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Understanding medicine access strategies for innovator medicines registered in South Africa

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Abstract

Background South Africa is composed of a two-tier healthcare system. One tier is a private healthcare system that is funded through medical insurance, and comprised of people who can afford to make monthly payments towards their medical insurance. Second tier is a government-funded public healthcare system, which covers the majority of the population. This study explored the perceived barriers and current strategies being utilised by the pharmaceutical industry to increase access to innovator medicines.

Objectives The objectives of the study were to: (1) quantify and classify innovator medicines registered between 2010 and 2020 by the South African Health Products Regulatory Authority (SAHPRA); (2) identify barriers to accessing innovator medicines in South Africa through interviews with market access managers from innovator companies; and (3) explore the current market access strategies used by the pharmaceutical industry.

Design This study employed a quantitative and qualitative methodology. Whereby the former involved the extraction of a list of innovator medicines from the regulator database, and the latter involved 9 semi structured interviews. Purposive sampling was conducted through pharmaceutical association member companies. The interviews included seven market access managers and two medicine managers from one of the payers in South Africa. Thematic analysis was used to interpret the data collected from the study.

Results According to the regulator database during the review period, 238 innovator medicines were registered. Only 14.77% were available in the public sector in the form of tenders, whereas in the private sector (based on the products having a SEP), 76.92% were available. From the interviews six themes emerged: reimbursement of medicines, types of reimbursement, partnerships, technology, legislative challenges, and other factors (e.g., real-world evidence).

Conclusion Access to innovator medicines in South Africa is a challenge, as the price of these therapies is high. Therefore, various stakeholders in the health sector must collaborate to identify and implement solutions that are locally relevant. The government needs to proactively update policies that would allow for alternative reimbursement methods to be explored.

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Introduction

It is imperative that people are not denied life-saving medicines for economic and/or social reasons. The need for safe and effective medicines is also recognised as a basic human right by the World Health Organisation (WHO) [1]. Health care is fundamentally important because it affects our ability to pursue life goals, reduce pain and suffering, and prevent premature loss of life [2]. Having good health is important, as it also contributes to other goals, such as education, freedom from poverty and overall improvement in quality of life [3]. Access to pharmaceuticals is an important aspect of health care [4]. Access to innovator medicines includes both an availability and an affordability component [5]. The availability is constrained by patent protection as innovator medicines are new chemical entities, which could result in high prices for the patented medicine [5]. This in turn impacts decisions as to whether to include innovator therapies in formularies for reimbursement [6].

Section 27 (1)(a) of the South African Constitution states that everyone has the right to have access to healthcare services, including reproductive health care [7]. The South African healthcare system is two-tiered, composed of privately funded healthcare paid for by individuals and a public healthcare system funded by the government. The majority of the population relies on the government to provide healthcare, therefore the government holds the key to the pharmaceutical market [8]. As most of the public relies on government to provide healthcare, the affordability of innovator medicines is a challenge, due to budgetary constraints that exist. The government of South Africa uses a competitive tender system to procure medicines for the public sector, at a reduced cost due to competition. To increase transparency and enable access of innovator medicines and generics in the private sector, the government introduced the single exit price (SEP) [9]. The SEP comprises of the manufacturer price including value added tax and a logistics fee.

There has been research conducted in South Africa on the pricing and affordability of medicine. However, no publications are available on the challenges in accessing innovator medicines and the reasons for this. Therefore, understanding the barriers to improving access to innovator medicines may result in workable solutions being sought. The study aims to identify these challenges and to propose solutions that could be implemented to address these challenges.

Methodology

Study settings

The study was conducted in South Africa, with members of a pharmaceutical association. This association comprises member companies that are research-based pharmaceutical companies. This makes up 43% of the pharmaceutical private sector in South Africa [10].

Study design

The study employed a quantitative and a qualitative design. The quantitative design involved extracting the number of innovator medicines that were registered between 2010 and 2020 from the SAHPRA database. A qualitative study design was employed, with interviews being conducted as the primary means of collecting data.

Study population and sampling strategy

The data for this study concerning innovator medicines registered by pharmaceutical companies in South Africa between 2010 and 2020 was retrieved from the SAHPRA health products database. These medicines were then identified and extracted from the South African National Department of Health Tenders repository.

For the private sector, innovator medicines that had a registered single-exit price as indicated on the Medicines Price Registry between 16th and 26th March 2023 were extracted. Interviews were conducted to obtain information on the market access strategies that are employed, and to identify barriers to accessing innovative medicines in South Africa. Market access managers who were from companies that were members of the pharmaceutical association were requested to be part of the study. Interviews were also conducted with representatives of private payers.

