands ready to support the development and/or use of new and/or existing non-discriminatory incentive-based laws and policies which will create an enabling environment for innovation and investment. This approach requires:

- Equal treatment of local and foreign companies in line with the South African Constitution;
- Promoting conditions for enabling innovation—including a focus on strengthening scientific capabilities;
- Developing international-standard regulatory systems;
- Developing predictable and fair pricing, reimbursement and public procurement schemes;
- Creating incentives for research and development.

Requiring local manufacturing as part of IP reforms might be impractical on a global basis. As discussed, it may also have unintended consequences and not necessarily lead to increased access at a reduced cost.

3.2 PATENTS – SUBSTANTIVE SEARCH AND EXAMINATION (SSE) SYSTEM (SECTION 4.1.2)

Section 34 of the Patents Act of 1978 does permit the examination of a patent in South Africa.

IPASA and its members support the development of a Substantive Search and Examination System (SSE), which will result in the issuance of strong patents. IPASA maintains that a pre-requisite for a sustained, effective, and efficient SSE system requires investment in building this infrastructure; capacity building that includes adequate and appropriately trained human resources, with required administrative, technical skills, and appropriate intellectual property regulatory infrastructure to avoid a backlog and ensure that the entire system runs effectively and efficiently. We are therefore encouraged that the Companies and Intellectual Property Commission (CIPC) is considering

²¹ IDA Ireland (2013), "Pharmaceutical Industry in Ireland," Infographic, Retrieved from www.idaireland.com/how-we-help/resources/infographics/pharmaceutical-industry-in-ireland/pharmainfographic.pdf.

²² EDB (2013), "Singapore Biotech Guide 2012/2013," p15.

²³ w.whitehouse.gov/the-press-office/2015/10/21/fact-sheet-white-house-releases-new-strategy-american-innovation.

partnering with highly efficient global patent offices to help build capacity. Recognition of decisions made by these patent offices will go a long way in preventing backlogs and duplication of efforts at a local level.

It is noted that no legislative changes would be required in order to implement SSE. The Framework notes the various positions in relation to SSE in terms of its implications on costs and human resources, as well as the benefits of SSE (not disclosed in the Framework, but assumed to be preventative of so-called “ever-greening”, for example). The question is whether an assessment has been undertaken so as to establish what proportion of patents would not have been granted, had South Africa adopted an SSE process? This means, what is the cost-benefit ratio in implementing SSE?

The pharmaceutical industry is supportive of a Substantive Search and Examination (SSE) System, noting;

- The proposed SSE System will require substantial financial resources and significant human capital to conduct SSE.
- The proposed SSE System should be appropriately resourced to accommodate all sectors, including the appropriate expertise and infrastructure to support search and examination (human resources, administrative, technical, and intellectual property regulatory infrastructure).
- Patents should be examined and granted within a “reasonable timeframe”, i.e. the timelines for examination of patents will need to be properly regulated and predictable. Brazil, which created an SSE system, for example, is experiencing an acute patent backlog (as long as 10 years) as a direct result of an overwhelmed, resource constrained SSE system.²⁴ There are lessons to be learnt from the Brazil experience. The situation is little better, but not satisfactory, in India, where it takes an average of 6 years or more to secure a patent. Patent backlogs will affect the right of access to healthcare and may delay access to medicines.
- The matter of discrimination under TRIPS is raised in this regard, i.e. South Africa could not implement SSE only for medicines, for example. However, more important is section 9 of the South African Constitution, which requires equal protection of- and benefit of the law. This section would find application in cases where there are different levels of IP protection afforded to certain categories of products (e.g. medicines) as opposed to others (e.g. medical devices).

Our industry supports the proposal to conduct *full SSE for domestic filings*—this will allow local innovators to have access to quality examination of the proposed patent. If done effectively and in a timely manner, such examination will improve regulatory certainty, which will in turn improve investor confidence and therefore has the potential to boost the local economy.

²⁴ National Law Review, “The Brazilian Patent Office Places the Fight against the Patent Application Backlog as its Top Priority” Thursday, November 6, 2011. Retrieved from <http://www.natlawreview.com/article/brazilian-patent-office-places-fght-against-patent-application-backlog-its-top-prior>.

We recommend that the introduction of SSE for domestic filings ought to be based on SA's technological capacity. The SSE process could begin with areas where SA has strong technological capacity (mining, mechanical and agricultural technologies). Alongside this, there could be a longer term commitment to continually evaluate the technical capacity of South Africa to add new technological sectors as and when capacity is developed. Even though in this instance, full SSE will be limited to domestic filings, we strongly recommend that it should meet and be consistent with internationally accepted standards in order to be viewed as credible.

The CIPC will also need to establish sophisticated databases and other information management infrastructure in order to conduct the searches. It will be essential that this capacity for search and examination be established and functional before commencement of the new system to avoid the substantial examination backlogs that have been experienced in other countries, such as Brazil.

Local examination will therefore require significant investment in the training and hiring of expert patent examiners skilled in various fields. We are encouraged to learn that twenty (20) examiners are currently in advanced training in collaboration with recognized patent offices. Our industry remains willing to partner with the SA government to support appropriate continuous training programs for the new patent examiners.

For foreign filings, we recommend that South Africa adopt the Singapore SSE model. Under this model, applicants can choose from various options for examination—including local SSE for Singaporean patents, as well as reliance on a positive foreign search and examination report from an approved examination authority with supplemental examination by the Singapore patent office. This menu of options helps to alleviate an immediate overwhelming backlog of patent applications immediately following the institution of the SSE process.

Our industry remains very concerned about the criteria that will be used to select the technology fields with “economic relevance” for full examination—we believe that such a process may potentially expose certain fields to differential treatment in contravention of TRIPs' Article 27.1 and the Constitution's provision on equal benefit of- and protection by the law. We also believe that such an approach, would be counter to the broad objectives of the Consultative Framework, which seek to promote investment and growth across all sectors of, the South African economy.

