HEALTHCARE SECTOR INQUIRY

PHARMACEUTICAL TASK GROUP'S RESPONSE TO THIRD PARTY SUBMISSIONS CONCERNING THE PHARMACEUTICAL SECTOR

INTRODUCTION

i. The Pharmaceutical Task Group (PTG) accepts the invitation made by the chairperson of the healthcare sector inquiry (the Inquiry), Retired Chief Justice Sandile Ngcobo, on 05 February 2015, to make submissions concerning misleading or inaccurate information contained in the publicly available submissions made by stakeholders in respect of the Inquiry

ii. The PTG is a liaison body involved in pharmaceutical matters within the Pharmaceutical Industry in South Africa and with several relevant stakeholders where appropriate. It represents over 90% of the South African pharmaceutical market in value and comprises a grouping of associations from both research-based innovative pharmaceutical companies and local generic companies. The PTG is made up of The Innovative Pharmaceutical Association of South Africa (IPASA), the National Association of Pharmaceutical Manufacturers (NAPM), Pharmaceuticals Manufactured in South Africa (PHARMISA) and the Self-Medication Manufacturers Association of South Africa (SMASA). The PTG is also joined by Roche Pharmaceuticals, as an independent company. A comprehensive list of companies included in the PTG Group is listed in Appendix 1 hereto.

iii. The members of the associations that belong to the PTG are providers of healthcare products in the form of medicines, scheduled and unscheduled to both the private and public sectors.

iv. Paragraphs 1 to 23 deal generally with the pharmaceutical sector and the context in which it has been referred to by stakeholders and seeks to contextualize the submissions made by the stakeholders.

v. Paragraphs 24 to 129 deal with the specific components raised by stakeholders as being contributors to the high cost of medicines.

vi. Finally, paragraphs 130 to 139 deal with the PTG's conclusion.

CONTEXTUAL SETTING

1. The PTG addresses herein the broader contention that the cost of medicines is an important cost driver in the healthcare sector.

2. It is respectfully submitted that the comments that follow are important in contextualizing the submissions made by stakeholders concerning the pharmaceutical sector and are equally important in ensuring that the health sector inquiry does not become a playing field for stakeholders to achieve policy reforms which have otherwise been unsuccessful in other fora or a commercial strategy by certain stakeholders to drive prices down for commercial gain.

Price as a Component of Access to Medicines

3. The comments that follow are important in contextualizing the submissions made by stakeholders that focus on the price of medicines.

4. Although not stated explicitly the implication is that the high price of medicines prevents access to them.

5. The debate concerning access to medicines is one which is before numerous fora at various levels of government. That said, the panel's attention is drawn to the following points:

   (a) Innovation drives growth in the pharmaceutical sector which results in greater competition and more substitutable products which realizes better and improved treatment options for patients. Patients are however denied quicker access to these new innovative medicines due to the slow registration process at the regulator, the Medicine Control Council (MCC).

   (b) When considering access due regard must be had to the fact that the majority of the population rely on the public sector in which the price of medicines is very low.

   (c) Price is not the only component in the access debate and a price-centric view to access is both misleading and irresponsible as this approach ignores other

fundamental components, such as regulatory, infrastructure, and functioning supply chains, critical to effective and efficient healthcare delivery.

(d) The right to access does not only extend to medicines currently available but also to new and/or improved medicines and technology, central to which is R&D and innovator pharmaceutical manufacturers and those domestic companies that license these products.

(e) Generic medicines are dependent upon the registration of new medicines in order to obtain regulatory approval. Without new medicines being registered in South Africa, especially if there is a negative environment to effect such investments, generic products will not follow and South African's will be denied access to these.

(f) Information asymmetry between the patient and doctor or funder is also a key consideration given the complex reimbursement and access system in South Africa in the private sector.

6. Finally, access is not only to be viewed in respect of medicines but also in respect of other factors such as the policy frameworks, public sector facilities and infrastructure, human resourcing, funding, local manufacture, or the lack thereof and the ability to provide the necessary support to patients in order to ensure patient compliance in the use of medicines.

Legislative and Policy Developments

7. The majority of submissions by stakeholders concerning the pharmaceutical sector cut across industrial, commercial and health policy considerations which are the subject matter of policy discussion and development in other fora.

8. While these submissions are useful as background to the healthcare sector they do not concern themselves specifically with those areas with which competition law is concerned, namely abuse of dominance, market power, co-ordinated conduct and restricted vertical practices, as it pertains to the pharmaceutical sector and the members of the PTG.

9. In particular, stakeholders have raised, in the context of the high price of medicines, international benchmarking and the need to substantively examine[1] patent applications for pharmaceutical products without which it is alleged that "weak" patents are granted and that such patents act as barriers to entry thereby preventing competition and raising prices.

10. Both the issues above are the subject matter of policy and legislative reform at government level and shall, in the near to medium term future be introduced, thereby changing the competitive landscape.

11. The PTG therefore respectfully submits that the arguments concerning pricing of medicines and the impact of patents may be relevant for background purposes but that such arguments are rendered moot, or at the very least, render any decision or recommendations based thereon academic given the changing landscape and the future re-adjustment of the market in the pharmaceutical sector as a result of new legislation in the form of :

    (a) Regulations relating to a transparent pricing system for medicines and scheduled substances (benchmarking methodology) (General Notice 354 of 2012 GG 37625 of 12 May 2014). The process for public comment has come to an end and the "Benchmarking Regulations" are expected to come into force on 05 July 2015. The impact hereof is discussed further below.

[1] This refers to the examination of the subject matter of a patent application on the basis of patentability. Patentability is to be assessed having regard to Section 25 of the Patents Act No 57 of 1978 (Patents Act).

Accordingly, the pricing of medicines will be comparative to international benchmarks, ensuring that the South African consumer pays a fair price for medicines.

(b) Substantive examination of patents is a recommendation made in the Draft National Policy on Intellectual Property, 2013 (General Notice 918 of 2013 GG 36816 of 4 September 2013 – the "IP Policy"). The IP Policy has been revised pursuant to public comment, in respect of which the price of medicines and access was fully ventilated, and it is believed that the revised draft should have been tabled before Cabinet by the end of February 2015.

Insofar as examination is concerned stakeholders were invited by the Consumer and Corporate Regulation Division (CCRD) Chief Directorate: Policy and Legislation and the Companies and Intellectual Property Commission (CIPC), in early February 2015, to attend a workshop on the manner in which substantive examination is to be carried out. It is abundantly clear that substantive examination is a *fait accompli*.

The Pharmaceutical Sector within the Context of the Healthcare Sector

12. Save for the medical device sector, the pharmaceutical sector is the smallest segment in the larger healthcare sector.

13. For example, of the 10.9% increase in claims expenditure for Medscheme, the cost of medicines is but a component of a residual 1.1% that was calculated as contributing to the average increase[2].

14. In the submission made by Mediclinic it is stated that 27% of a private patient's hospital bill is made up of pharmaceuticals[3]. It is then stated that out of this 27%, one third relates to drugs. Accordingly, pharmaceuticals actually only constitute 9% of the hospital bill, once again demonstrating the size of the sector. This latter figure is in line with the submissions made by Netcare.

[2] Competition Commission Market Inquiry in the Private Healthcare Sector; Medscheme Holdings (Pty) Ltd; October 2012, page 14.
[3] See page 20, paragraph 2.4.6.7.7.1

15. The pharmaceutical sector is also the most regulated sector, soon to be exposed to even greater regulation having regard to international benchmarking, potentially more stringent intellectual property provisions than most countries and other regulatory provisions such as those set out in the draft Regulations of S18A of the Medicines and Substances Control Act 101 of 195 and the soon to be regulated logistics fee capping.

16. Further, the value and volume evolution of the private sector can be summarized as clearly showing that the market is only growing marginally (not even keeping pace with inflation both in terms of volume and value). It is therefore inconceivable that it would be a contributor to health inflation in the private sector – indeed, warning signs should be flashing against the institution of any more severe price regulatory mechanisms of the nature asked for by some stakeholders:

	2010	2011	2012	2013	2014
Year Value	**R 23 206 023 067**	**R 25 383 499 423**	**R 27 360 923 047**	**R 29 769 785 710**	**R 31 170 948 695**
Value Growth	8.84%	9.38%	7.79%	8.80%	4.71%
Year Units	343 026 882	**372 879 723**	**391 861 756**	**408 557 073**	**419 225 042**
Unit Growth	5.89%	9.11%	5.09%	4.26%	2.61%

17. Also, the pharmaceutical sector and the submissions made in respect thereof must be viewed against the backdrop of a system where both the medical schemes and hospital environments have effective legislative measures to influence the usage of, and in many instances exclude, products from the market through formularies and other treatment protocols.

Cost Offsets and Best Value

18. The value of medicines should be a function of quality, outcomes and costs and must be assessed over time rather than focusing on the purchase price of a medicine.

19. Whether medicines increase or decrease costs depends upon factors such as:

    (a) The degree of substitutability of medicines in the market;

    (b) Whether the number of treatable conditions is expanded such that conditions hitherto untreated can now be treated or be treated more effectively. The result is that an increased provision of services is created such that there are more patients thus increasing healthcare expenditure;

(c) What the impact is on the delivery of care and whether the capacity to treat more patients is improved; and

(d) Whether the medicine or technology extends life thus increasing the number of years for which a patient requires additional healthcare.

