

SOUTH AFRICA / JUDGMENT

M.D and Another v Medihelp Medical Scheme and Another (2022-010668) [2022] ZAGPPHC 640 (26 August 2022) [2022] ZAGPPHC 640

COURT

North Gauteng High Court, Pretoria

BEFORE

Millar

CASE / FILE NUMBER

2022-010668

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IN THE HIGH COURT

OF SOUTH AFRICA

(GAUTENG DIVISION,
PRETORIA)

Case No. 2022-010668

REPORTABLE: YES/NO

OF INTEREST TO OTHER

JUDGES: YES/NO

REVISED NO

DATE: 26 August 2022

In the matter between: M[....]
D[....]
FIRST APPLICANT
RARE DISEASES OF SOUTH
AFRICA NPC
SECOND APPLICANT
And
MEDIHELP
MEDICAL SCHEME
FIRST RESPONDENT
THE
COUNCIL FOR MEDICAL SCHEMES
SECOND RESPONDENT

JUDGMENT

MILLAR J

1. This is an urgent application brought on behalf of Z[....] D[....], (“Z[....]”) a 3-year-old child who has been diagnosed with a rare condition called Hunters Syndrome MPS II (“MPS II”). This condition is genetic and has only one registered treatment within the Republic – an enzyme replacement therapy called Elaprase.
2. The application is brought in two parts – Part A for an interim order that the First Respondent be required to pay for treatment of the condition pending the outcome of Part B – a complaint to be lodged with the Second Respondent in terms of Section 47 of the Medical Schemes Act 131 of 1998. This judgment is dispositive only of the orders sought in Part A.
3. The First Applicant, Z[....]’s mother, is supported by Rare Diseases South Africa NPC, the Second Applicant – a non-profit organization which advocates for and assists the interests of persons with rare diseases.
4. The First Respondent is MediHelp Medical Scheme (“Medihelp”). Z[....]’s mother has been a member of this scheme for 10 years and he has been a dependant member from the day of his birth being 20 March 2019.
5. MPS II is a rare inherited genetic disorder which affects only 1 in every 100 000 people. The disease is caused by an enzyme deficiency in consequence of which the sufferer’s body cannot function normally. This deficiency, if left untreated, results in both bodily damage and developmental difficulties. These may affect not only appearance and mental development but also organ function and physical abilities[1].
6. It is not disputed that MPS II, being a genetic condition is incurable. However, Elaprase is the first and only registered treatment[2] that became available in the Republic and has been shown to be an effective treatment that can slow or even halt the progressive degenerative consequences which would ensue if left untreated with Elaprase.

7. Put simply, there is no other treatment available which has the efficacy of Elaprase. All the specialist medical practitioners who are treating Z[....] - Dr Govandragloo – a Specialist Paediatric Cardiologist, Dr Jeevarathnum – a Specialist Paediatric Pulmonologist and Dr Lamb a Paediatric Neurologist have motivated the provision of Elaprase as being an essential part of Z[....]'s treatment.
8. Z[....] was first diagnosed with MPS II when he was 2 years old. In July 2021, he was first prescribed Elaprase. His condition at that stage was relatively stable but was to be assessed every 6 months. A request for authorization by MediHelp to pay for the treatment of Elaprase submitted in July 2021 was declined.
9. A number of reasons were originally proffered by MediHelp for why it was not prepared to authorize payment for Elaprase – these included that treatment of MPS II was not a registered prescribed minimum benefit, that even if it were a prescribed minimum benefit condition, the treatment with Elaprase was not available in the public health service and was thus not a prescribed minimum benefit, that the health benefit plan of which his mother, and him being a dependent, was a member did not cover chronic medications that do not qualify as prescribed minimum benefit level of care and lastly that the benefit plan did not cover treatment with medications of the nature of Elaprase.
10. After Z[....]'s diagnosis and MediHelp's rejection of the authorization, it came to the attention of the Applicants that a similar matter involving another medical scheme was being considered by the Second Respondent – the Council for Medical Schemes ("CMS"). This matter was referred to by the parties in this matter as the 'Polmed' matter and will also be referred to as such in this judgment. Given that the time lines for submission, consideration and a decision on complaints is relatively lengthy, specifically having regard to the resources available to the CMS, a decision was taken by the Z[....]'s

mother, while his condition was relatively stable, to await the outcome of that matter as it was likely to be of assistance in

determining the dispute with MediHelp.