Discriminatory treatment of one sector would also be contrary to South Africa's treaty obligations under TRIPS Article 27.1:

Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (5) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

Overall, we strongly urge CIPC to adopt transparent criteria for the selection of the fields of technology and to clearly lay out the process for engaging with stakeholders in making those

selections. If South Africa is to engage in a selection process for certain technology sectors, we would recommend one that balances *the existing resources vs. capacity* that needs to be built in the future.

International Best Practice: The **Singapore** SSE model is one which we believe could serve as an important system for SA to learn from and implement in a transitional way. Under this model, all patent applications (partially or fully) under the positive grant patent system undergo examination by a Singapore Patent Examiner. Only patent applications that satisfy the patentability requirements receive a Notice of Eligibility indicating that the application may proceed to grant. Otherwise, a Notice of Intention to Refuse will be issued.

The Singapore Substantive Examination can be summarised as follows:

The applicant may file a request for local substantive examination within 36 months from the filing date or priority date. Under this option, the applicant may select any one of the following:

1. request a substantive examination based on a local search report issued by Singapore (only if a request for search is filed within 13 months);
2. request a substantive examination based on a foreign search report issued for a corresponding application; or
3. request a combined search and examination.

The Singapore Supplementary Examination comprises the following steps:

Alternatively, the applicant may opt to obtain a Singapore patent on the basis of a foreign examination issued for a corresponding foreign application by filing a request for Supplementary Examination within 54 months from the filing date or priority date. The documents required in filing the request are, as follows:

1. a copy of either the corresponding foreign patent or the final examination results with allowed claims referred to in the results; and
2. a table setting out how each Singapore claim is related to the allowed claims of corresponding application.

Then, if the Examiner has objections after substantive examination and supplementary examination, a Written Opinion will be issued and a response must be filed within five months and three months, respectively, from issuance of the opinion. The substantive examination must be completed within 18 months from the issuance date of the first Written Opinion, while a supplementary examination must be completed within six months. Thereafter, the Examiner will issue a Substantive Examination Report or Supplementary Examination Report along with a Notice of Eligibility or a Notice of Intention to Refuse. For the latter, the applicant would still have the option to file a request for an Examination Review or allow the application to be finally refused.

Patents that undergo a substantive search and examination ought to be entitled to a *presumption of validity*. We also strongly urge that the system include provision of a *patent term adjustment*

procedure to compensate for delays to the grant of patent applications meeting patentability requirements, where these are caused by administrative delays in the patent office. The system should also include an *efficient, effective and expeditious internal appeal and review procedure*.

3.3 PATENT OPPOSITION (SECTION 4.1.3)

International experience shows that a high quality SSE system, based on, and consistent with international patentability standards should, in itself, provide a sufficient guarantee of good quality patents.

We believe that the introduction of a **pre-grant** opposition process in South Africa risks introducing substantial delays and additional costs for patent applicants. Delays to the grant of a patent by pre-grant opposition proceedings act to substantially weaken the position of the applicant by delaying his or her ability to enforce legitimate rights, and also result in uncertainty for the public who are delayed in knowing the outcome of the patent application.

Section 44 of the Patents Act does allow for **post-patent challenges** to a patent, within 9 months after being granted, unless the Commissioner grants leave for this after 9 months, on good cause shown. It is unclear from the draft Framework why this section is deemed inadequate, or to see whether this had indeed yielded results and if not, why it had not.

Post-grant opposition proceedings should be robust, efficient and of high quality. IPASA believes that an extended period for post-grant opposition is neither reasonable nor necessary, as the post-grant revocation procedure is always available to provide an opportunity for a later validity challenge, or a counter-claim to patent enforcement proceedings.

The forum and nature of any opposition proceedings (pre or post), if proposed, should be clearly and definitively established, and should preferably be managed as an internal process before adjudicators drawn from a panel of independent patent experts, to ensure credibility, fairness and efficiency. We also strongly recommend that an appeal procedure, based on similar principles, be introduced.

International Best Practice: To address concerns over the possibility of a party having knowledge, during the pre-grant phase, of facts or prior art which may be prejudicial to the grant of a patent, but which have not been identified during the SSE process, we recommend the adoption instead of a third party observation procedure, similar to that used in the **European Patent Office**. IPASA will be willing to engage **the dti** on the manner in which this system works, and lessons South Africa could take from it.

In general, the following would have to be considered, if this is an option for South Africa:

- Timeframes to be set for post-patent opposition;
- The impact of the utilization of and compliance with the Promotion of Administrative Justice Act, 2000, which would apply in these proceedings; and

- Possibility of abuse of this process to simply delay a patent being granted, or to frustrate processes for commercial purposes.

3.4 PATENTABILITY CRITERIA (SECTION 4.1.4)

Through proposals within the Framework we believe there is a risk of significantly restricting the types of biopharmaceutical inventions that can be patented in South Africa under Article 27.3 of TRIPS. If implemented, such provisions could harm patients and the national healthcare system, and limit opportunities for generic and innovative biopharmaceutical manufacturers alike. Also, even where implemented, any such exclusion from patentability on the basis of access to healthcare should still have to pass constitutional muster in relation to both section 27 (access to healthcare) and section 25 (property).

Patents provide critical incentives to invest in “breakthrough” treatments and “incremental” improvements to existing medicines that use existing medicines to treat additional diseases and conditions.²⁵ In fact, nearly 25 percent of illnesses are treated by medicines initially developed to address a different disease or condition, and more than 60% of therapies on the World Health Organization’s (WHO’s) Essential Medicines List relate to improvements on older treatments.²⁶ New therapies accounted for 73% of the increase in life expectancy from 2000-2009 versus 45% from 1960-1997. By 2040, because of this medical innovation, there will be a 40 percent reduction in life years lost to cancer.

