Johnson & Johnson

WORLDWIDE GOVERNMENT AFFAIRS & POLICY

Competition Commission Inquiry:
Reply to submissions made
5 March 2015

1 Executive Summary

1.1. This submission is limited to responses to key stakeholder submissions in relation to issues raised regarding pharmaceuticals, medical devices and diagnostics.

1.2. Insofar as medicines are concerned –

1.2.1. Information is provided to the use of section 21 licences to make medicines available.

1.2.2. We address public sector medicines access, and the differences in the markets between the public and private sectors.

1.2.3. Cost-containment in medicines is discussed with specific reference to Janssen products, which have been named by other stakeholders in the Inquiry.

1.2.4. We illustrate the impact of the medicines price regulatory regime, as compared to CPI and exchange rate changes, including our SEPs for new products and the proposed international benchmark pricing method.

1.2.5. We briefly address the matter of therapeutic substitution, mooted by some as a solution to medicines expenditure.

1.2.6. Lastly we briefly touch on the necessity to do some further work on risk-sharing models.

1.3. In terms of our Medical Devices, we discuss products and pricing in relation to -

1.3.1. Orthopaedics, a field where many submissions are alleging expenditure increases in total costs and in prostheses costs.

1.3.2. Lifescan, in relation to allegations of price differentiation in consumables used with glucometers.

1.3.3. J&J Medical, where we provide information related to allegations on the costs of consumables. We also explain the processes to access hospital markets, and the processes that precede such access, and which is under the control of funders.

1.4. We make some brief remarks on patents, and allegations extracted by stakeholders from the Fix the Patents campaign.

1.5. Last, increases in utilisation, identified by most stakeholders as a cost driver, is responded to, as well as appropriate use, which goes hand in hand with interrogation of utilisation, viz. are procedures, products and treatments correctly used, for the correct patients?

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2 Introduction to Johnson & Johnson, South Africa

Johnson & Johnson has provided details on our footprint within the South African healthcare sector in its October 2014-submission to the Inquiry. This submission is made as a group of entities comprising pharmaceuticals (Janssen Pharmaceutica), medical devices [Johnson & Johnson Medical, DePuy Synthes] and its glucometer / diabetes business (Lifescan).

Submissions by other stakeholders have either mentioned products of the above entities by name, or have implied activities or pricing in relation to product categories that merit a response. J&J remains committed to assist the Panel with information on this industry and its experiences as a company. Its cross sector position covering pharmaceuticals, devices (consumables, equipment and implants) as well as consumer goods makes it a unique contributor with a good understanding of the total healthcare and health consumer markets.

3 Medicines

As a follow-up to the initial submissions by Johnson & Johnson in response to submissions made by other stakeholders, Janssen Pharmaceutica (Pty) Ltd (Janssen), as part of the J&J Group, wishes to provide additional information in order to lend context to some of the content included (as claims) in various submissions. Both access and cost-containment (including pricing), will be discussed below.

3.1 Ensuring patient access to medicine

3.1.1 Medicine registration and section 21

It is stated in the submissions that section 21's (i.e. the license to provide a medicine to the market whilst it has not gone through the formal registration processes yet) are abused. The reason for increased utilization of section 21's (which medical schemes cannot, by law be obliged to fund under the provisions of the Regulations to the Medical Schemes Act), relates to regulatory delays. These regulatory delays also have a direct impact on the effective product and market life in South Africa, which is significantly shorter than in other countries. It includes countries with which products are being compared by stakeholders, who therefore do not take into account the effect of regulatory differences between countries.

It is a fact that medicine registration timelines in South Africa are long. The table below outlines Janssen medicine registration timelines, for new medicines introduced in the last 5 years (2010-2014) in key therapeutic areas:

Therapeutic Area	Number of Products	Average Registration Time (months)	Registration Time Range (months)
Oncology	3	44	36+ - 60
Immunology	2	54	49 - 60
Neurosciences (pain & psychiatry)	2	43	36 - 51
Anti-infectives	1	22	n/a

The long local registration timelines for medicines invariably mean that:

- new medicines are only registered for use in South Africa more than 3 years after they become available for use in other markets
- heath care professional (HCP), and patient, access to new treatment alternatives is delayed/denied during the lengthy process

To lessen the impact of lengthy medicine registration timelines on access to treatment, HCP's are making use of section 21 (use of unregistered medicines) via either of two processes:

- clinical trial, where product is provided free of charge
- named patient basis (NPB) , where product may be sold to the patient

The local regulatory authority, the Medicines Control Council (MCC), only approves section 21 via NPB once a benchmark regulatory country has already approved the medicine. It is Janssen's policy to make medicines available, on section 21 NPB, only once an application for registration in South Africa has been submitted – it is important to note that at this stage there is at least one benchmark regulatory country approval.