11. The decision of CMS in that matter was subsequently handed down on 1 October 2020, then taken on appeal, and the appeal dismissed on 1 February 2022. In its ruling in the Polmed matter, CMS found that MPS II is a prescribed minimum benefit ("PMB")

condition and ordered that payment be made by Polmed for Elaprase as well as all ancillary symptomatic treatment.

12. Between the time of Z[....]'s initial diagnosis and the CMS ruling in the Polmad matter, his condition remained relatively stable. Application was made again for authorization after the dismissal of the appeal and on 15 February 2022, the authorization was again declined by MediHelp.

13. When Z[...] was examined in April 2022 by Dr Govandragloo, a significant deterioration in his heart valves was noted. By July 2022, when he was again examined by Dr Jeevarathnum, further damage to his heart valves was noted as well as enlarging of his liver. His conclusion after this latest examination was that 'ongoing failure to commence treatment will result in further decline of cardiac, respiratory and neurological symptoms decreasing his life expectancy.'
14. It was this report and the opinion expressed by Dr Jeevarathnum, that was the catalyst for the bringing of the present application and its enrolment on the urgent roll for hearing.
15. Somewhat lamentably, MediHelp opposed the urgent hearing of the application on 'The basis on which the application is brought is not commensurate with the actual degree of urgency and not justifiable on the facts.'

It was contended by MediHelp that any urgency was self-created and that the First Applicant ought to have brought the application at a much earlier stage – having effectively been supine for a year. MediHelp was dismissive of the reasons why an application had not been brought any sooner and displayed a marked lack insight into why the First Applicant, while Z[...]’s condition was relatively stable and had an expectation that the dispute could be resolved, would not want to embark on costly litigation against MediHelp.

16. The Applicants’ contention that the lodging of a complaint with the CMS would not address the imminent concern of Z[...]’s deterioration without Elaprase because of the time that such a process would take was met with the response that 'At the very least, the Applicant could and should, have lodged a complaint with the Council as the designated statutory Regulatory Body, which would not have involved in the Applicant in any costs at all. The Applicant could and should also have requested an expedited hearing by the Council, which the Council is fully empowered to do and, in my experience, has done previously in other matters.'
17. This notwithstanding that the First Applicant in her founding affidavit had informed MediHelp of the Second Applicant’s endeavour on her behalf to do just that and having a representative of the CMS inform the Second Applicant by WhatsApp message that 'The CMS has more cases than the system can handle. Our committee tries its best but the weight of the cases is heavy especially as cases are dealt with by Board members who are not full time employees. It would have been ideal to have a full time adjudication unit that resolves these cases on a daily basis instead of bi-monthly.'
18. In dealing with this aspect in reply, the Applicants provided a table setting out when the various complaints brought in respect of MPS II had been brought to the CMS and had been finalised. The average time period with the complaint being finalised within the shortest period of time taking 292 days and the one taking the longest period of time 713 days, the average time period was 486 days – more than a year. The Polmed matter took 680 days – almost 2 years. Given Z[...]’s condition and the deterioration thereof, he simply may not have at best just over a year and at worst almost 2 years to wait for a complaint to the CMS to be

resolved.

19. For the reasons set out above which clearly establish that the life and quality of life of a young child will be affected should this application not be heard, I find that the application is urgent.
20. The CMS appeal ruling in the Polmed matter of 1 February 2022 represented a positive outcome for Z[...] in that MediHelp conceded in its answering affidavit that MPS II is in fact a PMB benefit condition. MediHelp conceded further that it falls into PMB category 901K. In the present case MediHelp did not persist with any of the other initial reasons given for refusing authorization –

as set out above.