Small differences added together can account for significant differences over time. For example, in the treatment for colon cancer, over the last few years’ incremental benefits from various treatments have resulted in increased overall survival of metastatic colon cancer from 11 months in 1991 to 30 months in 2012. Ongoing research in this field will lead to even greater survival rates. It is often at the later stages of the development cycle where the real hurdles—involving fundamental issues like ease of manufacturing or safe product formulation—begin to appear. Continued innovation is critical in this phase.²⁷

The availability of patent protection for a new use provides substantial incentive for additional innovation, not only for the original innovator, but also to a wide range of companies and academic institutions, including those not having the capacity for development of new chemical entities.²⁸ Nearly a quarter of existing therapeutic indications are treated by medicines initially developed to address a different disease or condition.²⁹

²⁵ For example, Eisai and DNDi have [partnered](#) to adapt an existing anti-fungal medicine to treat Chagas disease.

²⁶ Cohen, J., and Kaitin K. (2008). “Follow-On Drugs and Indications: The Importance of Incremental Innovation to Medical Practice. *American Journal of Therapeutics*” 15: 89–91.

²⁷ International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), [“Incremental Innovation: Adapting to Patient Needs”](#) February 2013.

²⁸ Globerman S. and Lybecker, [“The Benefits of Incremental Innovation: Focus on the Pharmaceutical Industry”](#) Fraser Institute Report, June 2014.

²⁹ Guangxu J. and Wong S.T.C., [“Toward better drug repositioning: prioritizing and integrating existing methods into efficient pipelines”](#) *Drug Discovery Today*, January 2014.

As alluded to above, while the TRIPS agreement does include certain flexibilities that allow Members to deviate from specified Intellectual Property (IP) standards under certain circumstances, there are minimum standards that WTO Members must reflect in their IP systems. In terms of patentability criteria, the TRIPS flexibilities does not permit different criteria to be applied across technologies. This means that it would, under TRIPS, not be permissible only patent “breakthrough” treatments and “incremental” improvements to existing medicines.

Insofar as objections are often raised against the perception that biopharmaceutical inventors seek patents on new uses, forms and combinations of existing medicines to extend – or “evergreen” – the period of protection for those medicines, it must be noted that patents on new uses, forms and combinations do not extend the patent term of the existing medicines. This stays at 20 years for the specific product thus patented. A new patent on new uses, forms and combinations does not extend the duration of the original patent. IPASA believes, as it pointed out above, that even incremental innovations are valuable to patients and payers as they provide improved treatment options to patients and therefore result in improved health outcomes.

As a general principle, limiting patent and IP rights by means of an in-principle removal of the right to patent in certain circumstances, are unlikely to meet constitutional scrutiny favourably. However, creating a system whereby, in cases of national health emergencies, or in other circumstances where public health rights by necessity should trump property rights, would be more in line with the principles of the limitation of rights set by section 36 of the Constitution. For example, creating scope and recognition for initiatives such as voluntary licensing and patent pools, which constitute limitations to the unfettered enjoyment of IP Rights, are more likely to withstand constitution scrutiny.

International Best Practice: 80% of the world's patent applications are handled in five jurisdictions, one of which is China. All these major patent systems recognize the importance of incremental innovation and allow claims to subsequent medical uses for a known substance. This exclusion would also be discriminatory against biopharmaceutical inventions and contrary to obligations under TRIPS a 27.1

IPASA recommends that South Africa should follow the example of these major patent offices in recognizing that, with very few exceptions, all inventions, whether further medical uses of known substances, new formulations, or new forms of previously known substances, and whether pioneering or incremental in nature, should be evaluated by an effective SSE system, on their merits, according to properly and uniformly applied principles of patentability based on novelty, inventive step and utility. With this approach, it is unnecessary to resort to arbitrary exceptions to patentability, which only serves to discriminate and deny protection to legitimate innovation.

In summary therefore, any national IP system that fails to recognize the important role played by *incremental innovation* will ultimately prevent innovators from realizing the economic value of important inventions and also reduce the incentives for the development of local innovation-based pharmaceutical industries.

3.5 DISCLOSURE REQUIREMENTS (SECTION 4.1.5)

We support TRIPS Article 29 requiring that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. However, we caution against policies, laws or guidelines that place an undue burden on patentees and do not take into account the timeline realities of pharmaceutical development. As is the international norm, there ought to be provisions to supply post-filing data to meet any raised standards of sufficiency and to overcome any obviousness rejections.

It is therefore recommended that **the dti** considers the use of online resources, such as those of the EPO and USPTO to support the examiners in SSE. The burden associated with furnishing the offices with disclosures from other jurisdictions should be carefully considered.

It should be noted that, in the case of medicines, even disclosures of the nature envisaged may not lead to increased access or skills transfer. The process of medicines scientific formulation and manufacturing is where the skills and technology lies, not in the disclosure of details around the specific molecule being patented. Furthermore, unlike other patented goods, medicines are accompanied by package inserts that make plain various aspects relating to the specific product, and research that underpins it or aspects thereof are frequently published in peer-reviewed journals, or in updated treatment guidelines.

Furthermore, under the current Medicines Act³⁰ and the Guidelines³¹ issued by the Medicines Control Council, generic versions of products only have to prove bio-equivalence and bio-availability, and access to source data and the envisaged disclosures (beyond what is currently provided) are not necessary in order to achieve the stated objective of addressing public health needs.

There is already a so-called “early workings” or “Bolar” provision in the Patents Act (section 69A) to support early entry of generic molecules in the market and all technical and scientific work etc. to be commenced prior to the end of the patent period of the innovator. It is not clear from the framework why this provision is deemed inadequate under the draft Framework.

