South African Medical Technology Industry Association (SAMED)

Submission relating to GNR 3795 of 2023: Regulations Regarding fees payable in terms of the provisions of the Medicines and Related Substances Act 101 of 1965

3 November 2023

Department of Health

Dr Sandile Buthelezi

Director-General National Department of Health

Attention:

Director-General of Public Entities

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In re: Submissions on GNR 3795 of 2023: Regulations Regarding fees payable in terms of the provisions of the Medicines and Related Substances Act 101 of 1965 ("Draft Fee Regulations")

Introduction

1. On 20 July 2023, the Department of Health ("the Department"), published the Draft Regulations Regarding fees payable in terms of the provisions of the Medicines and Related Substances Act 101 of 1965, GNR 3795 of 2023 ("2023 Draft Fees Regulations").
2. SAMED – The South African Medical Technology Industry Association – represents the interests of 152 medical device, medical equipment and in-vitro diagnostic (IVD) (collectively referred to as "medical technologies") companies in South Africa. SAMED is committed to ensuring a sustainable, ethical and transformed medical technology industry.
3. SAMED urges that, prior to deciding on fees for regulatory activities, the following matters be addressed:
   3.1. The finalisation of the medical device regulations, as the fees must follow the extent and nature of device regulatory activities;

3.2. The finalisation of regulatory processes and timelines, as required by section 30(1)(xliii) of the Medicines Act, as an important indicator of the performance of key regulatory activities;

3.3. The impact of various fees and fee levels on companies, bearing in mind the numbers of SKUs in the market, and the short life cycles of medical devices. This requires a proper impact study, both in terms of the impact on SAHPRA and therefore the corresponding fee requirements, and on the companies, as fees will, so at seems at present, add to the cost of medical devices in the market.

4. SAMED, therefore, is of the view that the 2023 Draft Regulations are irrational in that there is no rational connection between the objective the 2023 Draft Fees Regulations seek to achieve and the means used to achieve it.

5. The 2023 Draft Fees Regulations also lack proportionality, as there may be other, less restrictive and less burdensome means which would achieve the objectives of the Medicines and Related Substances Act, 1965 and the still to be finalised medical device regulations. Moreover, it is anticipated that the 2023 Draft Fees Regulations, in their current form, will have significant negative consequences for the medical device and IVD industry. In light of this, we are of the view that the 2023 Draft Fees Regulations fall foul of the requirement of reasonableness, which is closely related to the principle of legality. Therefore, the 2023 Draft Fees Regulations is potentially unlawful and, once promulgated are susceptible to being reviewed and set aside. SAMED obviously wishes to avoid such a situation, and would prefer to partner with the regulator in, specifically, the studies referred to above.

6. Accordingly, and until the aspects set in par 3 above are met, the 2023 Draft Fees Regulations, at least insofar as the incomplete regulatory frameworks for medical devices and IVDs are concerned, should be withdrawn.

Overview of draft regulations

7. The 2023 Draft Fees Regulations introduces fees and has increased existing fees.

8. A comparison, in table format, between the fees charged in the 2020 Regulations and the introduction of new fees and the fee increases in the 2023 Draft Fees Regulations, is annexed hereto and marked as **"Annexure A"**.

9. Apart from the fees that have been newly introduced, not only are the monetary amounts for some of these fees unexplained, but the very the nature of these fees (i.e. when it would be applicable) are vague and uncertain.

10. SAMED is of the opinion that in the absence of any legitimate reasons provided for the introduction of new fees for the application and registration for medical devices and IVDs together with minor and major fee increases, the 2023 Draft Fees Regulations:

10.1. Are irrational and may be subject to a review under the Promotion of Access to Justice Act 3 of 200;

10.2. Violates s 22 and s 25 of the Constitution of South Africa; and

10.3. Are tainted in their publication with a procedural irregularity.

11. In what follows, we deal with each of these grounds in turn.

2023 Draft Fees Regulations are irrational

12. The introduction of new fees concomitant with instances of significant price increases for existing fees will have significant operational and cost implications for importers, manufacturers and distributors. SAMED goes further to argue that these increases would undoubtedly impact adversely on smaller manufacturers/distributors and manufacturers/distributors of niche/specialised medicines and medical devices. This direct contradicts government policy objectives in terms of the ease of doing business in South Africa, the reduction of red tape and the priority to be placed on nurturing the SME sector in South Africa.