21. MediHelp did persist however in arguing that it was under no obligation to authorize payment for Elaprase, notwithstanding its concession that MPS II is a category 901K PMB condition. It was argued that the prescribing of Elaprase was not a ‘prevailing predominant public hospital practice’ and that consequently it was not obliged to authorize payment for it.
22. The basis for this argument is found in Section 29(1)(o)[3] read together with Section 67(1)(g) [4] and Regulations 7 and 8 in terms of the Medical Schemes Act[5].
23. Annexure A to the Regulations of the Medical Schemes Act provides in the category ‘Endocrine, metabolic and nutritional’ that code 901K with diagnosis - ‘Life threatening congenital abnormalities of carbohydrate, lipid, protein and amino acid metabolism’ is to be treated by ‘Medical Management’.
24. The explanatory notes to Annexure A provide that:

“(2) Where the treatment component of a category in Annexure A is stated in general terms i.e. 'medical management' or 'surgical management', it should be interpreted as referring to prevailing hospital based medical or surgical diagnostic and treatment practice for the specified condition. Where significant differences exist between Public and Private sector practices, the interpretation of the Prescribed Minimum Benefits should follow the predominant Public Hospital practice, as outlined in the relevant provincial or national public hospital clinical protocols, where these exist. Where clinical protocols do not exist, disputes should be settled by consultation with provincial health authorities to ascertain prevailing practice”

25. In other words, while conceding that MPS II is a PMB condition for which it is obliged to provide cover, it is argued that the treatment to be provided is limited to ‘medical management’.
26. Since Elaprase is a relatively new treatment and carries with it a substantial cost, it was argued that while it may be the prevailing and preferred treatment protocol within the private healthcare sector, the same cannot be said for the public healthcare sector.

27. It was argued further that since it was not established that the prescribing of Elaprase is the prevailing public health sector

practice, Medihelp ought only to have to provide palliative or supportive care which it was argued by implication excluded Elaprase.

Thus, it was not the payment[6] per se that was being challenged but rather whether Elaprase was the treatment that had to be paid for.

28. The CMS Polmed ruling had found MPS II to be a PMB condition and had recorded an acknowledgement that there were differences between private and public healthcare service practice. Notwithstanding this however, the CMS had found that existing practice, without Elaprase, fell squarely within the ambit of Regulation 15H(c) which provides that 'provision must be made for appropriate exceptions where a protocol has been ineffective or causes or would cause harm to a beneficiary'.
29. The Polmed ruling did not deal at all with the issue raised by Medihelp in the present matter. The complaint in the Polmed matter had been first made on 23 March 2020 only 2,5 years after Elaprase was first registered. It is thus hardly surprising that there was at that stage, little or no evidence of any 'prevailing' or 'predominant' public hospital practice. The position is different now almost 5 years later.
30. Medihelps' concession that MPS II is a PMB condition was made in its answer to the application. It was only at that stage that the Applicants became aware of the fact that the opposition was to be predicated on this nuanced interpretation of what treatment should be provided having regard to the explanatory note.
31. That Z[....]'s treating team of Drs Govandragloo, Jeevarathnum and Lamb all of whom are in the private sector and all of whom supported the provision of Elaprase, put the question of prevailing private healthcare practice beyond issue.
32. It seems apparent that the only issue that MediHelp could place in dispute was regarding the practice in the public healthcare service. The argument was predicated on the following passage in the founding affidavit, dealing with the explanatory note in the Regulations relating specifically to a situation where there are significant differences in private and public sector practices and where it was stated: 'I submit that this step in the test is not applicable in the instance of a rare disease specifically as there is no 'predominant' standard of care, nor are there provincial or national hospital protocols.' The submission is specifically qualified with reference to 'a rare disease'.
33. The Applicants in reply dealt comprehensively with this argument and provided affidavits from the of heads of the Paediatric Rare Diseases Unit (Dr Varughese) and also the Rare Diseases Unit (Professor Jacobson) at Charlotte Maxeke Academic Hospital in Johannesburg
- a public healthcare facility.