Currently, it is our view that the effectiveness of the Bolar provision cannot be accurately assessed due to the long registration timelines for medicines (both generics and innovator medicines) by the MCC. Therefore, generics trying to enter the market early have not been able to do so practically due to the registration backlogs. The backlogs have also had a significant impact on the time taken for innovator medicines to enter the market. In both cases, the public health implications of the delayed entry of medicines onto the SA market are presumed to be significant.

³⁰ See, for example, regulation 2 of the General Regulations to the Medicines Act, 2003, as amended (GNR.510 of 10 April 2003).

³¹ See, for example, the Biostudies Guideline No 2.06, version March 2011.

3.6 PARALLEL IMPORTATION (SECTION 4.1.6)

The issue of parallel importation raises a number of questions specifically related to IP. The IP Consultation Framework document correctly points out that parallel importation as found in the current Medicines and Related Substances Act, 1965 (which incorporates amongst others the 1997 and 2002 amendments) It is designed as a relates specifically to measures of affordability.

Parallel importation of pharmaceutical products in South Africa could pose significant risks to patients. International experience demonstrates that parallel importation encourages and facilitates the sale of counterfeit, sub-standard, or uncontrolled pharmaceuticals. It is extremely difficult to police the supply of medicines once the chain of supply from manufacturer to authorized importer is broken.³² Without that link, counterfeit and/or poor-quality goods enter the drug supply more easily. Patients often cannot distinguish counterfeit or substandard pharmaceutical products. In the case of product withdrawal or recall, the manufacturer may not be able to identify parallel importers and alert them of recall decisions.

As a matter of principle, it should be noted that parallel importation in some cases accrue to intermediaries at the expense of *bona fide* pharmaceutical companies and patients. For example, the pharmaceutical industry is heavily regulated, and has to not only comply, but report on and actively engage with government officials in relation to its activities on a regular basis. For example, compliance with the Medicines Act requires a dedicated, expert staff complement of pharmacists and medical professionals; ensuring medicines pricing compliance requires a different set of expert staff handling pricing, price increases, price updates and new price processes, interacting with a special unit in the Department of Health; dedicated staff to handle research and others to sign off and ensure compliance in all marketing activities, including interactions with healthcare professionals.

Cost alone is not a good determinant of access. We suggest that beyond cost, the absence of a strong IP system and predictable and fair pricing, reimbursement and public procurement schemes are also impediments to access to medicines. These measures may be, in constitutional terms, more effective in achieving increased access to healthcare. We recommend that government develops a balanced IP Policy that incentivises innovation and allows for procurement schemes that go beyond cost but also price for value.

Whilst parallel imports may seem like an attractive short-term solution, it will most likely lead, in the long-term, to less local innovation; more compliance and enforcement challenges (as well as the associated costs). We therefore caution against any effort to incorporate total international exhaustion into the Patents Act if the sole intent is to weaken patent protection.

³² Kyle, M., "[Parallel Trade in Pharmaceuticals: Firm Responses and Competition Policy](#)" - ch. 13 in Barry Hawk, ed., *International Antitrust Law & Policy*, New York: Juris Publishing for the Fordham Competition Law.

3.7 EXCEPTIONS (SECTION 4.1.7)

Permitting what would otherwise be infringing activity prior to the expiration of a patent for the purposes of generating information necessary for presenting an application for regulatory approval is consistent with international norms.

It is unclear what **the dti** means when it states that “further exceptions could be considered if it is deemed that they could contribute to the furtherance of the objectives of the IP policy to the benefit of South Africa”, such as the cited “research exception”. Any “exceptions” must be consistent with South Africa’s international obligations and the South African Constitution.

In reading the Bolar exemption in South Africa, we would urge that international best practices inform the scope of exemption. We support Bolar-type exemptions but only when there is a fair benefit to the patent holder.

International Best Practice: The US Hatch-Waxman Act³³ and Directive 2004/27.EC³⁴ for the European Union provide examples of best practices in this regard. The **US Hatch-Waxman Act** struck a sensitive balance by allowing generics to conduct clinical trials during patent life for use in an abbreviated approval process (‘ANDA process’), while also allowing the innovator to extend the patent life to (a) fully compensate for the time lost during the (non-abbreviated = innovative) approval process, and (b) for half the time it took to conduct its innovative clinical program in support of the first approval. However, the innovator can never obtain more than 14 years of effective exclusivity (i.e. after approval of the product) – despite the delays the innovator was subjected to - in order to avoid the creation of very long exclusivity periods for pharmaceuticals.

Similarly, the **EU Directive** establishes a *sui generis* IP right that can be obtained solely in relation to patents that protect products that were subjected to regulatory delays, i.e. for the clinical testing and regulatory approval periods in the pharmaceutical sector (the “Supplementary Protection Certificate”, SPC). The duration of such SPC is calculated based on a formula that compares the patent’s filing date and the first (innovative) approval for said product. It compensates for up to 5 years of delays suffered, but can never provide an exclusivity term of more than 15 years after approval.

3.8 VOLUNTARY LICENCES (SECTION 4.1.8)

The statement is made that voluntary licences “may not always provide the requisite level of access in other disease areas”. It is not clear what this statement means, and which disease are envisaged in this regard, or why that would be the case. Disclosure of the reasons for these statements or the sources of research conducted are important to allow stakeholders to engage on these matters.

Insofar as a voluntary licence constitutes a self-imposed limitation on an entity’s right to property, and the exercise of those rights, it constitutes a fair and reasonable manner in which to dispose of,

³³ The Drug Price Competition and Patent Term Restoration Act (Public Law 98-417).

³⁴ Directive No. 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive No. 2001/83/EC on the Community code relating to medicinal products for human use.

or limit those rights. It is however important that to be truly voluntary, it cannot be coerced, whether politically or legally. Legally enforced limitations on property rights would require compliance with the property and limitation clauses in the SA Constitution.