Janssen has made oncology and immunology medicines available to patients in the Private sector via section 21 NPB. These patients did not qualify for inclusion in a clinical trial and had exhausted other treatment options. In most cases, patients paid for treatment with a medical insurer sometimes covering part of the cost.

Very few medicines are approved for use by the MCC, on a section 21 NPB, with only Phase II clinical trial data being available. The Janssen medicine, SIRTURO®, used in the treatment of MDR-TB (a government priority) was made available, free of charge to 200 patients in the Public sector, through an access protocol (not section 21 NPB) approved by the MCC Clinical Trials Unit.

3.1.2 Public sector medicine access

The public sector acquires medicines by means of a well characterized tender/contract system and process(es), built around specific predetermined product requirements and stipulated volumes, and are therefore priced accordingly.

The medicines procured via public sector tenders (developed on the basis of the Essential Medicines List) invariably have generic alternatives available. In the case of medicines required to address public/population health care need e.g. HIV, volumes are almost always higher in the public sector, as demonstrated in the table below (for Janssen's product DAKTARIN® Oral Gel, on tender for the past 5 years):

DAKTARIN® Oral Gel	
Year	**Public sector volume (as a factor of Private sector volume)**
2010	2.5x
2011	2.5x
2012	2.1x
2013	2.2x
2014	2.1x

The research such as that presented by hospitals to explain why private hospital costs, and public hospital costs cannot simply be compared "as is" is as relevant for the pharmaceutical sector. Ramjee in her work *Comparing the cost of hospitalization across the public and private sectors in South Africa*. In the addition, the concepts of "tiered pricing" (a commercial practice of systematically setting prices differently in different segments of the market with uneven buying power), and "equity pricing" (is a welfare economics and social development driven pricing mechanism intended to lower financial barriers to product access) are valuable tools to explore.

In responding to invitations to bid, companies have to address factors such as the available funding levels in the market being targeted, affordability (income distribution), health care coverage (insured vs uninsured, provincial and national budget sizes and spending priorities), volume, supply chains and/or health provisioning channel (publicly vs privately funded). Companies have to respond to these when pricing products for the South African public sector.

The desire by some stakeholders to access medicines at public sector tender prices will not have the desired effect, as most medicines required to implement even the most basic form of the PMBs, are not available in the public sector.

3.2 Cost Containment (including pricing)

3.2.1 Market and economic considerations

Pharmaceutical prices in South Africa's private sector are already regulated by (transparent) Single Exit Pricing (SEP) legislation, in place since early 2000's. The annual Council for Medical Schemes (CMS) Reports show the immediate impact of the price regulatory system since the pricing regulations were under discussion as drafts (2001 – 2003), and the impact of its implementation in 2004 and into 2005.

In addition, the last three (most recent) CMS reports covering the years 2011, 2012 and 2013, show that while beneficiaries have increased and more expensive medicines have been reimbursed, medicine claims (as a % of total benefits paid) remain fairly constant, at 16%, in spite of the widely reported impact of demographics (age, disease burden increases and adverse selection) by other stakeholders who all claim their above-CPI increases are related to these factors - see table below:

Year	Total beneficiaries	Weighted average gross contribution increase (%)	Total benefits paid (R bn)	Medicine claims (as % total benefits)
2011/12	8 526 409	8.9%	93.2	16.3%
2012/13	8 679 473	9.7%	103.3	15.8%
2013/14	8 776 279	8.9%	112.3	16.0%

SEP legislation makes provision for an annual Single Exit Price increase (SEPI), where the law allows for pro-competitive strategies in that an increase (up to that year's maximum SEP), can be taken at any stage during the year, but no more than once a quarter. However, as can be seen in the table below, the extent of this adjustment has not effectively covered the impact of inflation and exchange rate deterioration (Rate of Exchange, "RoE) on operating costs over the last 5 years:

Year	DoH SEPI (%)	Effective date	Effective SEPI (%)*	CPI (%)	Ave RoE (USD)	Ave RoE (Euro)
2010	7.4%	20 May	4.6%	4.3%	7.3215	9.7072
2011	0%	n/a	0%	5.0%	7.2602	10.0902
2012	2.14%	8 March	1.7%	5.6%	8.2166	10.5525
2013	5.8%	10 May	3.7%	5.7%	9.6493	12.8218
2014	5.82%	28 March	4.4%	6.1%	10.8475	14.4015

*Does not reflect the fact that maximum allowable price increase was not taken on all products/SKU's. This would further reduce the effective SEPI %

3.2.2 The SEP and Janssen medicines

Janssen wants to continue to play a role in an environment that appreciates and rewards the investments that it makes as a research-based pharmaceutical company. Three core principles therefore guide the approach to medicine pricing:

- sound business model → allow continued investment in R&D
- reflect value level of innovation → improved Quality of Life
- affordable access, that is robust/sustainable, transparent and legitimate

Pharmaceutical pricing should take into consideration economic conditions e.g. World Bank categorization, the structure of the health care delivery system and specific patient population(s) e.g. personalized medicine, highly specialized medicines, public/population health or diseases of the developing world (incl. neglected tropical diseases) and rare diseases. The development of a new pharmaceutical product is expensive and risky. The price of a drug is much higher than the mere cost

of manufacture since innovation (incl. R&D) accounts for most of the cost of production. In order to encourage/sustain investment in R&D, drug prices need to reward innovation and value (including value to the patient). Price is just one element in the complex healthcare debate, and not necessarily the most important one when it comes to efficacy and outcomes. New medicines can generate savings by reducing costs in other areas of healthcare such as the number of hospital stays or the degree of disability.

Janssen's approach to pricing focuses on securing appropriate access to its medicines for patients around the world, at a price justified by the therapeutic value and quality of life they deliver. In addition, in-country pricing takes into consideration the ability of citizens (incl. payers) to pay, and bear a fair share of the global recovery of drug development (and other) costs.

Due care needs to be taken when comparing medicine acquisition prices across markets, keeping in mind the nature/structure of the healthcare delivery system i.e. how it is funded and where patients are treated, how care is delivered and specifics regarding market dynamics, including whether there are national- and/or social health insurance systems in place, a private sector, a price regulatory, price negotiation or pricing trade-off system (e.g. whether more expensive medicines are provided at a higher price to funding entities, whereas discounts are provided for more widely-used products), etc.

There are mechanisms, other than price (comparison), that support cost-containment, including the availability of generics. The Medical Schemes Act and its regulations provide various mechanisms schemes can, and effectively do, use to contain medicines costs. These include the setting of specific benefits, benefit limits or caps and exclusion lists. It also permits the use of formularies and treatment protocols that limit both PMB and non-PMB care, and requirements of the filing and approval of treatment plans, in particular in fields where biologics or other high-tech medicines are used, such as in oncology and rheumatology and other auto-immune diseases.

The table below considers the new medicines that Janssen has had registered locally in the last 5 years (2010-2014), and using proposed DoH International Benchmarking Pricing (IBP) methodology compares local prices with those in suggested IBP comparator markets (Australia, Canada, New Zealand and Spain). In spite of not having adjusted for unique country factors (as regulation 5(2)(e) requires), Janssen prices compares very favourably with prices in the DoH's benchmark countries:

Therapeutic Area	**Scheduling**	**SKU's**	**% SKU with SA price below average**	**% SKU price points with SA price lowest**
Oncology	S4/S5	2	100%	100%
Immunology	S4	3	100%	100%
Neurosciences	S5/S6	10	80%	70%
Anti-infectives	S4	1	100%	100%

These data suggest that the most recently registered Janssen medicines, including biologics, are appropriately priced for the South African market. In addition, comparison (in accordance with proposed IBP methodology) of local ex-manufacturer prices for 2 oncology products i.e. 3 SKU's, with the UK – as was outlined in one administrator submission – shows the South African prices to be the lowest across all SKU's.