Data collection

The quantitative data was collected between 01 March 2023 and 14 June 2023. The qualitative data collection (interviews) took place between 13th April 2023 and 05 February 2024. A total of 23 participants were invited but only 9 participants agreed to participate in the qualitative research. There was no response from the remaining 14. The study was carried out in Gauteng, where the majority of the participants are based, as this is the location of the innovator pharmaceutical companies in South Africa. Participants were chosen based on their role in market access and reimbursement for medicines in South Africa.

The data was collected through online one-on-one semi structured interviews. Semi structured interviews are most frequently used in qualitative research and in the healthcare

context [11]. The semi structured interview method of data collection was employed due to its versatility and flexibility [11]. The interview questions included open-ended questions that explored market access strategies, barriers to such strategies, and opinions on what needs to change in South Africa to enable access to innovator medicines. The interview guide also explored policies employed by the government and their role in either increasing or impeding access, along with the role that industry played in shaping polices. The interviews were conducted virtually using Microsoft Teams, with each interview lasting approximately 1 h. Only one interview was held face-to-face (although it was still recorded through Microsoft Teams). The confidentiality of the participants was maintained. Participants were sent a consent form to sign along with the interview questions in advance.

Data analysis

Microsoft Excel was used to list products that were registered by innovator pharmaceutical companies between 2010 and 2020. The list was then used to extract information from pharmaceutical tenders that have been awarded by the South African National Department of Health. For the qualitative portion of the study, inductive analysis was adopted to analyse the data. Each recording was coded separately. Themes emerged from the coded transcripts, using inductive coding.

Ethical consideration

The study and questionnaire were reviewed and approved by the Biomedical Research Ethics Committee, University of KwaZulu-Natal (BREC/00005116/2022). To conduct the interviews and collect data, permission was sought and granted by the research participants in their individual capacity. Written informed consent was obtained separately for each interview from each participant. The anonymity of the participants was maintained during the data collection, analysis and reporting of the results. Participants were offered the opportunity to review their transcripts, but all declined.

Results

Quantitative study

There were 233 innovator medicines registered in South Africa between 2010 and 2020, according to SAHPRA (medapps.sahpra.org.za:6006), of which 166 were new chemical entities, 44 were clones and 15 were line extensions of the new chemical entities. According to the data extracted from the National Department of Health pharmaceutical tenders database only 33 (14.16%) innovator medicines have been awarded tenders and are thus available in the public sector since 2019. There were also 3 that had alternatives in the public sector, as they were clones of innovator medicines. The availability of innovator medicines in the private sector (those having a SEP) was 76% (178 of the 233).

The availability of these innovator medicines was divided into classes and their availability in both the public sector and private sector was reviewed. The percentage availability was based on the total number of innovator medicines that were available in that sector at the time of data collection. These results are presented in Table 1 below.

Qualitative study

A total of nine interviews were conducted. Seven of the interviews involved professionals who are market access managers, and two involved private funders. The themes that emerged were reimbursement of medicines, types of reimbursement, partnerships, technology, and legislative

Table 1 Class availability in the public sector and private sector

Medicine Class	Percentage (%) available in the public sector (*n* = 33)	Percentage (%) available in the private sector (*n* = 178)
Antibacterial agents	-	3.4%
Anticoagulation agents	9.1%	5.1%
Antidepressants	-	1.1%
Antidiabetic agents	3.0%	11.2%
Antiemetics	-	0.6%
Antifibrotic agents	-	1.1%
Antifungal	-	1.7%
Antihistamine	-	1.1%
Antihypertensive	-	9.0%
Antiretroviral agents	18.2%	3.4%
Antitubercular agents	3.0%	0.6%
Antiviral	3.0%	1.1%
Asthma and pulmonary agents	3.0%	2.8%
CNS agents	-	1.7%
Contraceptive	3.0%	3.9%
Contrast media	-	0.6%
Enzymatic agents	3.0%	1.7%
Hormone replacement therapy	-	0.6%
Hypercholesterolemia	-	0.6%
Immunological agents	-	2.2%
Immunosuppressants	3.0%	10.7%
Influenza agents	-	1.1%
Insulin	-	1.7%
Non-steroidal anti-inflammatory drugs (NSAIDs)	-	0.6%
Oncology	18.2%	18.0%
Ophthalmology agents	-	1.7%
Prostate agents	-	0.6%
Rheumatic agents	-	0.6%
Thrombopoietin	-	0.6%
Thyroid agents	3.0%	1.1%
Vaccines	30.3%	9.6%
Vasodilator	-	0.6%

challenges, as well as a broad category of other issues. These themes not only addressed challenges but also included suggestions for improving access to innovator medicines. The identified themes are presented in Table 2 and expanded further below.