20. The PTG submits therefore that it is necessary to consider all factors including those that have a positive impact on cost offsets (e.g. duration of treatment, length of stay at a hospital, number of medicine items prescribed and utilisation); years of life, quality of life, societal and economic effects and the like when considering the impact of the costs of medicines on healthcare expenditure. Further, where healthcare expenditure increases as a result of the provision of new technology such increases may not necessarily be as a result of the cost of the medicine per se but expanded treatment options, access and longer life of the patient.

The Public Sector and the Private Sector Generally

21. Notwithstanding that a number of parties call for parity of pricing of medicines in the private and public sectors, the PTG is of the opinion that this is out of scope of the panel's mandate. Given that stakeholders' submissions in this respect are superficial, the PTG does not believe that the panel is placed in a position to make any meaningful comment in respect thereof and, respectfully, should avoid doing so in the absence of a detailed consideration of the public sector and how it interrelates with the private sector. The PTG has therefore limited its comments in this respect.

22. It is submitted that in considering both sectors it must be noted that the Pricing Regulations were promulgated to apply to the private sector only.[4] The range and choice of products in the private sector, including those referred to in the Treatment Algorithms for the 25 chronic diseases in the PMBs in terms of the Medical Schemes Act and Regulations, are vastly different from the products available in the public sector, either through the state tender

[4] Section 22G, Medicines and Related Substances Act, 1965.

system, buy-outs or as part of discretionary spend, under the Public Finance Management Act and the General Treasury Regulations.

23. It must also be noted that in most countries private sector prices of medicines are not regulated, and regulatory measures are limited to the public sector systems of health services. The explanation for this peculiarity may lie in the statements found in most submissions to the panel, i.e. the incomplete regulatory reforms due to the policy change from a social health insurance (SHI) - to a national health insurance (NHI) system. Under the SHI system, private medical schemes would have formed the backbone of the funding of healthcare services, with state-sponsored funds providing funding to those who cannot afford medical scheme contributions.

SPECIFIC SUBMISSIONS

24. The PTG addresses the following topics raised by stakeholders in their submissions:

- Pricing generally and in the context of Single Exit Pricing, the introduction of a transparent pricing system as set out in Section 22G of the Medicines and Related Substance Control Act.
- Parity of Pricing between Public and Private Sectors
- Pricing in the context of International Benchmarking
- Pricing between innovator and generic medicines
- Prescribed Minimum Benefits
- Regulatory Timelines
- Innovation, Costs of New Technology, Biologicals and Biosimilars
- Intellectual Property
- Parallel Importation

PRICING GENERALLY AND IN THE CONTEXT OF SINGLE EXIT PRICING

25. Some parties[5] argue that notwithstanding SEP pharmaceutical manufacturers have a broad discretion concerning the prices they charge and that patent protection is a source of monopoly allowing a manufacturer to obtain economic profits higher than the marginal cost of production.

26. The above argument is academic given the introduction of international benchmarking and the effect it will have on medicine pricing. This notwithstanding, the following comments are to be taken into account.

27. The manufacturer of a product to be launched on the South African market is obliged to approach the Pharmaceutical Economic Evaluations Unit (PEE) of the DoH to seek 'approval' for a launch price of the medicine. This requires a comparison with the prices of that same product in all countries where the product is launched and thus over and above those countries identified in the draft international benchmarking regulations. Although benchmarking is not yet law, pressure is put on manufacturers by the PEE to conform to the prices in the identified countries. It should be remembered that the benchmarking will be introduced by the Regulator later this year. Hence the "discretion" asserted by some submissions is misleading.

28. The statement that '…..Medicine prices in the private sector have not been determined by competitive forces'[6] is erroneous. As a starting point it should be noted that more often than not the SEP that is determined is below the allowed value calculated using the SEP methodology. Further, within the SEP system all pharmaceutical products continue to face therapeutic or generic competition, which limits the ability of the manufacturer to increase prices, despite that allowed by the SEP. It can be shown that across the market, the actual price increase taken by manufacturers has been well below that allowed by the annual SEP increase approved by the Honorable MoH. (See below tables)

[5] See for example BHF's submission, paragraph 13.8, page 63. See also submission from Transpharm and MediRite, pages 3 to 5, page 7.
[6] See Transpharm and MediRite's submission at paragraph 3.1.1.

Year	Period	Methodology	Actual SEP increase	Difference
2004/2005 2006/2007	Catch up since SEP introduced	2.56% 2.56%	5.2%	N/A
2008	Aug 06 – July 07	8.4%	6.5%	- 1.9 pts
2009	Aug 07 - July 08	12.12%	13.2%	+1.08 pts
2010	Aug 08 – July 09	9.9%	7.4%	- 2.5 pts
2011	Aug 09 – July 10	(2.1)%	0%	N/A*
2012		6.9%	2.14%	- 4.76 pts
2013		8.2%	5.8%	- 2.4 pts
2014		8.9%	5.82%	- 3.1 pts
Shortfall (not compounded)				- 13.58 pts

Date of announcement	Approved SEP For the closest period	Net effect of price increases February to January Moving Annual Total (12 months)	
31 January 2014	5.82%	February 2014 to January 2015	3.1%
22 January 2013	5.8%	February 2013 to January 2014	2.4%
19 January 2012	2.14%	February 2012 to January 2013	0.9%
24 January 2011	0%	February 2011 to January 2012	1.2%
17 March 2010	7.4%	February 2010 to January 2011	3.1%

29. By way of further explanation of the above table :

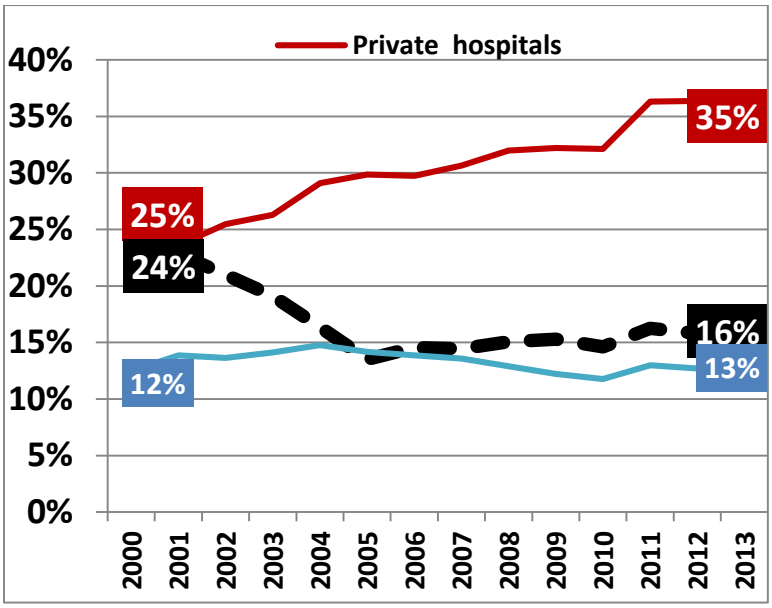
(a) The above data is sourced from IMS which is the recognised international source of pharmaceutical statistics. The data was run on a Moving Annual Total (MAT basis) for 12 month periods from February of one year to January of the following year, including Schedule 1 and above products. The time periods have been matched in the table as closely as possible. The figures above denote the contribution that price CHANGES made to Value growth in the MAT periods. This means that the figure also incorporates some price drops where applicable. The figure is the net difference between price increases and price decreases on products.

(b) The above data gives a very clear indication that the increases actually taken on pharmaceutical products overall are below that allowed by the SEP. The most important reason is that competitive forces do not allow manufacturers to take the full increase on all products, so the average increase due to PRICE is well below the permitted increase. Higher overall value growth (see table paragraph 16) would be attributable to other factors including the introduction of new, perhaps higher priced, products and the product mix. Further, the SEP regulations allow the reduction and subsequent increase of prices back to the same SEP for a maximum of four times per year, which could be one explanation for the small increase in a period when no increase was allowed (2011/2012). There will also be permanent price reductions for some products which will offset some of the increases – hence the data shows the net difference due to price.

30. Additionally, the price of medicines was reduced initially by an average of 19%[7] as a result of the introduction of SEP and it continues to contain costs until the present. Medicines as a percentage of the healthcare 'pie' have dropped from 22,3% in 2003, prior to the introduction of SEP, to 16% in 2013, according to the CMS annual reports. (See tables below)

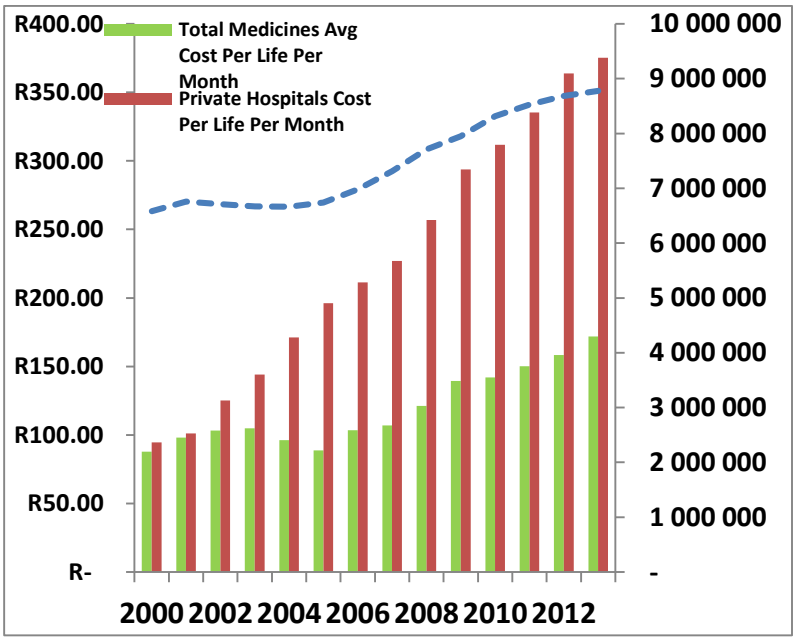
[7] See Medscheme's submission at page 35.