There are elements of the current proposed international benchmark pricing methodology for medicines, when it comes to determining individual SKU prices, that may cause some distortion (both locally, and relative to comparator markets) e.g. current requirement for pricing of specific product SKU's having the same concentration. The result is that prices may not be properly compared, but since Private sector medicine prices are already regulated, resolution of such inconsistencies is probably best left to an open consultation process between industry and the Department of Health.

3.3 Therapeutic substitution

It has been suggested that South Africa should permit therapeutic substitution as a mechanism to contain costs. Care should be taken with this practice, as the products substituted must be equivalent in its effect, but also in its side-effect profile. Although not permitted under the Medicines and Related Substances Act (only generic substitution is permitted), some medical schemes used this as a mechanism to differentiate on the basis of price. One example is MediKredit's Maximum Medical Aid Prices (MMAP).

The literature[1] suggests a more cautious approach may be appropriate given that while all health care systems are under economic pressure to minimize costs and generate savings, this should not come at the cost of patient care, and there is limited robust evidence to support therapeutic equivalence, with variation on how equivalence/bioequivalence is measured being a concern. Special patient populations, toxic drug, biologics etc. require a cautious review. It is also clear that there is not necessarily a way of easily measuring the cost saving achieved from therapeutic substitution i.e. drug acquisition cost versus patient outcome. In addition, the ultimate responsibility/accountability for any negative effect(s) resulting from therapeutic substitution needs to be agreed.

Thus, given that private sector medicine prices are already regulated (with further regulation likely to follow), it's not necessary to consider a potentially risky intervention like therapeutic substitution.

[1] Policy Statement: International Pharmaceutical Federation (Fédération internationale pharmaceutique), PHARMACIST'S AUTHORITY IN PRODUCT SELECTION THERAPEUTIC INTERCHANGE AND GENERIC SUBSTITUTION, Council of the International Pharmaceutical Federation (FIP) at its Council meeting in Vancouver on 5 September 1997; Johnston, A, et al. 2011. Generic and therapeutic substitution: a viewpoint on achieving best practice in Europe. British Journal of Clinical Pharmacology. 72:5. 727-730; Duerden M G and Hughes D A. Generic and therapeutic substitutions in the UK: are they a good thing? 2010. British Journal of Clinical Pharmacology, 70:3 335–341; Holmes, RD, et al. 2011. ACCF/AHA 2011 Health Policy Statement on Therapeutic Interchange and Substitution. Journal of the American College of Cardiology. American College of Cardiology Foundation and the American Heart Association, Inc. vol. 58, No. 12, 2011

3.4 Risk-sharing models

Janssen supports the notion that legitimate and fair risk-sharing models be permitted in the South African private sector market between funders and pharmaceutical companies. This would require amendments to the SEP regulations and/or to section 18A of the Medicines and Related Substances Act and it is proposed that this be done in accordance with a legislative framework, so as to avoid it becoming a ruse for unfair competition, price discounts and benefits not accruing to patients, etc.

4 Medical Devices

4.1 Products and Pricing

4.1.1 Orthopaedics

DePuy Synthes is the orthopaedic franchise of J&J. It sells non-commodity items, i.e. custom-made devices that suit the specific clinical needs of a particular patient. An implant comprises a number of items, of different types (e.g. different liners) the costs of which could differ depending on the clinical needs, etc. of the patient. Therefore quotations and invoicing are done on case by case basis, also bearing in mind the specific patient's medical schemes benefits.

More than 41% of our instruments, i.e. the equipment that is necessarily in order to do the implant procedure, e.g. so-called "reamers", are loan sets (i.e. we deliver the instrument sets to the hospital for every case). In the past, hospitals purchased the instrumentation sets and implants that were necessary for surgery. These sets were owned by the hospital and available to surgeons when the need presented itself. With the recent pace of technology, much of that equipment became obsolete before it was used. Surgeons, too, converted to different implants and implant systems, thereby diversifying their practice and the market to a larger extent and in doing so, being more responsive to the specific patient and his/her medical needs. As a result, hospitals decided that they would no longer purchase these products, but invited (i.e. essentially required) manufacturers and their representatives to provide that equipment on a consignment basis. The sales representative was subsequently charged with the task of delivering the instrumentation for each case, and the hospital only paid for what was used.