Theme 1: reimbursement of medicines

Cost of medicines

The participants in general felt that innovator medicines are expensive. They add tremendous clinical value to patients, but the price of these treatments impedes access. There was a feeling that "me-too" medicines should not have a premium price, as doing so does not benefit South Africans. For medicine to be considered innovator and reimbursed as such, it needs to be valuable to patients. The majority of the participants believed that the cost of innovator medicines needs to be based on value and innovation, which is priced based on the research and development that has gone into bringing the medicine into the market. Private funders need to see the value of the medicine, and then discussions on the price of the medicine need to take place. Prescribers and patients should also see value in that medicine. From the funder perspective, there was a feeling that the government failed to hold the pharmaceutical industry accountable for the pricing, which limits access to innovator medicines.

> *"Often you find that our innovator treatments have tremendous clinical value that they bring to patients. But with that comes a price tag" – Interview 3.*

> *"It's not about the patient, it's about Pharma profit margins, and they not held accountable. Government does not cross question pharma on their pricing. They don't adjudicate anything, and they get blanket increases, even though they've got exploitative pricing here. The entire system is bent towards appreciating the profit margins of pharma and not taking care of patients." – Interview 6.*

Table 2 Themes identified in access to innovator medicines in South Africa

Themes	Sub-themes
Reimbursement of medicines	Cost of medicines Pricing transparency Copayments
Type of reimbursement	Alternative reimbursement models Risk sharing Value based contracting Single Exit Price (SEP)
Partnerships	Relationships/Partnerships/Stakeholders
Technology	Use of technology Data integration
Legislative challenges	Lack of regulations and legislation NHI Lack of Pharmacoeconomics in government/HTA presence and usage
Other themes	EML Listing Fragmented insurer space Pharmaceutical industry Real world evidence Formulary listing and prescribed minimum benefits

Pricing transparency

Participants expressed the feeling that transparent pricing regulation in South Africa is counterproductive. It is meant to increase competition among pharmaceutical companies, thus resulting in a reduction in medicine prices and consequently an increase in access. However, this has proven to not work for innovator medicines, as pricing is visible globally.

> *"…for innovator medicines, we have the worst system in the world because we transparently disclose all our prices, which everybody else sees and benchmarks." – Interview 6.*

As a result, innovator medicines are being launched at a premium price. Participants felt that pricing should be confidential between innovator pharmaceutical companies and funders, including the government. This would allow patients to benefit by having increased access to innovator medicines through models such as discounting, bonusing and rebates. To increase competition, there was also a suggestion that transparent pricing should be kept within the borders of South Africa only, with controlled access that is available only to stakeholders within South Africa.

> *"I think it is probably one of the big things we need, that and removing the visibility of single exit prices." – Interview 9.*

> *"So the barrier is the visible price in South Africa. It's actually the biggest barrier currently that we have. It serves a purpose to ensure that prices are standardized and there isn't perverse incentives. However, the visibility of that price globally is impacting what we can give to South Africans." - Interview 9.*

Copayments

Some participants felt that the private payer benefit packages are designed such that for better benefits as a patient, you will have to go on a higher plan, which includes reimbursement for innovator medicine. The

higher plans subsidise the patients on lower plans if an innovator medicine is a prescribed minimum benefit (PMB). Each plan has a limit or a cap to which a funder will pay for a medicine, and then copayments will apply. Patient support programmes assist patients with copayments when an innovator medicine is not fully reimbursed to ensure access to innovator medicines.

> *"...an access barrier where the patient might have a copayment etcetera. There are also some programmes there that will support patients in terms of helping with a copayment." – Interview 4.*

This is seen by funders as the admission of guilt by the pharmaceutical industry with respect to highly priced innovator medicines.

> *"...the fact that you have patient support programs is your admission of guilt, that your price- is that your product is priced excessively in SA..." – Interview 6.*

Participants felt that the basket of medicines for a disease area should be increased for lower plan patients. Alternatively, they should be given the option to have copayments provided it is the most clinically appropriate medicine for that medical condition. The participants were concerned that this would result in funders losing people on the higher plans, as it would be pointless to remain on the higher plan.