34. They confirmed that within their facility Elaprase was prescribed to patients with MPS II and this was supported by an affidavit from Dr Klein of Sanofi Specialty Care, the pharmaceutical company that supplies Elaprase who also confirmed the supply of Elaprase to the public healthcare service and to facilities besides the Charlotte Maxeke Academic Hospital in Johannesburg.
35. They also confirmed that there are, due to the rarity of MPS II, no local protocols for dealing with it and that for this reason, the European guidelines are followed and are the de facto protocols.
36. Dr Klein also confirmed that Elaprase is also supplied to the Red Cross Children's Hospital in the Western Cape, Ladysmith Provincial Hospital in KwaZulu Natal, Steve Biko Academic Hospital in Gauteng, Frere Hospital in the Eastern Cape, Newcastle Hospital in KwaZulu Natal and Mossel Bay Hospital in the Western Cape.
37. It was argued for Medihelp that I should disregard the affidavits establishing that Elaprase is available in the public healthcare

service. The argument was predicated upon the contention that this aspect had not been specifically raised by the applicants in their founding papers. In this regard I was referred to the decision of the Supreme Court of Appeal in *Quartermark Investments v Mkhwanazi*[7] in which it was held that:

"[13] It is trite that in motion proceedings affidavits fulfil the dual role of pleadings and evidence. The serve to define not only the issues between the parties but also to place the essential evidence before the court. They must therefore contain the factual averments that are sufficient to support the cause of action or defence sought to be made out. Furthermore, an applicant must raise the issues as well as the evidence upon which it relies to discharge the onus of proof resting on it, in the founding affidavit."

38. Was the issue of the prevailing or predominant practice in the public healthcare service a foreseeable issue that the applicants ought to have dealt with in their founding papers? It is readily apparent that at no stage from July 2021 until the filing of the answering affidavit in August 2022 was this issue ever raised. It was raised for the first time in the answering affidavit and so at least insofar as the affidavits of Dr Varughese, Professor Jacobson and Dr Klein are concerned, they address this issue directly.
39. The Applicants approached this court for interim relief – the core issue being whether Medihelp would accept that Z[...]’s condition did in fact qualify as a PMB. The issue to be determined was raised for the first time by MediHelp in its answering affidavit.
40. The evidence relating to this contained in the replying affidavit is not new matter as was argued for Medihelp but rather a conclusive rebuttal of Medihelps’ allegation that ‘The Public Hospital and Public Sector practice has always been and still is limited to palliative treatment and does not include ‘Elaprase’ as treatment.’ This was a bald allegation without any basis having been laid for its making.

41. This issue was not in my view reasonably foreseeable and the applicants, given the nature of the dispute, quite properly dealt with it in reply. Insofar as the replying affidavits deal with this, they are admitted[8]. To exclude them from consideration in this matter would to my mind result in an injustice.[9]
42. What is apparent from the affidavits of all the doctors and undisputed to my mind is that the use of Elaprase is the only available treatment for MPS II in both the private and public sectors. It also was argued for Medihelp that 'availability' ought not to be equated with 'prevalence' or 'predominance'.
43. Elaprase is provided in the public healthcare service in the four most populous of the Republic's 9 provinces and in some instances, notwithstanding the rarity of the condition, in more than one public hospital in a particular province.
44. What is clear is that Elaprase is both available and used by both the private and the public healthcare service for the treatment of MPS II – given that the condition is so rare, it is hardly surprising that the numbers of patients for whom it is prescribed are so low. It seems to me to be self-evident that if 'prevalence'[10] or 'predominance' are to be the criteria upon which the use of Elaprase is to be measured then it must be so measured within the context of the very low patient numbers. The rarity of the condition means that the criteria that must be applied, and the regulations and their explanatory notes construed in this context[11]. To do otherwise would render them ineffective for rare conditions or those with low patient numbers.
45. By all accounts in the circumstances, the Applicant has established at the very least, that prima facie, the use of Elaprase is a prevailing and predominant public hospital practice for this rare condition.
46. There is another aspect to consider. Medihelp has characterized the treatment available in the public healthcare sector as being
- 'palliative'. Palliative[12] treatment is treatment to alleviate the symptoms of a disease. It must be distinguished from curative[13] treatment which cures a disease. It is not in issue that Elaprase is not curative of MPS II but is in fact a palliative treatment. This serves to reinforce my view that the applicant has established a prima facie right.
47. For the reasons set out above, I find that the Applicants have met the requirements for the granting of the interim relief sought in Part A of the application. In summary, the Applicants have established:
- 46.1 That MPS II is a PMB condition and that prima facie there is no significant difference between private and public sector healthcare practice with regards to prescribing of Elaprase.
- 46.2 That the deterioration in Z[...]'s condition over the last year but in particular since April 2022, means that if he is not afforded treatment with Elaprase, his life and quality of life will be irreparably adversely affected;

46.3 That the balance of convenience on consideration of the matter as a whole favours the granting of the interim order sought and;

46.4 That there is no alternative remedy that is available having regard to the deterioration in Z[...]'s condition and the time it is likely to take for the CMS complaint[14] to be finally determined.