Figure 1: Medicines declining in share of Medical Scheme expenditure



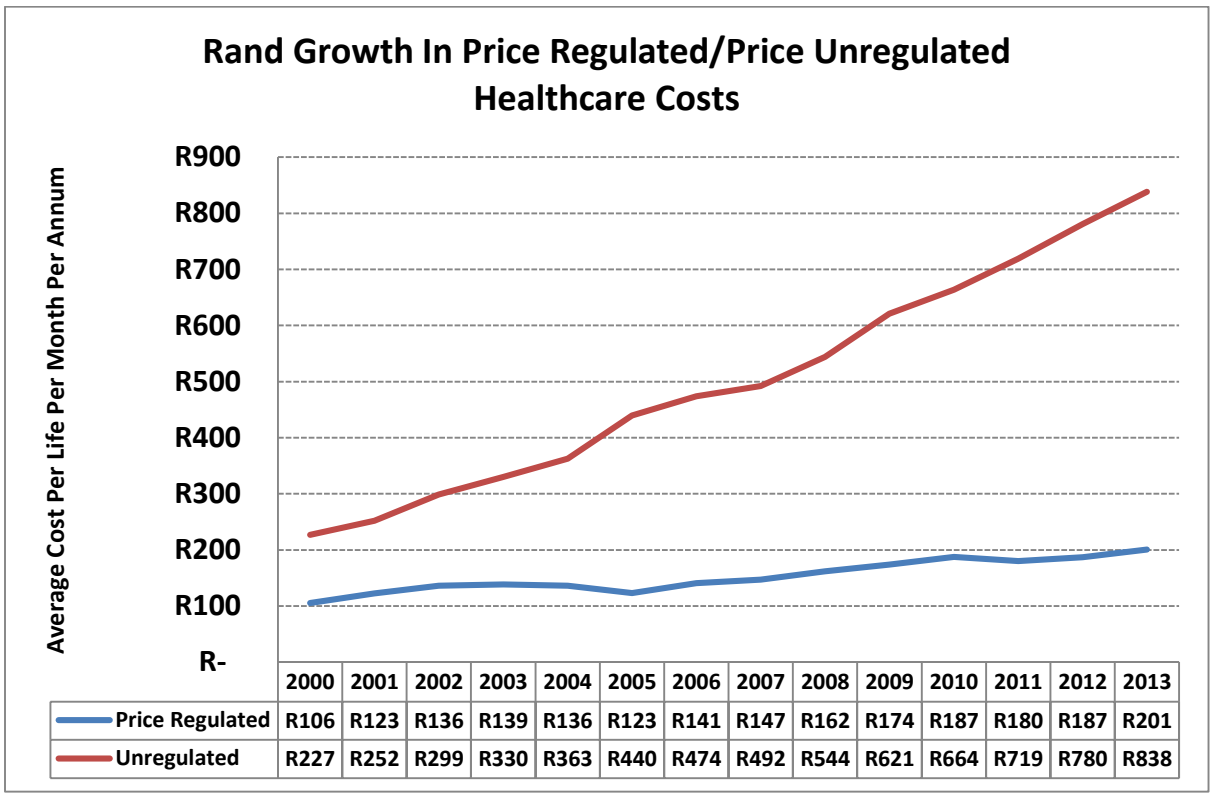
CMS annual reports

Figure 2: Cost per capita for medicines well contained



31. Further, as can be seen from the below graph, the PTG confirms that the pricing regulations that have been put in place by the regulator have led to a situation where medicines costs are firmly in control below the level of general healthcare inflation and are not a cost driver for medical schemes as is alleged.

Figure 3



	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Price Regulated	R106	R123	R136	R139	R136	R123	R141	R147	R162	R174	R187	R180	R187	R201
Unregulated	R227	R252	R299	R330	R363	R440	R474	R492	R544	R621	R664	R719	R780	R838

Single Exit Pricing and CPI

32. Notwithstanding the above information concerning SEP increases with respect to inflation, the PTG is of the view that the Consumer Price Index (CPI) is an inappropriate comparator when it comes to considering inflation with respect to medicines. The CPI is a broad indicator of general inflation at the consumer level. The inflationary pressures experienced by the pharmaceutical industry are perhaps closer to the Producer Price Index (PPI), but even that is not found to be a good fit by industry analysis.

33. Components of locally manufactured medicines ("active pharmaceutical ingredients" – API's) are, for a large part, globally manufactured and have to be imported, making both

locally manufactured and fully, or partially imported medicines subject to exchange rate fluctuations and vagaries. Local materials, labour and utilities (electricity and water) have been identified as playing a much greater role for local manufacturers in terms of cost drivers, for example. These are not included in the CPI which measures the change in household spend over time, considering items such as food, clothing, household contents, education and transport.

34. Various other input costs have also had an impact on the pharmaceutical industry. Administered prices have increased above inflation. For example, the SA Reserve Bank's December 2014 Quarterly Bulletin noted that following an acceleration to 8,9% in May 2014, administered price inflation moderated to 5,1% in October 2014. Health sector stakeholders have no control over administered price inflation.

Bargaining Power of Healthcare Funders and Hospitals

35. It is noted that in the submission by Discovery Health is stated that "current pricing bears little relation to the economic value of the product".

36. First, to the extent that it is intimated that current prices are too high, and therefore excessive, no assessment has been undertaken by Discovery Health, or any other party, concerning dominance. Excessive pricing can only be analyzed in the context of dominance. Also, "economic value" is a complex term to unpack[8], an exercise that Discovery Health does not undertake.

37. Second, Discovery Health and other medical scheme administrators exercise effective control over market access by requiring of companies to submit exactly this type of evaluation prior to a product being included and being reimbursed, either in part, or in full, by the schemes administered by the specific administrators.

38. The mandate for these investigations originate from the managed care regulations to the Medical Schemes Act, which requires of medical schemes to set their disease caps,

[8] See "A healthy market? What price for a year of life? The threshold discussion in Health Technology Assessment"; Stokholm Network – 2008 – Appendix 2 hereto.

formularies and protocols in line with evidence-based medicine, taking into account "cost-effectiveness" and "affordability".

39. The Panel's attention is drawn to the fact that there are extensive regulations in the Medical Schemes regime that governs access to medicines. Both price levels and utilisation are effectively controlled through the measures listed below. Utilisation (and to some extent price) is highlighted as a cost driver in many submissions. However, all administrators and schemes have the power to limit utilisation and/or exclude a product from the markets they manage. The impact of this is however more severe the larger and/or more dominant an administrator or scheme is.

40. Some of these measures are:

    (a) The way in which patients access medicine (as is required by the Medicines and Pharmacy Acts), enables very effective control over the availability and reimbursement levels of products. If a product is to be dispensed, dispensing software in the pharmacy would warn that a product is not available on the patient's medical scheme plan, or is only available when a certain co-payment (often more than the regulation 8(5)-requisite real difference in price) is made, or only available when certain forms and applications have been made.

    (b) The publication of medicine formularies and maximum medicines amounts for certain conditions, which pre-determine and guide patients away from out-of-formulary, or more expensive medicines.

    (c) The operation of call centres that inform patients that there are cheaper medicines available, even after prescriptions have been issued, or after patients have been on a particular treatment.[9]

    (d) The existence of systems that pay healthcare providers higher professional (consultation) fees for keeping the total price of a prescription below pre-determined

[9] This raises concern in terms of whether the provisions of the National Health Act on informed consent, the provisions of the Medicines Act (who may prescribe and dispense a medicine), the Good Pharmacy Practice Guidelines on patients being counseled on their medicine and the ethical rule against supersession of care, are being adequate acknowledged and adhered to.

values. These systems are problematic and potentially perverse to the prescriber, as they could compromise quality of care to the patient, and no outcomes data is being collected in respect thereof, e.g. on hospitalization. Measurements appear to be made only on price.

(e) Models of vertical integration, where administrators and/or schemes would buy wholesalers and distributors, and enter into deals to ensure that products are only available to members via these channels. Not entering into a deal with these integrated entities could leave one's product out of the supply system, which is being promoted to scheme beneficiaries as the preferred system.

(f) Certain funders for example Discovery are presently contemplating acquiring their own pharmaceutical products and product registrations. This would lead to the introduction of a vertical relationship, compounded by the fact that this same funder recently established its own mail order company, all of which is set to restrict market competition, rather than enhancing it.

41. These systems are exemplified in the submissions. For example, in Mediclinic's submissions it states:

"4.21.10.3 Mediclinic does not adopt new pharmacy technology unless proven effective……."