> *"...forcing the members to buy up to be able to get the innovator products, because otherwise there'd be no reason to buy the bells and whistles everyone would be on the bottom plan and have access..." – Interview 1.*

Theme 2: type of reimbursement

Alternative reimbursement models

Overall, the participants expressed frustration because there was a lack of alternative reimbursement models (ARMs) in South Africa, which was attributed mostly to the SEP.

> *"... you know with South Africa we have this SEP limitation legislation which actually literally limits us to do any alternative models..." – Interview 5.*

Participants felt that alternative reimbursement models would allow for varying methods to be introduced to fund innovator medicines. This would increase access to these innovator therapies.

> *"It's a great consideration where you've got inherent risk, so if you launching an innovator product and your funder is not sure..." - Interview 4.*

The participants strongly felt that ARMs would allow risk sharing between the funders and the innovator pharmaceutical company. They would also allow funders to reimburse innovator medicines based on the value of the medicine.

> *"managed entry agreements are absolutely what we need." – Interview 9.*

> *". There's actually even like a group that has come together that comprises of the innovator pharma industry, patient advocacy groups of funders as the key stakeholders that are putting forward a proposal to Department of Health, to allow alternative reimbursement models to be included in the law in the regulations..." – Interview 3.*

Risk sharing

To increase access to innovator medicines in the public sector, there could be some form of risk sharing whereby the government commits to numbers as well as a budget to treat those numbers. When those funds are exhausted for the year, then the pharmaceutical industry can take over to assist for the remainder of the year.

> *"I would even go to an extent of saying why don't you also prove that your product is actually innovator by entering into those agreement where you will pay for performance." – Interview 2.*

> *"I think in managed entry agreement then allows this particular type of risk sharing between the company and the and the payer and I think it is a good tool to consider to allow access to innovation in my knowledge at this point in time" – Interview 4.*

Value-based contracting

Participants believed that there should be a mindset shift, whereby the value of the medicine should be considered before the pricing negotiations, as this would result in an outcome-based focus. However, the difficulty would be in proving the actual outcomes and agreeing with the funder on what the outcomes should be, as the value of a

medicine should not result in that medicine being made unaffordable.

> *"if we can start having the mindset change? From just looking at a price of the product but looking at the value that the product is providing to a specific patient." – interview 1.*

> *"Then you've got to both parties have got to agree that the outcomes that have been measured are accurate." – Interview 3.*

Single exit price

The greatest hurdle to ARMs is the Single Exit Price (SEP), as stated by participants; the SEP has negatively impacted access to innovator medicines. Participants believed that scrapping the SEP policy would increase access.

> *"...why not just take away the Single Exit Price and because we're the only ones in the world with the SEP." – Interview 7.*

The argument raised is that the SEP is the ex-manufacturer price, the logistic fee and the value added tax. However, the manufacturer price and logistic fee are determined by the manufacturer, so there is no real transparency.

> *"Because SEP in as much as it's supposed to be bringing in transparency, there's no transparency in SEP." – Interview 7.*

Some participants believed that the SEP has done well and therefore should not be completely scrapped; however, it should have flexibility that allows for alternative reimbursement models.

> *"We don't want SEP to be scrapped because we understand the fundamental role of SEP" – Interview 5.*

SEP allows for annual increases in which funders feel that the pharmaceutical industry accepts, at times even when it is unwarranted. This further increases lack of access, as innovator medicines are already highly priced.

> *"...they get blanket SEP increases, and they take these increases..." – Interview 6.*

Due to pricing transparency as a result of SEP, medicines are launched at premium prices, as the South African price could then be used for reference pricing by other countries, as the SEP is visible globally.

> *"So as global companies that visibility hinders our ability to give the best value of price for the market because there's something called international reference pricing where they reference prices" – Interview 9.*

The pharmaceutical industry does, in certain instances, offer temporary price reductions (TRPs), which assist with affordability. However, since they are temporary, when the price increases, affordability decreases. To try and increase access to the public sector, differential pricing is used, which normally offers innovator medicine to the public sector at a reduced cost.

> *". So another thing that's done is temporary price reduction. So TPR's. So now and again, companies will, you'll notice will do a TPR, which is basically reducing their price by a certain amount or percentage for a given time." – interview 8.*

Theme 3: partnerships

The participants expressed the importance of having relationships with various stakeholders, such as those between the pharmaceutical industry, private funders, patient advocacy groups, healthcare providers, patients and the government. Participants within the private sector believe that there is a lack of willingness from public sector stakeholders to partner. They believe that the government views the pharmaceutical industry as a profit-driven industry and not as a partner to improve the lives of patients. There needs to be more private–public partnerships in healthcare to be able to address the accessibility of innovator medicines to everyone irrespective of the payment plan.