An important element of the provision of loan sets is the provision of a company representative in the theatre. Due to the ranges of products, and the lack of skilled theatre staff, as well as the Consumer Protection Act obligation in relation to the correct use of products, it has become necessary that a representative advise on the equipment use and the loan set. Providing this service is also necessary in order to stay competitive in the market.

The prices of products offered to the market are influenced by trading conditions, and are subject to significant competition, with at least five major companies operating in this field and a number of smaller distributors, totaling 300 suppliers in the orthopaedic market, according to Medikredit data.

The costs of providing our products to the market include, but are not limited -

- The cost of instrumentation (loan sets) and all aspects related thereto, such as washing, packing and delivering of instruments, transportation (i.e. fuel and vehicle costs, etc.) and freight;
- The cost of representatives (total cost to company) and training costs including but not limited to representative and doctor training, product training, and training required by the private hospital sector;
- Training costs of surgeons, who have to be able to correctly use the instrumentation and the prostheses;
- Landing costs of implants and all aspect such a receipting, packaging and delivering of implants, transportation, i.e. fuel and vehicle costs and freight.

Other costs include the Rand exchange rate and in particular the Rand depreciation, over the past three years.[2] Long-overdue debt in the public sector business where some accounts have been outstanding for three years, negatively impacts the business.

[CONFIDENTIAL: [redacted] **CONFIDENTIALITY END]**

Hospitals buy our products, and they issue requests for proposals, and buy products on a type of tender process. They also use fixed fees and global fees as cost-containment mechanisms. Medical schemes limit or refuse reimbursement. Medical device companies are therefore truly price takers, as without matching their prices at scheme reimbursement levels, they are effectively excluded from the market.[3] The fact that prostheses prices have not increased to any extraordinary levels are supported by the graph included in the submission by the Life Hospital group.

[CONFIDENTIAL: [redacted]

[redacted]

[2] http://www.sharenet.co.za/marketviews/article/What_On_Earth_Is_Happening_To_The_Rand/2556.
[3] To see how this works in practice, one can visit any medical scheme website and look at implant limits.

[redacted]

CONFIDENTIALITY END]

Our price increases are set only once per year, and is aligned with the CPI.

It is also alleged by some stakeholders that implants may be cheaper in other countries. Straight price-to-price comparisons do not do justice to the contextual- and market factors that influence the price at which a product is delivered to consumers in various markets. For example, if transportation and training costs are different, volumes sold and the agreements associated with sales differ from market to market, where taxation of healthcare, and the mechanisms of funding differ, the end-price to consumers are also likely to differ.

Our calculations (based on information obtained from the UK Inquiry and Discovery Health) show that, in Rand value, arthroplasty in the UK costs around R240 000, whereas it would cost around R11 000 in South Africa. But, as many stakeholders point out, the problem may not lie with individual product prices, professional tariffs or hospital fees, but rather in the incomplete regulatory framework, and factors outside of the control of stakeholders, such as the exchange rate, demographics (age – older patients who nowadays live longer).

It is also due to the factors set out above, that we do not propose price regulation for medical devices. Unlike medicines, the input costs and related costs are varied. We rather propose that appropriate medical device regulations be implemented as soon as possible, so as to ensure that products on the market are safe, of good quality and perform as intended. Post-registration market access and pricing are effectively controlled through hospital procurement systems, medical scheme reimbursement practices and policies, as well as competitor activities, including pricing and the value offering (e.g. longer lasting implants, faster recovery days, etc.).

4.1.2 Lifescan (glucometers)

The allegation has been made that there are differential pricing in the market of consumables associated with glucometers, i.e. the strips used to test one's blood glucose level by using the glucometer. Lifescan can assure the Panel that it does not supply glucometers or testing strips to hospital groups, and where supplied to private sector customers, it operates on the same price list with an equal value discount scheme.

For the period 2013 – 2015 Lifescan has not increased its prices, in spite of inflation and the effect of the devaluation of the Rand.

In addition to its products, LifeScan provides quite extensive educational support to HCPs and invest in Professional and patient education in South Africa. This is necessary, as correct treatment depends on being able to correctly operate the glucometer, so as to obtain accurate readings and then to ensure that the correct treatment regime is followed.