"4.21.1.7 Mediclinic applies strict procurement policies in respect of pharmaceuticals in order to be cost effective……Mediclinic also promotes the use of cost effective medicines in its hospitals.."

42. In Discovery Health's submission it is stated that it has decisive tools to manage medicine prices and utilization, for example preferentially priced medicines, active SEP price negotiations, clinical protocols to manage medicine utilization, drug utilization reviews and DSP arrangements.[10] The rest of the measures are redacted as being confidential.

43. Accordingly it is arguable that under the current legislative framework and the prevailing market practices and systems of certain healthcare funders and administrators

[10] Section 85, Discovery Health Submission.

pharmaceutical manufacturers have become price takers, because irrespective of the SEP pricing system the administrators set benchmark prices for medicines to be on the respective formularies failing which manufacturers may lose their listing.

Exploitation of Logistic Fees

44. The allegation is made by Transpharm that the logistics fee is being exploited by pharmaceutical companies, and that it should therefore be a fixed fee. This matter is currently regulated by the 2005 Pricing Regulations, and these have been interpreted by the Constitutional Court in the New Clicks matter[11].

45. Firstly, transparency in the logistics fee is required by regulation 21(2)(d). Secondly, regulation 5(2)(f) states that the manufacturer and logistics provider must agree a fee; and, thirdly that under regulation 5(2)(g) a cap on the logistics fee (as opposed to a fixed fee).[12] Even if a cap were to be determined, it would still be possible for companies to agree to logistics fees below that cap.

46. These aspects were ruled on as follows by the Constitutional Court:

"[298] A logistics fee determined by agreement between the parties to the transaction is a fee determined by market conditions between parties free to bargain with one another, and whose interests do not coincide in all material respects. That is an appropriate fee, bearing in mind the provision for the fee to be capped if that should be necessary in the public interest."

47. There have been instances where the variations between the ex-manufacturer-logistics fee split year-on-year have been queried by the Department of Health, showing the de facto control being exercised by the Department in this regard. This is often done when price increases, or price reductions are taken in terms of regulations 7 and 8 of Section 22G of Act 101. The regulations permits a free market system in this part of the supply chain, even where there would be a cap, and, bar the existence of market power and proven competition

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[11] Minister of Health and Another v New Clicks South Africa (Pty) Ltd and Others (CCT 59/2004) [2005] ZACC 14; 2006 (8) BCLR 872 (CC); 2006 (2) SA 311 (CC) (30 September 2005)

[12] (*g*) The Minister, on the recommendation of the Pricing Committee, must determine a maximum logistics fee where, in the opinion of the Minister, such a determination is necessary to promote or protect the interests of the public in—
(i) ensuring reasonable access to affordable medicines;
(ii) the realization of the constitutional right of access to health care services contemplated in Section 27 of the Constitution;
(iii) the efficient and effective distribution of medicines and Scheduled substances throughout the Republic.

law violations in that regard, there should be no competition law objections against this system.

PARITY OF PRICING BETWEEN PUBLIC AND PRIVATE SECTORS

48. A number of parties[13] call for pricing in the private sector to mirror that in the public sector or that public sector pricing constitute a factor in determining SEP or that state tender prices should be accessed by medical schemes for serious illnesses.

49. The SEP system dictates that all sales in the private sector must be at the SEP, irrespective of volume or channel. Thus the call for State sector pricing to be offered for PMB usage is inappropriate, as it means that the lower price would have to be offered to all customers in the private sector i.e. a general decrease in the SEP.

50. In order to emphasize the disparity between public and private sector prices for medicines one party[14] selectively cites 12 medicines as an example while another selectively cites 9 medicines[15]. It will be appreciated by the panel that a proper comparison should be based on a comprehensive or representative sample of products, appropriately weighted, following standard index number methods. For example, one of the former members of the PTG, known as PIASA, conducted a study of the prices at which state sector tenders were awarded to products identified in the eighteen largest tenders for the 2012 tender awards. In this study 1473 line items were identified, which although not the total for all tenders, shows the large number of line items purchased by the state. Examples raised by stakeholders that are not truly representative of the position and are based on a small selection of data should not be accorded any weight.

51. Returning to the call for public / private sector pricing parity, the PTG reiterates that it is wholly inappropriate to refer to public sector pricing in determining the price of a medicine in the private sector.

[13] See Discovery Health submission, 136 to 137. See Mediclinic submission at page 170 and note that the 27% referred to in paragraph 4.21.5.3. is misleading in that only 1.3 of the 27% hospital bill constitutes medicines.
[14] See submission by Transpharm and MediRite at page 4 and Annexure E thereto.
[15] See Discovery Health submission, table 3-10; page 137.

52. The legal frameworks under which products find their way into the public and private systems are significantly different. In the private sector, the SEP system is combined with a system of cost-effectiveness motivations to medical schemes and tender-type submissions to private hospitals. Procurement in the public sector rests solely with the systems created under the PFMA, but is effectively under the control of the National Department of Health. It has also become customary that bidders are invited after the closing of bids to discuss and further lower their prices.

53. Furthermore, pharmaceutical companies in South Africa base their business on the sales they can achieve in the private sector which potential market is based on less than 20% of the total population. The sales to the private sector must cover both the variable and fixed costs for the company to remain in business. State tender business is neither consistent not guaranteed, considering that new tenders are called for approximately every two years.

54. Therefore, State sector business is approached from a marginal income point of view. It is a fact that State tender pricing is usually below that of the private market and this varies according to a number of factors including volume called for. The additional State business has only to cover variable costs and provided that there is spare production capacity, can be offered at lower prices. This differential pricing is permitted by the transparent pricing regulations, allowing the state to gain an advantage for the huge volumes that it purchases.

55. Large volume State sector business is also a contributor to absorption of manufacturing overheads. Due to the majority of the population that it serves, the State volumes of a restricted range of medicines is substantially more than the private sector, as indicated in the published tender requirements. Basic business dictates that a monopsonistic purchaser (single or only purchaser in this segment) will command lower prices for very large contracted volumes. If a company were to sell all products at the same price – sell private sector products at the tender price - the foundation of financial return achieved in the private sector would be non-existent, putting companies out of business.

56. Also, it must be recalled that there is a social commitment on the part of the pharmaceutical industry to supply the state sector, (which is the regulator, the biggest provider of healthcare in South Africa and purchaser and supplier of medicines), with medicines at competitive prices, at cost or below cost, when required. Further, not all manufacturers supply the State with medicines, for various reasons such as simply not having an appropriate product

portfolio. In the light of such a call for universal application of State sector prices in the private sector, this means that only some manufacturers would be required to sell products at these low prices as others would not have a State sector contract and thus no State sector price benchmark, being a non-participant in the supply to the State sector.

57. There is yet a further factor to consider. Apart from the types of products available in the public sector due to the different emphases (primary care versus hospital-based care), the supply chain differs significantly. In the private sector the manufacturer pays for all logistics costs to the patient. The funder of the product could be either the patient, a medical scheme, the Road Accident Fund, the Compensation Commission or an occupational health clinic, for example. There is only one funder in the public sector, viz. the State. Payment is made via provincial treasuries and dependent on provincial budgets and availability, which also adds another dynamic to the supply chain complexities of doing business with the State. Nonetheless, pharmaceutical companies remain committed to doing business with the State.

58. It is unfortunate that submission have indeed made the public / private comparisons, and on a seemingly ad hoc basis.

59. Incidentally, the PTG sees no evidence in any of the submissions made by the hospitals that hospital groups offer spare capacity to the State at reduced prices. By parity of reasoning this should apply to the hospital groups however presumably it is not addressed in order to avoid debate thereon.

PRICING IN THE CONTEXT OF INTERNATIONAL BENCHMARKING

60. The PTG submits that the comparison of the price of drugs to other countries[16] is academic given the advent of international benchmarking later this year.

61. As stated, benchmarking is due to take effect on 05 July 2015.

[16] See Mediclinic submission, pages 168 to 170. The price comparison needs to be contextualized in that it is reflective of but a fraction of medicines available in South Africa. Also, it fails to take into account associated costs with the importation of products into South Africa.

62. Notwithstanding the above the PTG draws the panel's attention to those submissions that have undertaken a direct price on price comparison between medicines in South Africa and other countries. Such comparisons are of little use and do not find economic basis let alone legislative basis. For example, regulation 5(2)(e) of the Pricing Regulations states:

"(e) The Minister on the recommendation of the Pricing Committee must determine and publish in the Gazette a methodology for conforming with international benchmarks, taking into account the price, and factors that influence price, at which the medicine or Scheduled substance, or a medicine or Scheduled substance that is deemed equivalent by the Minister on the recommendation of the Pricing Committee, is sold in other countries in which the prices of medicines and Scheduled substances are regulated and published and the single exit price of each medicine or Scheduled substance must, within 3 months of publication of such methodology in the Gazette conform with international benchmarks in accordance with such methodology".

63. The regulations therefore do not permit a straight price-to-price comparison, it requires the factors that influence price, to be given due consideration. One such factor is volume of sales, another is whether a product is still under patent protection, or subject to generic competition in a comparator-market.

64. Many of these factors have been canvassed by the pharmaceutical sector in a number of submissions relating to the implementation of regulation 5(2)(e). Furthermore, a fluctuating currency, in benchmarking mock-up studies, has previously proven to be the determining factor in price comparisons. In addition, country-specific factors, such as unprecedented unemployment rates in Spain or the absence of innovator products in New Zealand, also impacts on these types of assessments.