> *"...the biggest thing is partnerships." – Interview 7.*

> *"it's really about partnering with somebody to actually support the patient." – Interview 4.*

The participants felt that the government needed to update its policies.

> *"I think we are still lagging from government side to actually have a clear policy on alternative reimbursement models" – Interview 5.*

Theme 4: technology

Use of technology

Participants stated that South Africa could use technology to strengthen healthcare. The use of technology was not harnessed because it could assist in improving healthcare and allowing access to medicines.

Data integration

Participants mentioned that technology can be used to harness real-world evidence. This would assist in determining the value of innovator medicines.

> *"I don't think that the technology isn't there. The technology is there. It's about now getting it implemented and maintaining it after that." – Interview 3.*

> *"It's really about again, the data opening up a registry so that we actually have the data collection, real-world evidence that we're able to collect that real world evidence and demonstrate impacted people" – Interview 4.*

Theme 5: legislative challenges

Lack of regulations and legislation

As previously mentioned above, one of the greatest hurdles to accessing innovator medicines according to most participants was the SEP. SEP is unique to South Africa and does not allow for alternative reimbursement models. Although the SEP has benefits, as the only pricing mechanism in South Africa, it has become regressive rather than progressive.

> *"...why not just take away the Single Exit Price and because we're the only ones in the world with the SEP." – Interview 7.*

When participants were asked about policies and what could be done from a policy perspective to increase access to innovator medicines, they all pointed to the government's inability to implement such policies. Participants also pointed out that there is no legislation that governs risk-sharing agreements or outcome-based contracts in South Africa. There is also no implementation of current legislation.

> *"There is guidelines on pharmacoeconomics and all this stuff, but this is it. They haven't applied it." – Interview 2.*

> *"the government does nothing to increase access to innovator medicines" – Interview 6.*

Participants felt that the government needs to look at policies that govern alternate reimbursement models., This will allow for risk-sharing agreements between the industry and payers. New legislation needs to be introduced that will support alternative reimbursement models, as well as legislation to fight corruption.

> *"I would definitely look at these types of value-based contracting agreements and being more flexible in terms of within governance obviously, I'm not saying move outside of governance and transparency, but I think that we need to be a lot more flexible in terms of putting forward, reviewing and approving value-based type of pricing and contracting so that we can actually start implementing it" – Interview 4.*

> *"I think we are still lagging from government side to actually have a clear policy on alternative reimbursement models. And like I said, it's been a topic for over 10 years now, but nothing is happening" – Interview 5.*

National Health Insurance (NHI)

Participants agreed that the NHI is important and should be implemented. However, in its current format, it cannot be implemented. Rather, the government should look at public-private partnerships. To make the NHI a success, participants believe that it is not a one-size-fits-all project. Rather, South Africa should learn from other countries where it has worked and where it has not worked and then tailor it to meet the needs and challenges of South Africa. For the NHI to succeed, it has to make use of alternative reimbursement models to be able to access innovator medicines.

> *"We can leverage of global experiences. We can see what not to do. That didn't work in their countries, and we can tailor South African rules for South African people. I guess it's not a one size fits all. It's never going to be we have challenges that other people don't have." – Interview 6.*

The government has to leverage private funders' experience and skills with operational matters, such as using technology to ensure that patients are not lost in the system, being able to track claims, process payments, and negotiating with service providers.

"So there's a lot that government can learn. We can learn a lot from government in terms of how they establish their standard treatment guidelines and because it's very robust, so that joint learning is what's needed." -interview 9.

Lack of health technology assessment capacity

Another issue raised regarding the success of the NHI is that there is no HTA to speak off from the Department of Health. It would benefit the country if South Africa had one independent HTA body.

"There's so much that needs to be done in creating an independent HTA body." – Interview 7.

Knowledge sharing also needs to occur, whereby the pharmaceutical industry learns from the government on how to create robust standard treatment guidelines. The pharmaceutical industry was looking at ways to support the government with the strengthening of pharmacoeconomics, such that there is a fully functional independent HTA body to guide policy on alternative reimbursement models for medicines in South Africa.

"So, pharmacoeconomics is not there in the government. It's only there as a word, but not being used to manage the cost." – Interview 2.

"But right now, there is no HTA process in place, nothing." – Interview 5.