48. In the circumstances it is ordered:

47.1 The condition that Z[...] D[...] ("Z[...]") has been diagnosed with, namely Hunters Syndrome MPS II is declared a Prescribed Minimum Benefit (PMB) Condition under the category 901K as listed in Annexure A of the Regulations of the Medical Schemes Act, 131 of 1998.

47.2 Pending the resolution of Part B, the First Respondent is ordered to:

47.2.1 authorize the treatment and care costs of all medical interventions required by Z[...] and prescribed by his treating practitioners for Hunters Syndrome MPII as PMB level of care, which treatment includes inter alia Elaprase, a registered enzyme replacement therapy, within 30 days of this order;

47.2.2 to pay accounts and/or claims for healthcare services rendered by the treating practitioners within 30 days of presentation of the account and/or claim thereof, in accordance with regulation 6 of the Medical Schemes Act, 131 of 1998.

47.3 The First respondent is ordered to pay the costs of the application to date.

A MILLAR

JUDGE OF THE HIGH COURT

GAUTENG DIVISION, PRETORIA

HEARD ON:

23 AUGUST 2022

JUDGMENT

DELIVERED ON:

26 AUGUST 2022

This judgment was handed down electronically by circulation to the parties' representatives by email, by being uploaded to the Caselines system of the GD and by release to SAFLII. The date and time for hand-down is deemed to be 10H00 on 26 August 2022.

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NO APPEARANCE FOR THE SECOND RESPONDENT

- [1] <https://www.mayoclinic.org/diseases-conditions/hunter-syndrome/symptoms-causes/syc-20350706>.
- [2] 29 September 2017
- [3] ‘The scope and level of minimum benefits that are to be available to beneficiaries as may be prescribed’
- [4] ‘The prescribed scope and level of minimum benefits to which members and their registered dependents shall be entitled to under the rules of a medical scheme’
- [5] 131 of 1998
- [6] Distinguishing this matter from Council for Medical Aid Schemes and Another v Genesis Medical Scheme and Others 2016 (1) SA 429 (SCA)
- [7] 2014
- (3) SA 96 (SCA) at 100J-101B; National Director of Public Prosecutions v Zuma [2009] ZASCA 1; 2009 (2) SA 277 (SCA) at 290E-G
- [8] Rens v Gutman NO and Others 2003 (1) SA 93 (C) at 99I; Body Corporate, Shaftsbury Sectional Title Scheme v Rippert’s Estate 2003 (5) SA 1 (C) at 6G/H – H and I
- [9] Section 28(2) of the Constitution of the Republic of South Africa provides that a child’s best interests are paramount in every matter concerning the welfare of the child.
- [10] “prevailing” – ‘generally current or accepted’ but also ‘predominant in extent’ – The Shorter Oxford English Dictionary (SOED), Oxford University Press, 2007, 6th Edition, Volume 2, page 2340
- [11] Constitutional Court in Minister of Police v Fidelity Security Services (Pty) Ltd [2022] ZACC 16 – decided on 27 May 2022;

[12] “Palliative care” – from ‘palliate’ – alleviate the symptoms of (a disease) without effecting a cure; relieve or ease (suffering) superficially or temporarily. SOED supra, Volume 2, page 2079.

[13] “curative” – “able or tending to cure” – SOED supra, Volume 1, page 582

[14] The order sought is an interim one and is susceptible to alteration subject to the outcome of the CMS complaint. It is accordingly not a final order nor, given the palliative nature of treatment with Elaprase is it final in effect. See *City of Cape Town v South African Human Rights Commission* (144/2021) [2021] ZASCA (22 December

2021) at para 8

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