13. In addition, the 2023 Draft Fees Regulations may have far-reaching consequences, as importers of medical devices and IVDs, who also have to comply with the regulations, might be inclined to withdraw their products from the market as a result of the fee increases, unexplained fees and the inability to anticipate when certain fees would apply, and when not. This could ultimately result in disinvestment, lack of access for patients to niche/specialised medical devices and IVDs which would no doubt have a major knock-on effect on the country's trade and the economy in general.

14. Significantly, this will impact the right of access to healthcare to patients, and the link between access to healthcare, and the viability of the business of medical device suppliers. The fees may have an impact from a logistical and supply-chain point of view, which would inevitably affect the users, for example healthcare professionals, nurses etc and patients in a further challenging predicament, namely the availability of medical devices and IVDs, in that the smaller manufacturers and distributors will have to engage in a highly complex and expensive "balancing act", unduly to their detriment, in order to comply with the 2023 Draft Fees Regulations.

15. All affected parties, be it importers, manufacturers, distributors, would be financially prejudiced by the 2023 Draft Fees Regulations on a plethora of levels including, but not limited to, marketing, sales and profitability. This could never have been the intention of the regulations.

16. In this regard, there has been absolutely no impact analysis assessment, debate or justification proffered for the introduction of new fees and the significant fee increases, when compared with the 2020 Regulations. This is contradictory to the requirement that laws must promote legal certainty and be clear to those who are required to comply with them.

17. No justifiable reasons are provided why certain new fees have been introduced and why existing fees were subject to significant increases.

18. It is our view, with respect, that the Draft 2023 Fees Regulations are arbitrary and capricious, rendering them susceptible to possibly being subject to a review under section 6(2)(e)(vi) of Promotion of Access to Justice Act 3 of 2000.

19. Every importer, distributor and manufacturer, affected by the fee changes and new fees, must be provided with reasons for the introduction of new fees and significant increases.

20. SAMED has conducted a survey amongst its members and preliminary feedback confirms that the impact on companies, and the cost of bringing products to market, including upgraded products (amendments), would be significant, if not prohibitive. This will therefore impact access to healthcare, the availability of products and the competitiveness of companies, and the country, in terms of investment.

21. In view of the fee comparison provided in Annexure A, it is submitted that the 2023 Draft Fees Regulations evince irrationality.

22. As alluded to above, final amended Medical Device Regulations have not yet been published, nor have medical device and IVD product registration procedures, requirements and timelines been finalised. It is SAMED's view that introducing medical device and IVD registration fees is premature and irrational until such time as the regulations and processes governing medical device and IVD registration are finalised i.e. a situation of putting the 'cart before the horse'. Fundamental decisions, such as the non-review, but only listing of class A medical devices, have not yet been made, and therefore the introduction of fees for all classes of medical devices makes little sense.

Violation of Freedom of trade, occupation and profession, and the right to property

23. Given SAMED's submission that the 2023 Draft Fees Regulations are irrational and disproportional, the question arises whether the regulations are consistent with the Constitution of South Africa. SAMED would submit that they are not.

24. As a point of departure, section 22 of the Constitution states that: "Every citizen has the right to choose their trade, occupation or profession freely. The practice of a trade, occupation or profession may be regulated by law."

25. On the interpretation and application of s 22 of the Constitution it has previously been held by the Constitutional Court[1] that:

    25.1. *the right to engage 'freely' in economic activity should not be construed as conferring such a right on unqualified persons; nor should it be construed as entitling persons to ignore legislation regulating the manner in which particular activities have to be conducted, provided always that such regulations are not arbitrary*; and

[1] See S v *Lawrence* 1997 (1) SA 1176 (CC) at para 33.

25.2. *Arbitrariness is inconsistent with 'values which underlie an open and democratic society based on freedom and equality', and arbitrary restrictions would not pass constitutional scrutiny*."

26. In the circumstances, SAMED is of the view that the 2023 Draft Fees Regulations are arbitrary and violate the rights of importers, distributors and manufacturers to exercise their trade freely, in that the 2023 Draft Fees Regulations may be irrational as there is no legitimate reason or rationale behind the introduction of new and exorbitant fees without providing any justification for them.

27. Section 25(1) of the Constitution prohibits the deprivation of property except in terms of a law of general application. It further specifies that no law may permit arbitrary deprivation of property. The 2023 Draft Fees Regulations are a law of general application.

28. Medical devices and IVDs constitute the property of either the manufacturers, importers and/or distributers. More strikingly, the Constitutional Court had previously assumed, without finding, that a claim for loss of earning capacity or support is property.[2]

29. Hence, in the present circumstances, the sale of property in the form of medical devices and IVDs is the basis of which importers, manufactures and distributors derive an income.