3.9 COMPULSORY LICENSES (SECTION 4.1.9)

This approach also aligns with the position of IPASA, i.e. the use of compulsory licenses to expropriate patent rights is a limited exception under TRIPS as explained below (and a limitation under the South African Constitution). It should therefore, as a matter of international and local law and policy, only be used in exigent circumstances, such as health emergencies, when all other alternatives have been exhausted. Assessments of particular compulsory licensing policies and decisions need to be made on a case-by-case basis, taking into account a number of factors.

IPASA does not support the regular use of compulsory licenses, for example, to support industrial policy objectives aimed at favouring domestic industries or a routine cost-containment measure. In sub-Saharan Africa, most antiretrovirals are produced under voluntary licenses to local firms.³⁵

The SA Constitution's right to property, and the limitation clause, as well as international law insofar as public health emergencies are concerned, should be applied prior to embarking on measures such as compulsory licensing.

The biopharmaceutical industry supports the Doha Declaration on the TRIPs Agreement and Public Health and the limited use of compulsory licenses (CLs) to address national emergencies or other circumstances of extreme urgency. **The dti** and Department of Health should consider compulsory licensing only in exceptional circumstances and as a last resort – and do so only in manner that is consistent with WTO rules.

The dti refers to the Doha Declaration to assert that South Africa has the unrestricted freedom to “determine the grounds upon which [to] issue a compulsory license.” That statement is indeed problematic and the interpretation should be consistent with the broader context of the Doha Declaration. Compulsory licensing is fully limited by all the restrictions that exist in WTO rules. It is furthermore subject to limitations set by the South African Constitution.

Of the 409 medicines on the World Health Organization's [Essential Medicines List](#) (EML), 375 (about 92%) are off-patent. Compulsory licensing patent-protected medicines would discourage development of new treatments for common diseases, as the risk of such licensing would hang over any such developments.

Compulsory licenses are rarely the best policy option to promote access to medicines. It does not necessarily lower prices,³⁶ speed access³⁷ or improve health outcomes. Compulsory licensing

³⁵ Chien, C., [“HIV/AIDS Drugs for Sub-Saharan Africa: How Do Brand and Generic Supply Compare?”](#) *PLoS One*, March 2007.

³⁶ Beall, Reed F. et al., [“Compulsory Licensing Often Did Not Produce Lower Prices for Antiretrovirals Compared to International Procurement,”](#) *Health Affairs*, March 2015.

undermines the predictability and certainty necessary for the development of new medicines and its availability in a country. Access to healthcare is as much about availability, as it is about affordability.³⁸ Furthermore, it does not address systemic barriers to access – from weak healthcare delivery systems to critical shortages of trained healthcare workers. Compulsory licensing is, in IPASA’s view, far less effective than other access measures, including market access programmes and differential pricing, voluntary licensing and non-assert declarations.³⁹ All of these can be implemented within existing legal frameworks, and with minimal legal and policy changes required.

The use of CL may not achieve its intended purpose, necessarily lower prices or speed access.⁴⁰ There are a number of examples to illustrate this:

According to a recent comprehensive study of antiretrovirals, compulsory licensing typically *does not result in lower prices* for medicines compared with international procurement programs and other alternatives.³⁶ For example, after India granted a compulsory license to Natco to produce a generic version of Bayer’s cancer drug Nexavar®, the price for that generic version – \$178 per month – remains inaccessible to two-thirds of the Indian population who live on \$60 per month. Bayer, on the other hand, has a comprehensive patient access program aimed at reaching those patients who cannot afford the medicine at any price. The issuance of a CL in India has done little to address India’s access to medicines problem. When Brazil issued a compulsory license for an antiretroviral treatment in 2007, it took the local manufacturer two years to launch production of a generic version.^{37 37} A study by two Indian academics finds compulsory licenses issued across countries had no impact on health outcomes.⁴¹

Compulsory licensing does not present a sustainable or comprehensive solution to increase access to healthcare because:

- It undermines the longer-term stability and predictability of intellectual property systems that incentivize development of new medicines and enable alternative measures like voluntary licensing.
- It deters foreign investment and may discourage the introduction of valuable new medicines for patients who need them.
- It does not address systemic barriers to access – from weak healthcare delivery systems to low national healthcare funding and high taxes and tariffs on medicines.

³⁷ Bond, Eric and Kamal Saggi, [“Compulsory licensing, price controls, and access to patented foreign products,”](#) Vanderbilt University, April 2012.

³⁸ Constitutional Court in NewClicks case, 2005.

³⁹ International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), [“Voluntary Licenses and Non-Assert Declarations”](#) February 2015.

⁴⁰ When Brazil issued a CL for an antiretroviral treatment in 2007, it took the local manufacturer two years to launch production of a generic version. See above reference 37 - Bond, Eric and Kamal Saggi, [“Compulsory licensing, price controls, and access to patented foreign products”](#) Vanderbilt University, April 2012.

⁴¹ Banik, N. et al., “The WTO on drugs: Have compulsory licenses on medicines improved health outcomes?” Geneva Network Working Paper, forthcoming.

The dti identifies the importance of models, such as the Medicines Patent Pool (MPP), that rely exclusively on such voluntary licensing arrangements. Many of our members participate in the MPP and support other programs designed to promote access to medicines and accelerate discovery of treatments that address urgent global health challenges, including:

- The [Tuberculosis Drug Accelerator](#) (TBDA),
- The [Drugs for Neglected Diseases Initiative](#) (DNDi), and
- WIPO Re:Search.