65. The PTG notes Mediclinic's statement that out of a basket of 76 medicines, said medicines are cheaper in Switzerland[17]. The PTG wishes to point out that the healthcare system in Switzerland is not comparable to South Africa's private sector nor is it one of the benchmark countries selected for the benchmarking regulations. In fact, it is a recurring theme that South African private sector medicine prices are compared to Public Health Insurance Plans in other countries which markets are regulated. Such comparisons are inappropriate.

[17] Paragraph 4.21.5.2. of Mediclinic's submission, page 167.

PRICING BETWEEN INNOVATOR AND GENERIC MEDICINES

Paragraphs 66 to 70 that follow below this heading are those of the National Association of Pharmaceutical Manufacturers, supported by PharmiSA, and not a general submission of the PTG or its other constituent members. The latter is a voluntary, non-profit organisation consisting of South African and Generics based pharmaceutical manufacturers and distributors.

66. Discovery Health asserts that the price of generic medicines in the United Kingdom is lower than in South Africa[18]. Without stating the bases for this claim, the comparison is not valid and no meaningful comment can be made in respect thereof, for example the Discovery comparison excludes the South African public market, thereby creating significant distortion of the facts.

67. Discovery Health also states that the gap between the generic equivalent and the innovator medicine prices are much narrower than in other countries such as the USA, UK, India etc[19].

68. It should be considered that in South Africa there is a private market and a state sector or public market. With no detail behind the accusations made, we would assume that the comparison is being made between the private sector pricing in South Africa and prices enjoyed by national health or government purchasers in other markets.

69. If that is the case, the public sector price of the generic versus the originator or aggregated pricing in the private and public markets of the generic versus the originator, might give a different result, showing a much larger gap.

70. In the USA, the first generic product to launch is given 180 days exclusivity. Thereafter competitors can come to market. However the competitors enter the market en masse, thus driving prices down. In other jurisdictions the level of competition in marketing generic medicines is intense. Through mainly the slow registration process in South Africa, which often takes more than five years, generic competitors dribble onto the market over an

[18] See Discovery Health Submission at paragraph 3.4.1.3.
[19] See Discovery Health Submission at paragraph 3.4.1.4.

extended time period. Also the low potential volumes detract from the market attractiveness for large numbers of competitors.

PRESCRIBED MINIMUM BENEFITS

71. Numerous submissions link the Prescribed Minimum Benefits (PMBs) to the high cost of private healthcare. Although most submissions recognise that the incomplete regulatory framework (i.e. mandating cover, but not mandating membership or not having a risk-equalisation mechanism, the absence of which creates unsustainability in the market, especially since it was the basis upon which the framework was based) is largely to blame, some stakeholders are of the view that limiting the PMBs will address the problem. This limitation can take the form of one of two ways, i.e.:

    (a) Limiting the description of the care to be provided in Annexure A to the PMB regulations by for example excluding certain treatment options from the care to be provided (level of cover limitation); and

    (b) Limiting the number of PMBs, i.e. reducing the 270 DTPs to possible fewer conditions (scope limitation).

72. Some of the submissions disclosed the cost of PMBs. For example, Metropolitan Health states that it costs them, on average, per beneficiary per month for all the schemes (all closed schemes) they administer, R700 per month to cover the PMB package. The CMS Annual Report, 2013, states that the average cost of providing the PMB package per beneficiary per month is R512, 80.

73. Given that the PMBs are the core of what medical schemes must, on all options, fund, i.e. the social security safety net of all medical scheme members, further limiting the scope will lead to an increase in public sector use (exactly what the PMBs intended to avoid[20])

[20] Introduction to the PMB's Annexure A, General Regulations: "The objective of specifying a set of Prescribed Minimum Benefits within these regulations is two-fold:
(i) To avoid incidents where individuals lose their medical scheme cover in the event of serious illness and the consequent risk of unfunded utilisation of public hospitals.
(ii) To encourage improved efficiency in the allocation of Private and Public health care resources."

74. Even if the PMBs are deemed to be expensive, medical schemes have two tools in law (regulation 8, and regulations 15, and 15Aff), to manage the costs associated with the PMBs, viz.:

    (a) DSPs; and

    (b) Managed care tools, including but not limited to case management, disease, management, pre-authorization, formularies, protocols and disease or condition caps. In addition, schemes have chronic disease amounts / limits, reference pricing and other tools to curb the cost of care, as well as requirements that products must pass health economics muster.

75. The above tools are all designed to limit the choice and level of cover to be provided. Pharmaceutical companies are very aware of the success of these interventions – products priced above reference prices are not included in formularies, or blocked from reimbursement systems. Products not funded by major medical schemes are not stocked in all hospital pharmacies.

76. In the view of the PTG, there are therefore sufficient tools for medical schemes to manage the cost of the PMBs. There should be no vagueness in the PMB interpretation, neither in the meaning of regulation 8.

77. What is amiss, apart from the incomplete regulatory reforms, is the statutorily-required two-yearly review of the PMBs. This is to ensure that the list (scope) is still appropriate and also that the level of cover keeps pace with scientific developments, and the way in which evidence-based medicine is applied:

    "The Department of Health recognises that there is constant change in medical practice and available medical technology. It is also aware that this form of regulation is new in South Africa. Consequently, the Department shall monitor the impact, effectiveness and appropriateness of the Prescribed Minimum Benefits provisions. A review shall be conducted at least every two years by the Department that will involve the Council for Medical Schemes, stakeholders, Provincial health departments and consumer representatives. In addition, the review will focus specifically on development of protocols

for the medical management of HIV/AIDS. These reviews shall provide recommendations for the revision of the Regulations and Annexure A on the basis of—

(i) inconsistencies or flaws in the current regulations;
(ii) the cost-effectiveness of health technologies or interventions;
(iii) consistency with developments in health policy; and
(iv) the impact on medical scheme viability and its affordability to Members"

78. This review exercise cannot however, as was proposed in the past, become a "race to the bottom" where there is absolute agreement that all schemes only provide the list of services and goods, and there is no competition in the provision of the PMBs. In the past the members of the PTG regarded this as anti-competitive, and participation was limited in related projects, such as the "Benefit Definition" project.

79. Reducing the PMBs to the "Essential Medicines List", which is primary-care focused, and services a different population segment from medical schemes (mostly free of charge, as reports from Treasury on the income generating activity of the various provinces show and in spite of the existence of a Uniform Patient Fee Schedule), misses the initial point of why the Medical Schemes were required – a social security (insurance) mechanism to cover aspects of care individuals cannot fund out of pocket.

80. The PTG however does support the inclusion of some primary care cover in the PMBs, but not at the risk of reduction of the scope of the PMBs so that patients are unable to fund catastrophic events.

REGULATORY TIMELINES

81. The PTG supports the submissions made by stakeholders concerning the long delays in obtaining regulatory approval for medicines.

82. Lengthy registration timelines have been a challenge for both the industry as well as the Medicines Control Council for a prolonged period of time.[21]

83. The Medicines Amendment Bill which is currently before parliament proposes the formation of a new regulatory agency with a broadened scope of the regulatory oversight which will include several other categories of health products, including medical devices, IVD's, cosmetics and foodstuffs.

84. This broadened scope could potentially exacerbate the situation. This was once again noted in the Parliamentary presentation by the Department of Health (DoH) which estimates the current backlog for medicines registration at approximately 2,900 applications.[22]

85. During October 2014, public hearings were held in parliament regarding the Medicines Amendment Bill during which many key stakeholders from the healthcare sector presented views and recommendations on the Bill. Unfortunately, most of the recommendations made were rejected by the DoH in their responses to the Portfolio Committee.

86. Implementation consequences that will result from the promulgation of the Bill need to be carefully considered so as not to exacerbate the lengthy regulatory timelines that companies experience in getting all medicines registered and in turn making them available on the SA market. This inefficiency has negative consequences both from a public health perspective as well as from a market competition perspective.

87. During 2014, IPASA commissioned a study to investigate the status of outstanding regulatory submissions made by IPASA member companies. Data was provided for 308 outstanding submissions by 19 companies. The results confirm that long delays in the registration process and are exemplified below:

    Minimum and maximum review timelines for outstanding submissions in dataset (review responses do not indicate approval) for the various steps in the review and approval

[21] Parliamentary Monitoring Group. Medicines and related substances amendment bill departmental briefing. 2014; Available at: http://www.pmg.org.za/report/20140903-medicines-and-related-substances-amendment-bill-departmental-briefing.
[21] Parliamentary Monitoring Group. Medicines and related substances amendment bill departmental briefing. 2014; Available at: http://www.pmg.org.za/report/20140903-medicines-and-related-substances-amendment-bill-departmental-briefing. Accessed 09,09, 2014.

process. At the time that the study was concluded all the submissions below were still awaiting approvals at either various or all steps in the review and approval process.