South Africa's HTA body needs to function independently of the government to make pharmacoeconomic recommendations that are based on the evidence presented, as well as global best practices. There also needs to be HTA in both the public and private sectors. The HTA needs to clearly communicate what affordability is like for South Africa for both the state and private sectors.

", if you have one national HTA body that basically has got people who are not biased and that can basically look at the different models for the different therapeutic areas." – Interview 7.

"I would still say the government should have a proper HTA process across 2 sectors… Even if we have one private HTA process and then the government HTA process but then the government should take ownership in terms of owning the policies." – Interview 5.

Therefore, industry could design alternative reimbursement models that cater to the findings of HTA. Due to the limited financial resources available to the government, there is an opportunity for alternative reimbursement models. With the latter, the industry can introduce various models that cater to the limited resources available to the government to increase access to innovator medicines.

Theme 6: other themes

Some participants also mentioned that SAHPRA needs to reduce its registration timelines to ensure timely access to medicines. The government could perhaps look at tax exemptions for innovator medicines to decrease the price of medicines and provide rebates to support distribution. These savings could then be passed on to the patient.

"So why are we being taxed for accessing meds?" – Interview 3.

Funders promote the enforcement of generic substitution, since it encourages innovator pharmaceutical companies to rethink their pricing strategy, as some generics may form a therapeutic alternative to an innovator medicine. Thus, innovator medicines have to demonstrate value over other therapies irrespective of whether they are first-line or third-line treatments. The introduction of a medicine to funders is supported by cost-effectiveness data as well as positioning the product in a niche, whereby it targets patients who have failed in currently available treatments.

"The biggest thing that the government did actually was just enforcing the use of generics, because then that forced the companies to price differently." – Interview 1.

EML listing

The pharmaceutical industry also looks at ways to obtain a formulary listing based on the proven clinical benefit that the medicine can provide. The Essential Medicines List (EML) and Standard Treatment Guidelines (STG) were used to determine which medicines were the standard of care.

"So I think being included on a formulary will facilitate and enable access. If a product is not on the formulary, it's not a complete barrier to access, and I think also the converse there is that even if a product

is on the formulary, it does not guarantee access." – Interview 4.

Pharmaceutical industry

In an attempt to increase access, participants stated that innovator pharmaceutical companies, as another initiative, are working together to partner with the government as well as private funders to put through a proposal to the National Department of Health to gazette into law alternative reimbursement models. Participants also provided solutions based on current global trends to address barriers to accessing innovator medicines in South Africa. The proposed solutions are provided below, as they have been identified as initiatives that could aid in increasing access to innovator medicines in South Africa.

- The Council for Medical Schemes needs to update treatment algorithms proactively to make it simpler for payers to fund innovator medicines, so that they will be on the treatment guidelines.
- There also needs to be an increase in clinical trials conducted in South Africa, as this would provide data that are relevant and specific to South Africa.
- Payers suggested that innovator pharmaceutical companies need to be more flexible in pricing for innovator medicines.
- Within the public sector, there needs to be strict implementation of the Public Finance Management Act. (PFMA), to increase funds in the public sector.
- The South African treatment guidelines need to be updated proactively to be in line with international standards of care to ensure that patients receive a clinically appropriate product in line with international standards.

"so ideally someone actually needs to actively update the algorithms because that actually makes funding decisions easier." – Interview 1.

"...many clinical trials globally are focused on European and U.S. markets. So many of our clinical trials, I mean, most of them actually are done in those markets."

One participant suggested that there needs to be decentralisation of funds in public hospitals and to allow them to function as a business. Hospitals should use the funds that are paid by patients who can afford to do so, however small, to improve the functioning of the hospital, which could aid in increasing access to medicines. Consideration should be given to reducing hospitalisation due to innovator medicine, reducing polypharmacy, and improving the overall quality of life of patients.

"...let the hospitals also run as a business." – Interview 2.

Fragmented insurer space

The private insurance sector needs to have one program that is not as fragmented as it is currently and to make uniform decisions. Currently, different payers offer different copayment percentages. Within the private insurance space, there needs to be uniformity within the specific disease areas. This approach would aid in providing the same level of assistance for all impacted patients. In addition, within the private insurance space, the gap between the different plan types is too wide, which disadvantages certain patients who cannot afford the higher plan. The benefits for a disease area should be driven by treatment protocols, irrespective of the plan. Private payers should try to find common ground for various treatment baskets for the benefit of the patient.

"Another barrier would be within the private sector because you know that we have a very fragmented insurer space. So you do find different levels of reimbursement." – Interview 5.