30. In the circumstances, introducing fees to register medical devices and IVDs may, as already stated above, cause financial prejudice, adversely affect the economic viability of the respective importers, manufacturers and distributor entities, and cause irreparable harm and loss.

31. Furthermore, the 2023 Draft Fees Regulations interfere with the rights of importers, manufacturers and distributors to use and benefit from their property, including commercialising it as they see fit. This interference amounts to a deprivation as referred to in section 25 of the Constitution.

32. In view of the 2023 Draft Fees Regulations, the SAHPRA and the Department has, for example, failed to explain why a fee is charged for a request for an application number (per number)(in the amount of R 2000 or for a request for a borderline product status review in the amount of R15 000 in Regulation 2. The allocation of application numbers are part of the run of the mill activities of SAHPRA, which should not require an additional fee. The "review" of a borderline product would require a simple evaluation of compliance with an existing guideline, and should also not be excessively burdensome or costly to SAHPRA to do.

33. Moreover, no explanation is provided why a set of fees for medical devices (IVDs and non-IVDs) in Regulation 8 is introduced, for example, charges for reliance; full assessment; registration approval and the rest of the fees charged in the mentioned regulation, in the absence of any regulatory framework relating to these as it would pertain to medical devices and IVDs specifically, most significantly relating

[2] See *Law Society of South Africa and Others v Minister for Transport and Another* 2011 (1) SA 400 (CC) at para 84. See also *The National Credit Regulator v Opperman* 2013 (2) SA (CC) at para 62.

to what those regulatory activities would mean, in practical terms for various classes and types of medical devices and IVDs.

34. The Department- and SAHPRA's failure to provide sufficient reasons to justify the deprivation of property in this manner may be arbitrary in that:

    34.1. There is no correlation, or even nexus, between the goal sought to be achieved, presumably to cater for all administrative costs incurred (to undertake the regulatory activities) and the means selected to do so, namely the introduction of specific types of fees and the quantum or increase thereof;

    34.2. The objectives sought to be achieved by SAHPRA and the Department do not justify the 2023 Fee Regulations, given that no legitimate reasons have been provided nor an explanation that the fees are proportional, to achieve those objectives;

35. Importantly, it is an accepted principle that where the property in question is ownership of land (such as the site of a local manufacturer or distributor) or a corporeal moveable (such as the products at stake), the Department must provide a more compelling purpose in order for the depriving 2023 Draft Fees Regulations to constitute sufficient reason for the deprivation, as is this case in the present matter.

36. For all of these reasons there is no justification for the deprivation of property caused by the 2023 Draft Fees Regulations. The deprivation caused is accordingly arbitrary and is of a nature that is prohibited by section 25(1) of the Constitution.

37. As such the 2023 Draft Fees Regulations are unreasonable and unconstitutional. They are reviewable under section 6(2)(i) of PAJA for being unlawful and unconstitutional.

Procedural irregularity: Notification to the World Trade Organisation ito the interpretation and application of s 22 of the Constitution

38. The World Trade Organisation ("WTO") was established under the Marrakesh Agreement Establishing the World Trade Organisation ("WTO Agreement"). On 1 January 1995 South Africa became a member of the WTO. As a result, South Africa is bound by all agreements annexed to the WTO Agreement such as the Technical Barriers to Trade Agreement ("TBT Agreement").

39. According to article 2.9 of the TBT Agreement:

    "Whenever a relevant international standard does not exist or the technical content of a proposed technical regulation is not in accordance with the technical content of relevant international standards, and if the technical regulation may have a significant effect on trade of other Members, Members shall:

    "2.9.2. Notify other Members through the Secretariat of the products to be covered by the proposed technical regulation, together with a brief indication of its objective and rationale. Such notifications shall

take place at an early appropriate stage, when amendments can still be introduced and comments taken into account;"

40. In light of the above, South Africa was required to notify the WTO of the 2023 Draft Fees Regulations after publishing same in the *Government Gazette*; however, this was not done. The 2023 Draft Fees Regulations had not been published on the WTO website.

41. The Department's failure to comply with South Africa's notification obligations under the Technical Barriers to Trade Agreement:

    41.1. has caused the regulations to become tainted with procedural unfairness; and

    41.2. has had a direct and substantial impact on SAMED and all other local and international entities.

42. All parties with a direct and substantial interest to the 2023 Draft Fees Regulations must be afforded an opportunity to comment, as they materially affect the operation of their business, as already stated above.

43. This failure would, undoubtably, be a ground to review and set the 2023 Draft Fees Regulations aside in that an incorrect process was followed in the publication of the 2023 Draft Fees Regulations.