Variable	NCEs (n=109)	Clones (n=99)	Line Extensions (n=66)	New Indications (n=34)
Screening Times (days)	**N=96**	**N=91**	**N=61**	**n/a**
Minimum	1	11	9	
Maximum	1808	272	550	
Pharmaceutical & Analytical (days)	**N=33**	**N=46**	**N=34**	**n/a**
Minimum	223	62	76	-
Maximum	3088	2068	2031	-
Clinical Review Times (days)	**N=33**	**N=53**	**N=30**	**N=11**
Minimum	267	23	122	200
Maximum	3587	3676	2280	3641

INNOVATION, COSTS OF NEW TECHNOLOGY, BIOLOGICALS AND BIOSIMILARS

88. The costs of new technologies (as it relates to pharmaceutical products) have been argued as being a cost driver[23]. Such new technologies and their development must be viewed not only in relation to the R&D spend on the development of such technologies but also in respect of the "best value" method as discussed above and the development of access systems for selecting appropriate patients and providing care instead of systems that serve primarily to restrict access.

89. It is beyond the scope of this submission to deal with the development process for a pharmaceutical product (i.e. from discovery, to clinical trials and finally to market) however several stakeholder submissions[24] have indicated that new technologies drive costs, including indicating that adverse selection plays a major role in medical scheme members accessing high cost biologics.

[23] See for example the Medscheme submission, page 31, which refers to "new technologies" generally.
[24] See for example Discovery Health submission, page 131; Medscheme submission, page 38.

90. More particularly, the funder contention is that new molecules, including biologics and biologicals[25], drive costs to unaffordable and unsustainable levels for the private healthcare sector due to the relatively high cost and small patient populations that are treated with these new molecules. Although allegations are made, there is no evidence that these products have impacted on the overall medicines expenditure, or the overall cost of care in the medical schemes environment.

Smart Medicines (Biologics, Biologicals, Oncology Agents)

91. In a study[26] conducted jointly by manufacturers of biologics over a 5 year period to assess whether biologics were in fact a cost driver in terms of both overall medicines cost as well as overall healthcare costs, the following conclusions were made:

    (a) Biologics (the broad definition) made up 11.8% of total medical spend based on IMS data;

    (b) Biologicals made up 2% of total medicine spent;

92. In order to further provide a substantive quantification of the cost impact of smart medicines on the total medicines market and the private healthcare market as a whole, the following private market study was conducted on 57 “HIGH COST” smart medicines that funder stakeholders have expressed concern about in terms of providing sustainable patient access and funding for going forward. The methodology concerning the data below is set out in Appendix III hereto.

93. The below graphs show that smart medicines, together with high cost cancer drugs, contributed ONLY 4.3% of total medicine costs to the private sector in 2011 as demonstrated below:

[25] Biologics - in its broadest sense, that is any "medicine" that is farmed from a living organism (including humans) or human molecules.
[26] Biologics: The Magic in our Midst, Trends in South Africa: Costs and Usage – A study by Hexor (health economists and outcomes research).

Figure 4

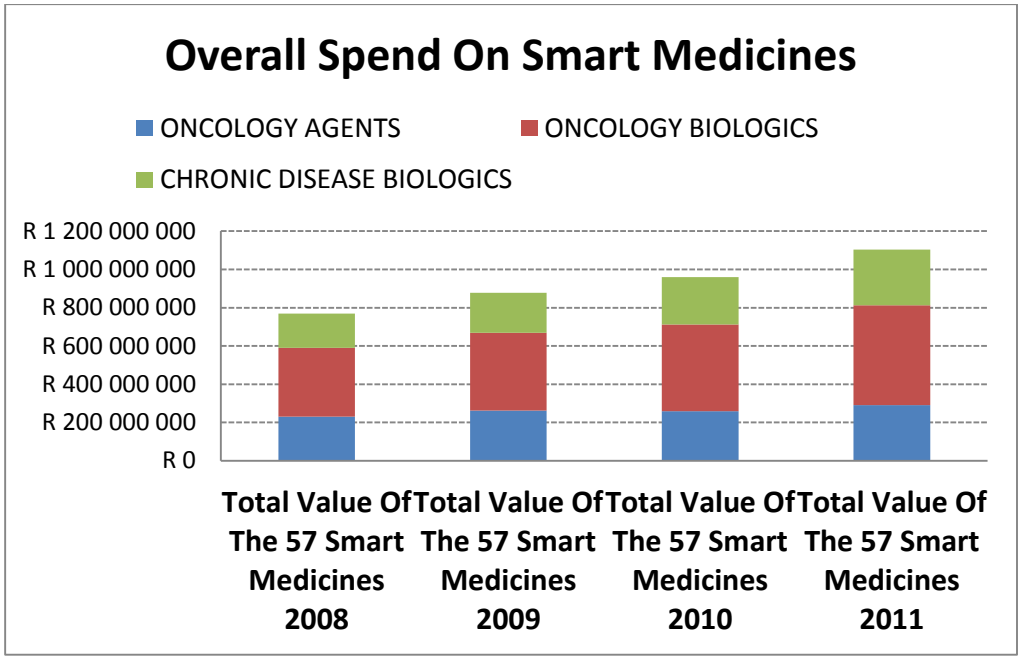
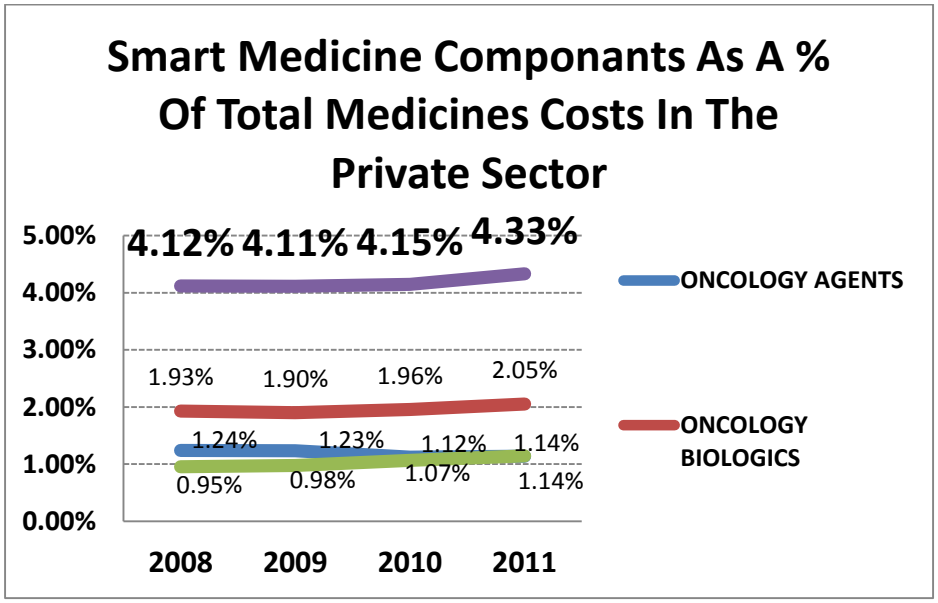
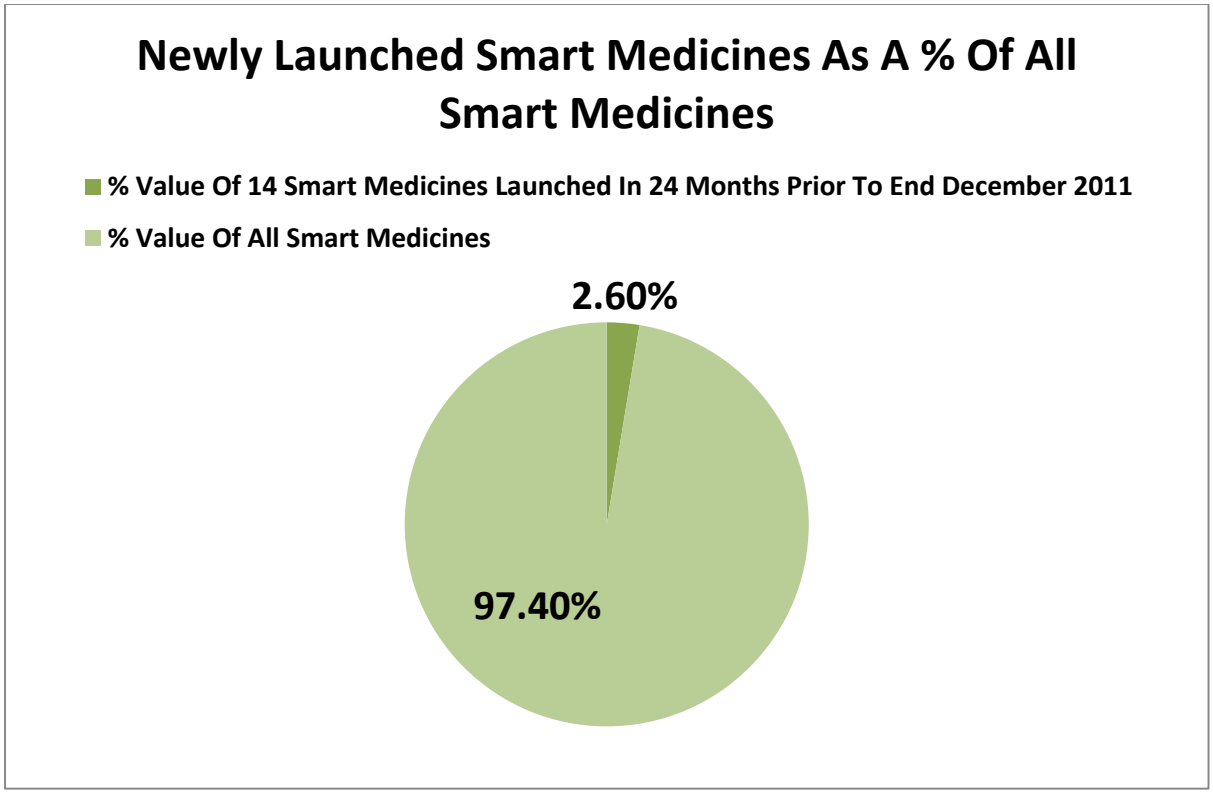