4.2 J&J Medical

Over the last few years Johnson & Johnson Medical has been actively focusing on delivering optimal outcomes at affordable pricing. We have done this through seeking economies of scale, appropriate offerings and mix of offerings and inventory requirement and management in various institutions in both public and private sector.

Mention has been made in some submissions of sutures and we would like to present this as an example of our activities in the market to manage costs and ensure price increases are kept to a minimum.

[CONFIDENTIAL: [redacted]

[redacted]

[redacted]

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A key barrier to ensuring an equitable and fair market, in particular in the consumables space, relates to the absence of an appropriate regulatory framework. Johnson & Johnson would like to see a number of considerations around registration of products:

1. The registration process is appropriate for the category and therefore evaluation is done along appropriate lines for the category under review. A medical device cannot be evaluated against standards and requirements for a medicine as these products are vastly different
2. The evaluations for registration are considered under technical aspects of the product and the benefits to patients, ultimately the patient outcomes need to be under review. A Commercial evaluation should not be coupled with Technical evaluation at the product registration stage. This is done further down the chain and should be independent.
3. The registration time frame needs to be reviewed as many devices being forced through medicines registration would undergo a lengthy process of upwards of 4 years. This retards access to market significantly and may delay benefits of innovation to the market.

Coupled with this once registration has been obtained there would be further processes for the supplier to undergo in the private sector to ensure access to the market. The supplier would need to gain funder reimbursement approvals and once these are obtained the supplier needs to get approvals from the various hospitals to promote and sell their products within the hospital group. These additional processes can add significant delays to market access and much of these discussions would be around quality, clinical indications and price. These market access entry processes are extremely effective and there should be no complaint from stakeholders that they are unable to contain these costs.

Medical devices and listings with funders and private hospital groups is a rigorous and multifaceted process and could effectively bar products from entering the market or parts thereof. In order to be

able to market products in the various private hospitals the supplier needs to provide approvals from funders that these products will be reimbursed.

In the funder approval phase a number of requests are made of the supplier such as:

- Nappi Code
- Certificates of quality -ISO, FDA / CE, SABS if available etc.
- Company / supplier information
- Country of manufacture
- Indications for use
- Clinical evidence
- Contra-indications / restrictions
- Comparator in the market which this product would be benchmarked against (we feel this is inappropriate and try to compare against our wo line of products)
- Max Nett price in the market

Funders in some cases refuse reimbursement based on price premium or differential to a heritage or comparator offering, even if this comparison made is not strictly correct. In fact there are often long durations of negotiation around price during which there is no access to hospital markets in which such funders are pertinent. In some instances if the price is the same an auto approval can be actioned highlighting the power of the funders to exercise control over pricing in the market.

Once approval has been obtained and letters of approval are secured then the supplier is able to approach the hospitals for permission to promote. The major three hospital groups ask for funder letters of approval, some ask for more than 2 funder approval letters and all the large hospital groups look for funders that service large portions of the market and as such Discovery is often under consideration in these submissions. In addition, Once again requests for information on the product are asked by the hospital groups. The information generally required is:

- Funder letter/s of approval and criteria of approval
- Indications for use / contra-indications
- Warnings and usage restrictions
- IFU / Information for Use insert
- Certificates of conformity and quality (CE / FDA / ISO / SABS if available etc.)
- Some have specific new product introduction and technology applications forms
- Product category / Device Risk category and nomenclature
- Class of device and risk category according to GHTF (Global Harmonizing Task Force) or now replaced by IMDRF recognized by WHO
- Country of manufacture
- GMDN term name and 5 digit code as per Global Medical Device nomenclature for Medical Devices with similar features, characteristics and intended use (www.gmdnagency.org)
- Product brochures / product description and range if applicable
- Clinical data / evidence supporting use of the product