44. The promulgation of the 2023 Draft Fees Regulations is tainted with procedural unfairness, rendering the 2017 Regulations reviewable in terms of section 6(2)(c) of PAJA.

Recommendations

45. In the light of the above, it is evident that the 2023 Draft Fees Regulations are fundamentally flawed and potentially in contravention of PAJA and/or inconsistent with the Constitution of the Republic of South Africa, and are therefore susceptible to being reviewed and set aside. We are therefore of the view that the 2023 Draft Fees Regulations should be withdrawn.

46. SAHPRA and the Department must engage with SAMED and all other stakeholders so that legally compliant regulations can be promulgated.

47. A detailed impact analysis assessment should be conducted to identify the impact of the introduction of fees on the viability of the industry and potential impact on access of medical technologies for patients and users of medical technology i.e. regulations should do no harm.

48. It is SAMED's view that together with industry, research be undertaken to identify an activity based/defined fee model i.e. link the fee to the type and amount of activity required in terms of registration of different types of medical devices and IVDs.

49. Currently the wording of regulation 8(a) i.e. 'per application for a device' implies that registration fees will be required per device. This will cripple the industry, particularly small to medium companies who could have 1000's of devices in their catalogue. SAMED strongly urges that registration of medical devices and IVDs be done by type or family and/or group.

50. Considerations for start-up companies should also be considered. For example, a reduced fee be considered where a business, be it an importer, manufacturer and distributor, is in its first year of business in which it sells medical devices or if it has not yet completed a fiscal year.

51. The majority of medical device and IVD companies in South Africa are small to medium companies. In addition, company product portfolios differ substantially and it would be unfair to penalise and charge a company that sells lower priced, simple medical devices at the same rate as that of companies that sell very sophisticated more expensive items. The cost of doing business for different companies must also be taken into account.

52. SAHPRA should also consider adding wholesaling to the scope of a manufacturing and distribution licence. This would eliminate the need for two licences and therefore reduce cost for industry and unnecessary administration for SAHPRA. Manufacturers and distributors already have the required systems for good wholesaling practices in place.

53. As "Reliance" is one of the registration approval mechanisms referred to in the proposed fees schedule, large fees are unjustified as the intensive review of technical files would be performed by Conformity Assessment Bodies (CABs) and Regulators outside of South Africa (per mutual recognition agreements). The Reliance Model is clear, and tested, where medicines are concerned. This is not the case with medical devices. In addition, one should consider the additional cost of CABs, which does not apply to medicines. CABs fulfil much of the role that SAHPRA fulfils for medicines registration, in the case of medical devices. This must be considered in order to get to an appropriate fee. The actual administration for product registrations should be minimal (as benchmarked with the Radiation Control process that requires an application form and approximately 5 supporting documents which do not require lengthy review). Reliance as it pertains to medical devices and IVDs is also not defined. Mention is made of 'reliance' countries and WHO Prequalification in the medical device and IVD establishment licencing requirements but no official definition of reliance has been published. What if these reliance countries change over time? How will this be accommodated. And on what basis is reliance arrived at? These are details that should be clarified and finalised prior to deciding on the necessity for and quantum of registration fees.

54. Fees should also be levied according to some form of reciprocal "contract" with performance measures and a commitment to achieving efficiency. SAHPRA should also consider automating and / or creating on-line systems and processes. This will reduce cost and reliance on manual resources.

55. There are also discrepancies and ambiguities in the 2023 Draft Fees Schedule. It is unclear how registration of medical device categories, families and groups will be handled – this will make a material difference to the quantum levied on companies and must be clarified before any sensible assessment or comment can be submitted. This again illustrates the necessity to first formalise the Medical Device Regulations, and the Guidelines that will accompany it, prior to making decisions on appropriate fees and the quantum thereof.

56. Some classes in the schedule seem to be redundant – a duplicate fee is levied that has already been listed under another section. The schedule should be clear and unambiguous.

57. The 2023 Draft Fees Regulations appear to have been, largely, derived from a framework designed for medicines. SAMED requests that SAHPRA develop and publish a separate Fees Payable Notice in terms of medical devices and IVDs and/or clearly state in the current Draft which regulations are applicable to medical devices and IVDs, and which not.
58. SAMED and its members are a key role player in the implementation of the Medical Device Regulations and the costing thereof. We request that we be provided the opportunity to meet in person with SAHPRA to discuss the contents of our submission and arrive at a fee schedule better suited to our industry.
59. We trust that you will be guided accordingly and await to hear from you.

Yours Sincerely
Tanya Vogt
SAMED Executive Officer

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