Figure 5



94. The study further looked at the contribution of smart medicines launched into the market in the 24 months prior to the end of 2011:

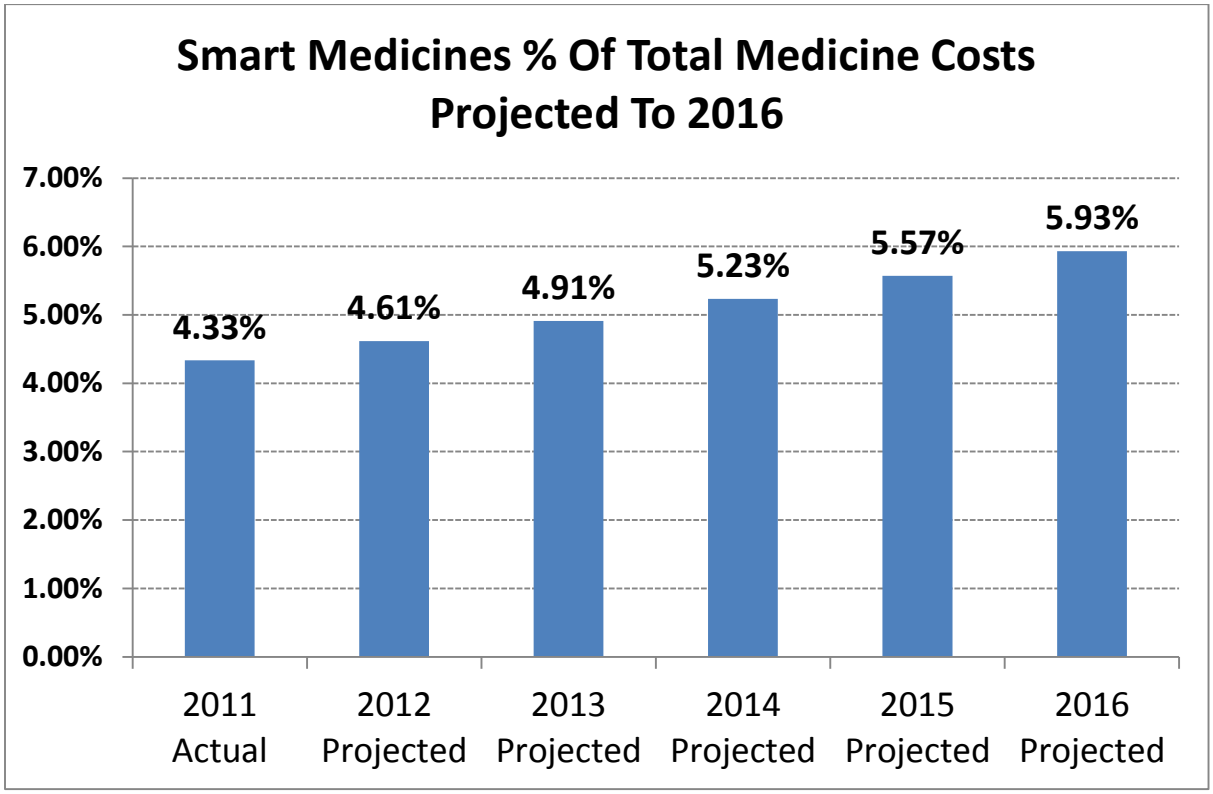
Figure 6



95. The data demonstrated that smart medicines are not a driver of medicines costs in the private sector.

96. The study further projected that the use of the above medicines would contribute only up to 6% of total medicines costs if they continue their growth trajectory into 2016.

Figure 7



97. It is clear therefore that smart medicines are only a small portion of the spend on medicines.

98. Additionally, and although some of the submissions provide extensive information regarding the cost impacts of the use of these class of medicines, there is no information provided about the clinical outcomes as well as the avoidance of potential downstream costs through the use of these medicines.

99. Taking a view based only on cost (diagnosis, medical related costing of procedure, medicines, laboratory costs, etc.) rather than the impact (recovery rates, impact on productivity, quality of life, impact on social grants and therefore burden on the state) of using clinically appropriate therapies to treat in many cases life threatening and potentially debilitating diseases will be a disservice to the very people that the health system should serve and protect. Accordingly, and as previously mentioned, access not only relates to price but the ability of patients to access new medical technology.

100. The panel is reminded that with the advent of new cancer drugs and ARVs, many years ago, such drugs were also labeled as cost drivers. With so many of these drugs now being off patent and subject to generic competition they no longer are. The timeous registration and launch of "biosimilars" will ensure price reductions in biologics and biologicals.

Biosimilar Registration

101. Due to the complexity of a biological molecule, and from a regulatory point of view, a generic manufacturer cannot rely on the dossier and data submitted by an innovator with the aim to obtain registration of a biosimilar product.

102. Contrary to what some parties have submitted, South Africa's regulatory structure does make provision for the registration of biosimilars and has even issued guidelines in respect thereof[27]. The regulatory delay in accepting such applications is part of the systemic issues concerning the processing of applications for medicines and is dealt with elsewhere in this submission.

INTELLECTUAL PROPERTY

103. It is beyond the scope of this submission to deal with all aspects relating to intellectual property and its effect on access to medicines, including the pricing of medicines. As indicated above, this is the subject matter of debate and policy reform at government level.

104. That said, the PTG wishes to contextualize and point out some inaccuracies made by stakeholders in this respect.

[27] See: http://www.mccza.com/genericDocuments/2.30_Biosimilars_Mar2012_v2.pdf.

International Obligations

105. South Africa is a signatory to, and has acceded to, inter alia, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which is an international agreement administered by the World Trade Organization (WTO) that sets down minimum standards for many forms of intellectual property (IP) regulation as applied to nationals of all WTO Members.

106. An important article to note is Art 27.1 which states that patent rights shall be available and enjoyable without discrimination as to the place of invention, the field of technology, and whether products are imported or locally made. (emphasis added)

Substantive Examination

107. Stakeholders refer to the grant of weak patents as a result of South Africa following a deposit system when it comes to filing patent applications[28].

108. The PTG supports substantive examination of patent applications in accordance with TRIPS noting that the application of different standards as to what is patentable or not (e.g. the inclusion of additional requirements for patentability only in respect of certain fields of technology, such as efficacy in the case of pharmaceutical inventions) would contravene TRIPS. The PTG also notes that a substantive examination process should provide for the efficient processing of patent applications without undue delay[29] and is in support of such a process provided that it is properly resourced. Delays as experienced in Brazil would not be acceptable, especially keeping in mind that a pharmaceutical product normally comes onto the market with 5 to 7 years left of the 20 year patent term as a result of clinical trials and delayed regulatory approvals.

109. As already indicated above, substantive examination is a process which will be introduced by CIPC.

[28] Discovery Health Submission, s198 (page xxix); section 3.4.1.2 (pages 131 – 132); p298 and paragraph 850, p325. Bayer's drug Yasmin is given as an example. It must be noted that the patent for Yasmin and its validity was fully ventilated before the Supreme Court of Appeals, which court upheld the patent as being valid (Pharma Dynamics (Proprietary) Limited v Bayer Pharma AG and Another (468/2013) [2014] ZASCA 123; [2014] 4 All SA 302 (SCA) (19 September 2014)..

[29] TRIPS Art 62 requires reasonable procedures, within a reasonable period of time, which are governed by principles of fairness and equity and which are not unnecessarily costly.

Paragraphs 110 to 122 below are not supported by NAPM. NAPM supports the Draft National Policy on Intellectual Policy published by the Department of Trade and Industry in the Government Gazette on 4th September 2013.

110. In order to contextualize the debate concerning "weak patents" the PTG draws the panel's attention to the following:

(a) Notwithstanding a depository system, the system is self-regulating. Under the Patents Act, a patent that is partially valid (i.e. has some claims[30] which are valid and others which are invalid) cannot be enforced[31].

(b) As part of the self-regulatory environment, and especially in the pharmaceutical sector, patents rarely proceed to grant without the claims of the patent being conformed with the claims of a corresponding patent that has undergone substantive examination from an international examining office, such as the United States or European Patent Offices.

(c) If a third party feels that a patent has been wrongly granted, then such party may apply to have the patent removed from the register of patents. This may be done at any time e.g. when the patent holder takes steps to enforce the patent. In some cases, stakeholders take the view that where they believe a patent is invalid, they shall launch a generic product notwithstanding the existence of a patent.

Number of Patents Granted

111. The contention that South Africa grants more patents than some other countries[32] needs to be contextualized.

112. First, it must be recognized that Brazil and India are late starters concerning the introduction of patentability for pharmaceutical products, both recognizing the need to provide intellectual property protection for such inventions. Whereas South African patent law

[30] The claims of a patent define the scope of exclusivity offered by the patent.
[31] Section 68 of the Patents Act
[32] See for example Discovery Health submission, paragraph 346 to 347, page 132.

provided for pharmaceutical patents at least since 1952, countries like Brazil and India only became obliged to provide such protection in 2005, after the prolonged transitional period as stipulated in TRIPS Art 65.4 and 70.8. In Brazil, in particular, the current delay in examination is 3 to 6 years and having commenced examination in 2008 one can expect low numbers emanating therefrom while the patent office catches up with examination.