International Best Practice: A better model, which would effect the balancing act referred to in the Framework, is to improve access to medicines would be to partner with research-based pharmaceutical companies in developing innovative pricing approaches such as:

- *Differential pricing*, which enables pharmaceutical manufacturers to offer significantly discounted prices for innovative medicines to lower- and middle-income patients within a country who would otherwise face significant affordability barriers. At the same time, manufacturers are allowed to maintain value-based market pricing for upper-income patients who either have insurance coverage or can afford to pay out of pocket. If effectively implemented in partnership with the SA government, this framework could help achieve two linked policy goals that are critical for an emerging economy like SA: (i) significantly expand patient access to innovative medicines, and (ii) preserve the SA market as an attractive destination for pharmaceutical R&D investment and new drug launches. For example, *Pfizer, together with the Bill & Melinda Gates Foundation* and several large American and European innovative manufacturers, is partnering with the governments of Ghana and the Philippines to pilot the implementation of differential pricing policies. In 2015-2016, the partners will offer differentially discounted prices to identified patient population segments that currently face major affordability barriers. The pilots are providing the partners the opportunity to learn about implementation challenges and to measure the impact on patient access to medicines. This model can also be replicated in SA.
- *Voluntary licensing*, which allows other companies to make, use, sell or import a patented medicine with the consent of the patent holder. For example, *ViiV Healthcare, the HIV joint venture created by GSK, Pfizer and Shionogi*, grants royalty free voluntary licenses on all of their current medicines (including those in their pipeline, once licensed) for public sector and donor agency programmes in all Low Income Countries, all Least Developed Countries and all of Sub-Saharan Africa. ViiV Healthcare has given 16 voluntary licenses for their ARVs to generic manufacturers. These companies are based in a broad range of different locations. ViiV does not charge royalties in respect of these countries. Some Middle Income Countries are also covered by ViiV's licenses on which royalties may apply. In total 138 countries are covered.⁴²
- *Non-assert declarations*, by which the patent holder commits not to enforce certain patents in certain places and circumstances.³⁹

⁴² <https://www.viivhealthcare.com/what-we-do/we-improve-access-to-our-medicines.aspx> Accessed on 24 August 2016.

One of the reasons advanced by the draft Framework for compulsory licensing (CL) is to increase affordability of medicines and restrain anti-competitive practices (par iv). Apart from the fact that the current Patents Act does provide for CL,⁴³ the following should be considered:

- Affordability of medicines is already within the regulatory remit and mandate of the National Department of Health and the National Treasury. For the price sector, price regulations are already in existence;
- Competition law already provides an effective remedy to address any anti-competitive effects of the exercise of any IP rights. IP legislation or IP policy do not require amendments for this remedy to be available to any stakeholder.

The Framework proposes certain actions with respect to compulsory licensing (at Sections 4.1.9.1 and 4.1.9.3) that would be inconsistent with international rules, including WTO requirements to:

- (i) Make decisions authorizing compulsory licenses subject to judicial review, and
- (ii) Make efforts to obtain authorization from the right holder.

In the absence of the necessity to resort to CL, it is not clear what the basis of the statement “does not result in unnecessary delays” (par v) can be made. Although it is stated that TRIPS does not provide for a judicial process, the process before the Commissioner of Patents is not a judicial, but a quasi-judicial process. Irrespective of the process, the application of the Promotion of Administrative Justice Act, 2000, will result in certain delays, should due process and/or substantive disputes so dictate.

It seems to be suggested that the TRIPS flexibilities authorize a departure from so-called “judicial processes” (par 4.1.9.5). The South African administrative- and constitutional law dispensations will bring, and do require, processes that are quasi-judicial in nature. These principles are so deeply entrenched in the South African legal system that any policy reform should consider – so a “pure” “streamlined” administrative process would simply not be possible within these legal frameworks.

Compulsory licenses are therefore not a suitable tool to deal with the long-term healthcare issues confronting countries like South Africa. Access to medicines issues are highly complex and ought to be addressed in partnership with all stakeholders, including our industry—we are more than ready to partner with your SA government to address these long term issues in a meaningful way.

⁴³ Sections 55 and 56.

3.10 IP & COMPETITION LAW (SECTION 4.1.10)

The right to health and the rights of inventors to protect their intellectual property are both well established in international law. These rights are not in conflict. Rather, they are co-existing and mutually supporting.

However, in addressing the interface between IP and competition, the TRIPS Agreement and all its inherent Clauses must not be used in a punitive manner and as a “stick” but rather a consultative process must be instituted. Competition Law is an important instrument to achieve an appropriate balance between the interests of the creators and users of IP.

It is stated (par viii on page 13) that the cost of competition law litigation deters generic manufacturers from exploring instances where an innovator may be abusing its dominance, for example. It must be noted that there are many avenues, not all of which have to be costly, or have any significant cost to the aggrieved entity at all, and it is submitted that this is not the reason for persons not using this avenue.

Furthermore, there is currently a Competition Commission Health Market Inquiry (HMI) in place, which is looking at possible market failures, and participation in that process is free and an opportunity, had there been issues, to canvass same.

3.11 INTERNATIONAL BEST PRACTICE; A BRICS PERSPECTIVE (SECTION 4.2)

We fully understand the importance and need for South Africa to look at best practices in similarly situated countries--in this case, Brazil, Russia, India and China. However, the pharmaceutical industry has much experience to share outside of the BRICS countries—and as stated above, the largest patent offices in other jurisdictions account for more than 80% of the world’s patent applications. It is important for South Africa to look at and reference the practices in those countries and others that have demonstrated great success in the biopharmaceutical industry as it develops its own policies.

IPASA believes that using the BRIC countries alone as benchmarks for South Africa might not be the best examples of what might be regarded as best practices. A key differentiator is the existing patent protections afforded in South Africa, and its relatively long legal history in this regard. A further differentiator is its human rights and Constitutional framework which is not present or similar in all of the BRIC countries.