- Packaging / shelf life
- Benefits of the proposed product in the healthcare setting
- Benefits versus other competitors
- Does it replace technology / products and if so which
- Who / specialty to be targeted with this product
- Value added services offered with the product
    - This could be training of nursing staff / stock controllers / CSSD personnel etc.
    - Other value added services are aspects such as:
        - Emergency orders
        - Consignment stock placed in the hospitals
        - Management and sterilization of kits for application of the device such as used in orthopaedics (these kits are transported, cleaned and delivered to the hospitals for use by the suppliers in order that their products are used correctly with all the correct equipment needed for optimal outcomes)
    - Sometimes if the product involves capital equipment to utilize the disposable component the company is required to placed said capital equipment in the hospital in order that the disposables may be used. This t is at no additional charge to the hospital.
- In some instances samples
- Price forms a critical part of the negotiation of entry into the hospital. The hospital can and does rank / list the supplier based on price offered. The supplier can be excluded from their internal listings should the price offered not be deemed competitive / aggressive enough. Should your product not be listed on the hospital listing as preferred provider your sales staff are unable to promote the product to the Healthcare Professionals in the hospital, such as theatre or where the product is administered.

In essence there are numerous negotiation processes and pricing discussion which can often extend the process of access to the market. Also there are numerous countervailing power activities to which product and price offerings are subjected.

4.3 IP Policy and Substantive Search and Examination

We would support the enforcement of patents and intellectual property as these also protect patients and healthcare professionals. J&J does not oppose systems of substantive patent searches and examination, as long as those processes do not constitute a barrier to patients accessing technology without delay, and by considering the regulatory impact and resources needed to implement such a system in South Africa.

When a healthcare professional takes responsibility for the life of a patient and that patient entrusts their life in the hands of the healthcare professional a great deal of trust is placed in on another. There too need to be trust by the healthcare professional that the product he / she is using will deliver the exact expectations hey have around product design and capability.

Companies spend a great deal of time and money in developing and designing products to meet these requirements. They also spend a great deal of money protecting these rights as they take responsibility for the product's delivery and efficacy. Much of the revenue generated in selling the patented product provides further ability and resource to design more innovative products delivery improved patient outcomes.

Likewise many Funders also have copyright / IP on their models and category design. They also take responsibility for the quality and efficiencies these deliver and cannot be held accountable for what is delivered by a non-authorized entity who delivers outside of these patents or IP.

4.4 Utilization, quality and outcomes

Often the data used to make commentary on utilization is based purely on claims made through funders. This is in turn based purely on the prices paid for products and services. Johnson & Johnson have long held to the belief there are a number of permutations within the patient care and ultimately the outcomes need to be assessed for a clear indication of costs and benefits.

The full evaluation of the patient journey or downstream costs needs to be considered in any evaluation of utilization. The patient journey if you will needs to be assessed for various issues such as how quickly they recover and can become a productive member of the market. Consideration of the full outcomes for any procedure needs to be considered and not simply a claim for a specific ICD10 code in isolation of the entire patient assessment. In this J&J supports calls by some stakeholders to implement an independently run quality and outcomes entity.

We believe it would be of tremendous value to funders, hospital groups, surgeon associations and patient advocacy groups if more detailed analysis were done and available to show the effects of outcomes approaches in patient care rather than considering each issue as separate and perhaps reaching the wrong conclusion of over utilization.

4.5 Appropriate Use of Products

It is implied that utilisation is driven by (perverse) relationships between providers (HCPs) and/or hospitals and/or device suppliers. This implies that providers would use devices inappropriately on patients who do not need such devices, or in circumstances not aligned with such a device's indication. This is indeed a serious allegation, and J&J do not believe that most HCPs would risk their professional status or civil- or criminal sanction by inappropriate product use.

Due to the countervailing power exerted by funders and hospitals where suppliers are often curtailed in promotion and access with their products, as described above, we believe over utilization is an issue very quickly and effectively addressed.

Firstly Johnson & Johnson will only promote their products according to the IFU (Instructions for Use) or indications for the product. Coupled with this our training on the use of the product is to promote effective and efficient use of the product.

We do believe development of more Centers of Excellence (COE's) would be beneficial to costs reductions in the long-term as has been evidenced in a number of COE's around the world. Also these COE's can act as training facilities for skills and development of surgeons and healthcare professionals in South Africa. Peer and association review of clinical outcomes would also serve as a benchmark of care and standards and this could only have far-reaching benefits for funders of care and ultimately the patients who are the final recipient of that care.

5 Conclusion

J&J appreciates the opportunity to reply to the submissions made by others and that directly impacts the product portfolio of the companies in the group. It is willing to engage with the Panel on any matter if may deem necessary and look forward to the recommendations that will flow from the process.

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