Real-world evidence

In the public sector, there needs to be an increase in the use of technology to better monitor patients, as well as to have a central patient database. Within the usage of technology, there needs to be a single point where there is central data that is available to the payers as well as industry, whereby each stakeholder can access the outcome data of a medicine. This would then facilitate the reimbursement models, as the database would have been following a treatment over a certain period of time and linked to outcomes, thus showing the impact of the innovator medicine. This would have to be done within the confines to the current legal framework protecting personal information, as the purpose of the database would be to show the value of the innovator medicine in the patient journey.

"And then you imagine the amount of value you can get out of an electronic health system. The records you can get out of there, the real-world evidence generation, You could do such amazing data mining with that." – Interview 3.

Discussion

The quantitative results indicate that a limited number of innovator medicines were available during the time period studied. Between 2010 and 2020, the SAHPRA faced challenges inherited from the Medicines Control Council (MCC), chief of which was the revision and implementation of new regulatory pathways [12]. By 2018, the SAHPRA had up to 8220 applications, with a median approval time of approximately 5 years [12]. This could be attributed to the low number of new chemical entities registered by the SAHPRA (formerly MCC). The SAHPRA also faces the challenge of a lack of resources and therefore does not have sufficient capacity to evaluate a dossier [12]. This also results in delays in evaluating submissions, which then has a domino effect on the registration timelines [12] and availability of generic medicines.

One of the challenges mentioned by the participants was that innovator medicines were costly. The pharmaceutical industry's justification for high-priced medicines is that they add value and thus should be reimbursed for research and development [13]. The high cost of innovator medicines in South Africa was attributed to pricing transparency, which is visible globally. Price transparency has been implemented by some countries; however, there is no conclusive evidence of price control and/or a reduction in medicine expenditure [14]. To reduce the price of innovator medicines, pricing transparency should be used with other alternative reimbursement models, such as volume-based contracting [14].

Participants agreed that there is a need for alternative reimbursement models (ARMs) to be able to reimburse innovator medicines. ARMs involve value-based contracting, whereby the price of the medicine is linked to the perceived value, and this strategy is increasingly being utilised to try and increase access to innovator medicines [15]. Value-based reimbursement is considered a method of choice for new technologies due to advantages such as price negotiations or internal or external referencing; aligning the patient, the payer and the provider; and offering incentives to providers who can deliver better outcomes for the patient without necessarily increasing costs [16, 17]. However, there is no clear way to measure the value of an innovation and/or the value of a medicine; therefore, there should be clear policies that define value along with the factors to be measured [18]. There is also the reality that because value-based pricing looks at the value of the innovation, that value could be both unaffordable and unacceptable at a societal level [19].

Even though South Africa has SEP policies aimed at reducing the price of medicines, participants alluded to the fact that innovator medicines are still unaffordable in South Africa. The South African reimbursement model is based on the SEP, which provides transparency. The overall aim is to improve access to medicines by reducing the price of innovator and generic medicines and controlling the price of medicines [20]. As a single intervention, the SEP cannot provide affordable, innovator medicines to patients [9]. The cost of innovator medicines is driven primarily by factors such as patent protection, monopolistic markets for new entities, regulatory issues, taxes and tariffs, geographic location, income status and lack of internal price regulation [21]. South Africa, as an LMIC, will generally have limited negotiating power for medicine pricing [22]. The industry needs to evaluate ways in which the prices of these medicines could be reduced.

Payers indicated that the pharmaceutical industry needs to show flexibility in the pricing of innovator medicines. This means that there must be a balance between maintaining innovation and increasing access [22]. This could be achieved by considering models such as tax benefits, differential pricing, patent changes, medicine discounts, and national health insurance, as innovation must be rewarded and sustained [22]. Some participants mentioned that tax exemptions for innovator medicines can be applied to reward innovation and reduce the price of medicines. Globally, the value-added tax on medicines can reach 20%; when his tax is added to other taxes that are imposed during the supply value chain, the end price of a medicine increases [23]. Tax incentives are crucial to the investment choices of pharmaceutical companies, as seen in a study in Uganda; this was also evident in India, where a tax credit system supporting the private sector led to an increase in research and development investment within the pharmaceutical industry [24].

Participants felt that partnerships between stakeholders are critical to ensuring increased access to innovator medicines. However, currently the participants believe that the relationships between various healthcare stakeholders is fractured, primarily due to a lack of trust between the government and industry. Thus, there is fragmentation between national departments, between private and public funders, between national departments of health and provincial health departments, and within provinces and districts [25]. Partnerships can leverage the strengths of each sector based on experience, resources and expertise [26].