Not all BRICS countries have met the minimum requirements for IP, as set in international law. Brazil is in violation of Article 27 in that pharmaceutical patents are required to be reviewed by ANVISA – its regulatory health agency. Brazil also experiences examination delays and problems with enforcing patents in the courts. On Russia, we have available a draft of an IFPMA paper on Russia patent issues. It is provided and outlines clearly why Russia cannot serve as a benchmark. India is also not in compliance with Article 27 in that improvement patents in the pharmaceutical space, or new use patents are limited. The reason for this is listed as “evergreening”. However, improvement patents cannot extend the life of the original patent, that still expires and become subject to lawful copying.

It therefore does not extend the life of the original patent. China also appears to be in breach of Article 27 in that pharmaceutical patents have unfair data inclusion requirements for its specification not in existence for other patents.

3.12 INTERNATIONAL COMMITMENTS

As laid out in the Framework, South Africa is Party to all the key global multilateral agreements on intellectual property rights. As such, our industry fully supports SA's adherence to its treaty obligations as a global trading partner. The pharmaceutical industry has a long history of supporting free trade principles and studies demonstrate that IP components of free trade agreements have not historically undermined public health.⁴⁴

4. POLICY INTERSECTION CONSIDERATIONS

4.1 INTERSECTION OF HEALTH AND TRADE POLICY IN SOUTH AFRICA

Despite decades of implementation of national medicines policies, medicines access, affordability and use are still problematic in many low and middle income countries (LMICs). Medicines account for a high proportion of out-of-pocket (OOP) expenses in many LMICs and challenges exist to ensure equitable access in the face of geographic, economic and cultural barriers.⁴⁵

Markets have played an increasingly important role in the health systems of LMICs over recent years, particularly in drug development and in the delivery of related products and services. A thorough understanding of health market systems is needed to improve access to and use of medicines.⁴⁶

For South Africa, this is also an important consideration – the link between access to medicines, pricing and intellectual property need to be interrogated and intended and unintended consequences on access to medicines and ultimately health outcomes need to be considered.

In the end, any policy- and legislative proposal must be measured against whether it is, constitutionally speaking, reasonable, rational and fair, in particular where rights have to be balanced, such as healthcare rights and property rights. It also has to be relational, i.e. it should lead to increased access, for example. If there is a risk, or proof that access may indeed be hampered (e.g. there is no innovator medicines against which the Bolar provision would apply, due to the non-awarding of patents, or delays in patent processes), the specific measure would not be constitutional.

⁴⁴ Venkatamaran S. and Stevens P., "Are Free Trade Agreements bad for health? Quantifying the Impact of FTAs on Health Outcomes." Geneva Network Working Paper, 2015. Retrieved at <http://geneva-network.com/wp-content/uploads/2015/08/FTAs-and-health.pdf>.

⁴⁵ Shroff, *et al.* 2016. Using health markets to improve access to medicines: three case studies, *Journal of Pharmaceutical Policy and Practice*

⁴⁶ Bigdeli, M, Peters, D, Wagner, A (Eds) World Health Organisation (2014) *Medicines in Health Systems: Advancing access, affordability and appropriate use*. Geneva, WHO Press.

4.2 RESEARCH & DEVELOPMENT AND INDUSTRIAL POLICY

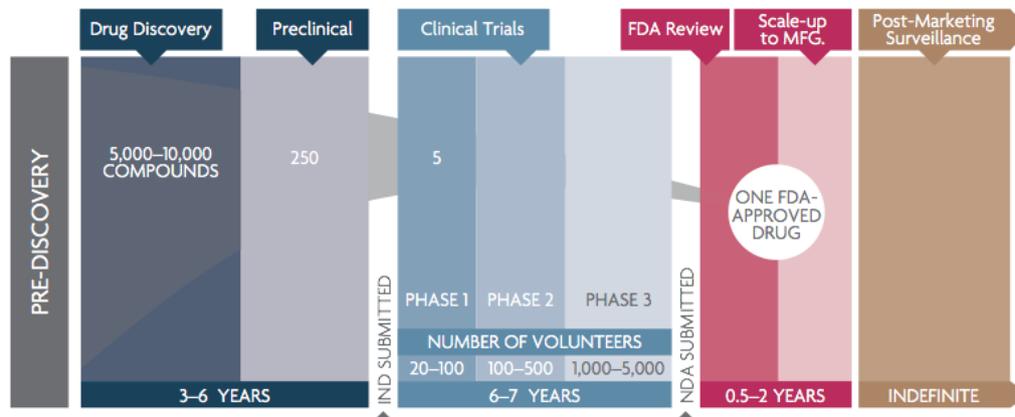


Figure 1: Value of Research and Development in Pharmaceuticals

A 2015 OECD study of global markets deploying localization policies found that these policies alone resulted in losses of imports of more than USD 10 billion.⁴⁷ In the biopharmaceutical sector, countries with localization barriers in place – such as Algeria, Thailand, Russia, Brazil, Turkey, India and China –tend to see much lower levels of clinical research activity than countries with more positive and non-discriminatory incentive based policies.⁴⁸

South Africa is under-performing in terms of its investment in research and development. The Department of Science and Technology’s annual R&D survey, released in May 2016 for the 2013/4 year, shows that only 0.73% of GDP is spent on R&D in South Africa which spend has remained flat, if not slightly down, over time.⁴⁹

Tax incentives intended to promote and drive investment in R&D have proven to be problematic for companies to access due to differing legal interpretations of what constitutes research & development. This has resulted in administrative costs and also in some cases legal disputes. Therefore, the intended purpose of the incentive has not been met. Subsequent revisions of the dispensation on R&D tax incentives have made provisions for a specific ‘carve out’ for pharmaceutical research which is limited to research relating to generic products, and research that is totally based on SA.⁵⁰

Local universities could increase capacity to undertake research and/or to participate in global research projects, including but not limited to clinical trials. A programme should also be embarked upon to ensure that historically disadvantaged universities reap the benefits of R&D expansion programmes. This is aligned to DST’s bio-economy strategy which envisages the transformation of South Africa into a knowledge-based economy.