113. Second, it must be recognized that not every patent covers a product that is commercially exploitable. Quite the opposite in fact. It is therefore necessary to consider the number of patents, out of those granted, that cover actual products on the market. It is also necessary to consider the number of off patent substitutable products in the same therapeutic class.

114. Third, it must be taken into account that of those patents granted a large number are allowed to lapse, especially when it becomes clear that the invention covered by the patent will not make it to a commercially viable product. Analysis of statistics from the CIPC shows that in year 8 +/- only 40% of granted patents are maintained, 20% by year 15 and less than 10% in the last year.

115. When one views this with the fact that on the WHO list of essential medicines less than 1.4% of such medicines remain patented and one factors in substitutability, the effect of patents on access is small.

Access in the Intellectual Property Space

116. The Supreme Court of Appeal has stated that "denying the public access to a generic medicine during the lifetime of a patent is the ordinary consequence of patent protection…[33]". The right to exclusivity is set out in Section 45 of the Patents Act[34], however Patentees usually apply this in a responsible manner that does not deprive the public of access, but still assert their rights to benefit from their Invention.

117. This notwithstanding, and in the context of determining whether a preliminary injunction should be granted in preventing a generic manufacturer from launching product in the market during the existence of a patent, it is now necessary to consider the public interest

[33] Cipla Medpro (Pty) Ltd v Aventis Pharma SA, Aventis Pharma SA and Others v Cipla Life Sciences (Pty) Ltd and Others (139/2012, 138/2012) [2012] ZASCA 108; 2013 (4) SA 579 (SCA) (26 July 2012).

[34] "The effect of a patent shall be to grant to the patentee in the Republic, subject to the provisions of [the Patents] Act, for the duration of the patent, the right to exclude other persons from making, using, exercising, disposing or offering to dispose of, or importing the invention, so that he or she shall have and enjoy the whole profit and advantage accruing by reason of the invention."

in granting such an interdict[35]. In considering public interest it will be necessary to consider the degree of substitutability between the patented products and other products in the same therapeutic class, whether the public sector is adequately supplied and the price of the patented product.

118. Finally, the panel's attention is drawn to the statement, trite as it may seem, that there is no linear relationship between the pricing of a patented product nor is there such a relationship to access, as should appear from what has been said herein before.

"Ever Greening"

119. The statements made by stakeholders concerning "ever greening"[36] need to be contextualized.

120. The term "ever greening" is raised in respect of those pharmaceutical patents that relate to incremental innovations over the basic molecule or compound or process for a pharmaceutical product and its manufacture. These relate to new crystalline forms, advances based upon an existing process and new formulations as well as new indications.

121. Incremental innovation can improve the safety, therapeutic effect or method of delivery of an existing medicine or vaccine, or improve the efficiency with which it can be manufactured, with positive outcomes for public health[37]. Further, most innovation is incremental by nature since technology normally progresses in incremental steps[38].

122. Insofar as the patentability of such incremental inventions is concerned, the PTG submits that the normal requirements for patentability as currently in force, particularly the requirement of an inventive step (defined as being not obvious to a person skilled in the art having regard to the prior art), adequately address whether such inventions are patentable or not. It also submits that to apply additional patentability requirements, such as proving

[35] See Cipla Medpro (Pty) Ltd v Aventis Pharma SAm [2012] ZASCA 108.
[36] See for example Discovery Health submission, paragraph 348, page 132.
[37] Promoting Access to Medical Technologies and Innovation, Intersections between public health, intellectual property and trade, WTO, WIPO, WHO 2013, page 130. https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf
[38] Promoting Access to Medical Technologies and Innovation, Intersections between public health, intellectual property and trade, WTO, WIPO, WHO 2013, page 131.

additional clinical efficacy, irrespective of whether this is before the patent office or a regulatory body, would be in conflict with TRIPS, particularly Art 27.1.

PARALLEL IMPORTATION

123. Some of the parties in their submissions call for the ability to parallel import medicines[39].

124. Parallel importation is the importation into South Africa by a person other than the patent holder, and without the express authorisation of the patent holder, of a genuine product that is subject to patent rights in South Africa. Parallel importation thus means the importation into South Africa of a genuine product obtained by a third person in another country from a legitimate source, but without the authority of the patent holder to import.

125. In practice, the main motivation for parallel importation on the part of the parallel importer is to benefit from price differentials in two countries or more. Manufacturing costs in some countries are lower than in others, as a result, the selling price in the country with lower manufacturing costs may be lower than that charged in countries with higher manufacturing costs. The objective with parallel importation is often a profit motive, whereby the importer exploits the price differentials aims to derive his/her profit. The importer does not aim to make more affordable products available to the people in the country of importation, but mainly to gain in the infrastructure and market created by the Patent Holder in the country of Importation.

126. A regulatory framework for parallel importation already exists in the form of Section 15(C) of the Medicines and Related Substances Act 101 of 1965[40].

127. Further, the issue of parallel importation of medicines, and its expansion beyond Section 15(C) of the Medicines and Related Substances Act, has been raised and commented upon in the context of the IP Policy[41].

[39] See Netcare Overview Paper, page 52.
[40] Guidelines for the importation of medicinal products by way of parallel importation have also been issued by the then Medicine Control Council.
[41] For a full consideration of parallel importation and compulsory licensing see the submission made by IPASA concerning the IP Policy at http://ipasa.co.za/wp-content/uploads/2013/07/Copy-of-IPASA-submission-on-the-draft-national-policy-on-IP-final-131016.pdf.

128. The PTG submits that expanding South Africa's parallel importation of pharmaceutical products would pose clear 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 authorised importer is broken. Without that link, counterfeit and/or poor-quality goods enter the drug supply lines more easily. Patients often cannot distinguish counterfeit or sub-standard pharmaceutical products from genuine products. Moreover, in the case of product withdrawal or recall, the manufacturer may not be able to identify parallel importers and alert them of recall decisions.

129. Also, in situations where adverse events are experienced on products Imported by parallel Importers, the responsibility tend to shift to the Patent Holder, wherein the Patent Holder may be expected to record Adverse events of possible Counterfeits as though they were caused by the Patent Holder's brand, to the detriment of the Patent Holder's product and the patients.

CONCLUSION

130. In light of the arguments advanced in PTG's submission it is clear that the pharmaceutical sector is but a small component of the wider healthcare market. It is a highly regulated sector in a changing regulatory and intellectual property landscape where current regulatory interventions will lead to further price savings for consumers, and therefore we believe the medicines sector should not be the core focus of the Panels inquiry nor should it generate a parallel Panel inquiry.

131. The majority of submissions submitted by stakeholders appear to address broader policy issues. Of those submissions that speak to the pricing of medicines, it must be recalled that pricing is but one component of access to medicines and due regard must be had to the right of patients to access new and innovative products too. Also, the other components affecting access need to be factored in.

132. It is clear from the submissions made herein that a price centric view of medicines is a short sighted view which ignores patient outcomes and cost offsets. This is particularly important with regard to biologics and biological medicines, which have been shown, herein, to be a

small component of the price of medicines and which are not driving costs in excess of healthcare inflation.

133. As for SEP, it is the PTG's submission that it has contained costs of medicines and that in an environment where some medical schemes and hospital groups have market power they are able to act as an effective restraint on the pricing of medicines. Notwithstanding the allegations made by stakeholders that the price of medicines are too high, such comments have been made absent a proper consideration of dominance and the economic value of a medicine. It will also be clear that the pricing of medicines will also be affected by the introduction of international bench marking rendering most of the price comparisons by stakeholders with medicines overseas moot.

134. The call for SEP prices to be adjusted to the prices of medicines in the public sector is, with respect, an unworkable one having regard to the fact that not all medicines are offered in the public sector, some pharmaceutical manufacturers do not supply the public sector at all and, importantly, the market dynamics in the one sector are markedly different from the other. With the public sector not being part of the healthcare enquiry, the call for public / private sector pricing parity is not meaningful.

135. Insofar as PMBs are concerned, it is PTG's submission that stakeholders have the necessary tools to manage such costs and that PMBs should be viewed in the context in which they were introduced - a social security (insurance) mechanism to cover aspects of care individuals cannot fund out of pocket.

136. In terms of the state of regulation in South Africa, the PTG supports the stakeholders that call for a quicker and more efficient medicine approval process. This will have a direct impact upon competition in the market, especially in respect of allowing patients to access new drugs more quickly and allowing generics to come onto market once a medicine is off patent.

137. From an intellectual property point of view, the submissions made by stakeholders concerning substantive examination of patents falls within the scope of the IP Policy, which is shortly to be approved by Parliament. Further, substantive examination is being introduced by CIPC and is supported by the PTG provided there is compliance with TRIPS and related agreements.

138. Finally, and insofar as the call by some stakeholders to be allowed to parallel import medicines, the PTG cautions there against having regard to issues such as quality control and counterfeiting, all of which negatively affect the patient ultimately.

139. The PTG welcomes any questions the Panel may have for it and will most likely be participating in the public hearings where it will expand on some of the issues herein to the extent necessary.