South Africa has no formal HTA structure, even though it is reminiscent of other healthcare decision-making bodies, such as private insurance companies, on the National Essential Medicines List Committee [27]. The participants expressed the willingness of the industry to partner with the government to assist in the development of policies that will aid in strengthening health technology assessment (HTA). The government would need to find a way to address the three-tier system of governance (national, provincial and local), each with executive and legislative authority, as healthcare falls under national

and provincial legislatures [27]. South Africa could emulate the National Institute for Health and Care Excellence (NICE), whereby various stakeholders (such as the National Health Service, clinical experts, external assessment groups, patient and carer organisations, companies, healthcare professionals, etc.) work collaboratively in a robust manner towards one goal, with a single vision of determining whether there is clinical efficacy as well as value for money into using a technology [28].

Consistent with the results of this study, Marsh and Truter (2019) found that to be able to develop a HTA that is open, trustworthy and acceptable to all healthcare stakeholders, the government needs to collaborate with the pharmaceutical industry as well as private funders to improve the South African Guidelines for Pharmacoeconomic Submissions (SAGPS), such that it covers medical, legal, social and ethical considerations [29]. The emphasis of the SAGPS is currently more on the economic aspect than on the medical aspect when it concerns new medicines [29].

Private insurers need to re-evaluate the basket of medicines for different conditions. A rich basket of medicines should be limited not only to those that contribute the most but also to other plans that are available. According to Mpanza (2016), if members do not see the value of paying monthly contributions and then have to pay copayments because a medicine is not fully reimbursed by the insurance, they will end up terminating their cover [30]. Since a formulary is used as a guide for reimbursement, to increase access to innovator medicines, private insurers should base their formulary on global standards of care for a condition to ensure the best clinical outcome for their members. There is little competition between funders who can benefit patients in terms of improved affordability and value-for-money coverage [31].

The pharmaceutical industry is an important player in the health sector, as governments around the world need to decide which new medicines will be included as part of their respective country health services [32]. As an important stakeholder in the health sector, there is a perception that the pharmaceutical industry's only focus is on the development of expensive novel molecules and/or technologies. They have lost interest in the production of cheaper medicines that are equally effective and affordable due to their pricing policies and aggressive patent policy issues [32]. The costs of medicines and healthcare in general are increasing, but there is a disparity between the amount of money spent and patient outcomes [33].

Limitations of the study

Some interviews were rushed due to time constraints due to participants having other commitments. The study could have presented a balanced view, if there had been stakeholders from the public sector to present challenges faced in accessing innovator medicines. There also was a lack of input from policymakers from the government reimbursement sphere in South Africa.

Conclusion

There has been a limited number of innovator medicines that have been registered in South Africa. The study attributes this to the various market access barriers that exist in the country. There have been strategies that are being used to ensure access to innovator medicines, however these have also experienced constraints that are policy related. Finding solutions to access barriers, including the prices of these barriers, requires various stakeholders in the health sector to collaborate to ensure that patients have access to the latest innovator medicines. Finally, the government needs to proactively update policies that would allow for alternative reimbursement methods or other access strategies to be explored.

Abbreviations

ARM	Alternative Reimbursement Model
BREC	Biomedical Research Ethics Committee
CNS	Central Nervous System
EML	Essential Medicines List
HTA	Health Technology Assessment
IPASA	The Innovative Pharmaceutical Association South Africa
LMIC	Low- or Middle-Income Country
MCC	Medicines Control Council
NHI	National Health Insurance
NICE	National Institute for Health and Care Excellence
NSAIDs	Non-steroidal anti-inflammatory drugs
PFMA	Public Finance Management Act
PMB	Prescribed Minimum Benefit
SA	South Africa
SAGPS	South African Guidelines for Pharmacoeconomic Submissions
SAHPRA	South African Health Products Regulatory Authority
SEP	Single Exit Price
STG	Standard Treatment Guidelines
TPR	Temporary Price Reduction
WHO	World Health Organization

Supplementary Information

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Supplementary Material 1.

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Authors' contributions

FS and TJ designed the study. TJ undertook the data collection and data analysis. FS performed the data validation and reviewed the paper. Both authors read and approved the final manuscript.

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Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available as the results are generated for a postgraduate degree which is still under examination but are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study was granted ethical approval by the University of KwaZulu Natal subcommittee of the Biomedical Research Ethics Committee (ethics number: BREC/00005116/2022). All participants provided consent to participate and signed informed consent forms.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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