⁴⁷ Stone, S., Messent, J. & Flag, D. (2015), “Emerging Policy Issues: Localization Barriers to Trade” OECD Trade Policy Papers, No.180, p60.

⁴⁸ Pugatch Consilium, PhRMA publication, p34.

⁴⁹ http://www.dst.gov.za/images/Attachments/2013-14_RD_Survey_Statistical_Report.pdf.

⁵⁰ National Treasury, No. R. 343 23 April 2015, Notice in terms of Section 11d(6)(b) of Income Tax Act, 1962 (Act no. 58 of 1962), in respect of certain categories of research and development deemed to constitute the carrying on of research and development.

Innovative pharmaceutical industries are generally the main sponsors of clinical trials in South Africa, and a stable and consistent intellectual property (IP) protection is critical to capitalizing fully on the opportunity clinical trials offer for patients and the economy.⁵¹ Such protections provide the predictability and legal certainty necessary to transfer technologies between innovators, researchers, and academic institutions, and create a robust generic industry. Economies with weak IP environments tend to host, on average, 9-10 times fewer clinical trials than countries with stronger IP environments.⁵²

Challenges in general relating to R&D have a specific manifestation in the health sector and goes hand in hand with the incomplete health research framework envisaged in the National Health Act (NHA). Under the NHA, there should be a National Health Research Committee, who should be setting and driving the national health research agenda (and who could, potentially, also engage with the Department of Science and Technology and National Treasury in relation to R&D and R&D incentives). There should also be a National Health Research Ethics Council, with oversight over research ethics committees in the health sector. Although research regulations⁵³ have been promulgated, access to Ministerial consent, as is envisaged for research involving children, has been virtually impossible to obtain.

In the case of medicines, obtaining approval from the Medicines Control Council for clinical trials often entail delays, and in some cases South Africa misses out on participating in global clinical trials due to such delays.

There is an opportunity to create policy cohesiveness to create a clear link between Industrial Policy and R&D policy, within the context of national health research priorities, which currently does not exist in any of the frameworks. Creating an enabling environment for R&D will also drive investment and create jobs and improve the knowledge capital of our country, whilst responding, through research, to South Africa's health sector priorities.

⁵¹ Wilsdon, T. Attridge J. et al., [Policies that Encourage Innovation in Middle-Income Countries](#), Charles River Associates, October 2012. ("The level of protection [of intellectual property] influences the prioritization of clinical trials in middle income markets and the location of basic research and preclinical research depends on the IP regime in the country. Although not sufficient, robust IP rules are required to encourage innovative activity.") See also the [2016 Scientific American Worldview Scorecard](#) ("To stay competitive, a country must hold biotechnology's keystone [intellectual property protection] firmly in place. Strong IP protection can support the industry, but the sector collapses if IP protection fails.")

⁵² Pugatch Consilium, "The Race for Biopharmaceutical Innovation: Biopharmaceutical Competitiveness and Investment (BCI) Survey", Third Edition, 2016.

⁵³ GNR.719 of 19 September 2014: Regulations relating to research with human participants (*Government Gazette* No. 38000).

5. CONCLUDING REMARKS:

As the industry most affected by the first phase of the policy formulation process, we respectfully request:

- That a formal engagement process with industry stakeholders continues to be developed in collaboration with IPASA – this will allow for constructive exchange of information and ideas throughout the policy formulation process;
- That the policy formulation process remains transparent and inclusive, especially as views are sought from diverse stakeholders including patients;
- That the policy formulation process be driven by evidence and guided by international best practices.
- That the government take a long-term view of the role of IP in the country's development - it is in the national interest of both small and large economies to support a global environment conducive to pharmaceutical innovation;
- That the biopharmaceutical industry be seen as a true partner - sharing in South Africa's stated goals and with a major stake in its success.
- That there be policy coherence and alignment amongst different government departments in the development of SA's IP Policy
- That a detailed regulatory impact assessment be conducted to assess the intended and unintended consequences of amendments to existing legislation and the implementation of new legislative requirements

IPASA wishes to express its appreciation to **the dti** for the approach it is taking in preparation for a Draft IP Policy – the IP Consultative Framework, to inform stakeholders of the preliminary analyses conducted, in order to select the best way of introducing an IP Policy in South Africa that the selected system will fit in with the policy and strategic objectives of the country, and will be designed and implemented in a manner that promotes South Africa as a destination for innovation and technology, and not impedes it.

It is encouraging that there will be an Inter -Ministerial Committee (IMC) on IP, to ensure that there is inter-governmental coordination, a process that will harness the collective resources in government, and ensure a consistent and coherent government approach to multilateral IP forums.

In the comments set out above and in the explanatory information provided, IPASA has endeavoured to address all of the matters put forward in the Framework, and has also endeavoured to set out its views and comments on the issues raised in a constructive manner.

The pharmaceutical industry in South Africa therefore stands ready to support the development of non-discriminatory incentive based laws and policies which will create an enabling environment for innovation and investment. This approach requires:

- Equal treatment of local and foreign companies;
- Promoting conditions for enabling innovation—including a focus on strengthening scientific capabilities;
- Developing international-standard regulatory systems;
- Developing predictable and fair pricing, reimbursement and public procurement schemes.

APPENDIX 1 - INNOVATIVE PHARMACEUTICAL ASSOCIATION SOUTH AFRICA (IPASA) MEMBER COMPANIES

1. Abbott
2. AbbVie
3. Allergan
4. Amgen
5. Astra Zeneca
6. Baxter
7. Bayer
8. Boehringer Ingelheim
9. BMS
10. Ferring
11. Galderma
12. GSK
13. Janssen
14. Key Oncologics
15. Lilly
16. Mallinckrodt
17. Merck
18. MSD
19. Mundipharma
20. Novartis
21. Novo Nordisk
22. Pfizer
23. Roche
24. Sanofi
25. Servier
26. Takeda