JOINT SECTION27, DOCTORS WITHOUT BORDERS (MSF) & TREATMENT ACTION CAMPAIGN SUBMISSION ON THE DRAFT GENERAL MEDICINE REGULATIONS MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT 101 OF 1965

28 APRIL 2017

INTRODUCTION

1. On 27 January 2017, the Minister of Health published Draft General Regulations to give effect to the Medicines and Related Substances Amendment Act 72 of 2008 and the Medicines and Related Substances Amendment Act 14 of 2015. These Regulations are made in terms of the Medicines and Related Substances Act 101 of 1965 ("the Act"). In this submission, we refer to the regulations as the "Draft Regulations".

2. SECTION27, Médecins Sans Frontières (MSF) and the Treatment Action Campaign (TAC) welcome the opportunity to comment on the Draft Regulations, which brings the operation of the South African Health Products Regulatory Authority (SAHPRA) another step closer. SECTION27, MSF and TAC have, for many years, been involved in advocacy for appropriate and efficient regulation of medicines and other products in line with the constitutional right of access to health care services. We also welcome the Minister of Health's efforts to finalise the long process of transitioning the Medicines Control Council (MCC) to a more efficient and effective SAHPRA.

3. The MCC plays a crucial role in safeguarding health in South Africa, by ensuring the quality, safety and efficacy of medicines that are registered, marketed and used in the country. With the transition of the national regulatory agency from the MCC to SAHPRA, it is crucial that this same role is maintained, and improved in areas where inefficiencies exist and that continuity and certainty is provided for the stakeholders, including the pharmaceutical industry, health care providers, health care users and the public at large.

4. This submission is made in the spirit of the MCC's aim of transforming itself into the transparent, efficient and effective SAHPRA.

GENERAL COMMENTS

5. Before commenting on the substance of the Draft Regulations, we have highlighted some of the key aspects of the context within which the Draft Regulations are intended to operate. At the heart of this framework is the right of access to medicines that comply with the requirements of quality, safety and therapeutic efficacy. This right should be advanced through the operation of the Draft Regulations as part of the Department of Health's constitutional obligations.

<u>The functions and duties of the Regulatory Authority in the context of the right to health.</u>

6. Section 27 of the Constitution of the Republic of South Africa, 1996 ("Constitution"), insofar as it entrenches the right to health, provides as follows:

> *(1) Everyone has the right to have access to –*
>
> *(a) Health care services, including reproductive health care;*
>
> *(b) . . .*
>
> *(c) . . .*
>
> *(2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.*
>
> *(3) No one may be refused emergency medical treatment.*[1]

7. The Act is one of the legislative measures referred to in section 27(2): it regulates, among other things, the public's access to medicines that comply with the requirements of quality, safety and therapeutic efficacy. In this regard section 1(3) of the Act provides that *"in determining whether or not the registration or availability of a medicine is in the public interest, regard shall be had only to the safety, quality and therapeutic efficacy thereof in relation to its effect on the health of man or any animal, as the case may be."*

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[1] Section 27 of the Constitution.
[2] Section 195(1)(a) of the Constitution.
[3] Section 195(1)(b) of the Constitution.
[4] Section 195(1)(g) of the Constitution.
[5] *Administrator, Cape v Raats Röntgen and Vermeulen (Pty) Ltd* 1992 (1) SA 245 (A) at 254B – E.

8. In addition to its obligations arising from the right to health, the regulatory authority, as an organ of state, is also bound by the basic principles and values governing public administration set out in section 195 of the Constitution. These include –

    8.1. A high standard of professional ethics must be promoted and maintained.[2]

    8.2. Efficient, economic and effective use of resources must be promoted.[3]

    8.3. Transparency must be fostered by providing the public with timely, accessible and accurate information.[4]

9. The importance of the role of SAHPRA's predecessor, the MCC, was described by Kriegler AJA (as he then was) as follows:

    Manifestly the [Medicines] Act was put on the statute book to protect the citizenry at large. Substances for the treatment of human ailments are as old as mankind itself; so are poisons and quacks. The technological explosion of the twentieth century brought in its wake a flood of pharmaceuticals unknown before and incomprehensible to most. The man in the street – and indeed many medical practitioners – could not cope with the cornucopian outpourings of the world-wide network of inventors and manufacturers of medicines. Moreover, the marvels of advertising, marketing and distribution brought such fruits within the grasp of the general public. Hence, an Act designed, as the long title emphasizes, to register and control medicines. The enactment created a tightly meshed screening mechanism whereby the public was to be safeguarded: in general any medicine supplied to any person is, first, subject to stringent certification by experts; then it has to be clearly, correctly and comprehensively packaged and labeled and it may only be sold by certain classes of persons and with proper explanatory information; to round it out

[2] Section 195(1)(a) of the Constitution.
[3] Section 195(1)(b) of the Constitution.
[4] Section 195(1)(g) of the Constitution.

detailed mechanisms for enforcement are created and ancillary measures are authorized.[5]

10. De Villiers J described the MCC's role as follows:

The respondents are public authorities who are charged with the duty of promoting and protecting the public interest through the mechanisms of the Act. It is common cause that it is necessary and desirable that the public interest should be protected by the regulation and control of medicines. The fact that Florex or the substances it contains do not appear to be directly harmful to the public is not conclusive of this issue because the respondents are not only charged with protecting the public against the use of unsafe or harmful substances, but also with protecting the public against ineffective substances of which the quality is not properly controlled.[6]

11. The duty on the Regulatory Authority may therefore be summarised as follows:

11.1. It is the right of members of the public to have access to medicines as defined in the Act.

11.2. This right of access applies to medicines of a high quality and of an established therapeutic efficacy. Where a substance is ineffective in achieving its intended purpose, the Regulatory Authority's duty in relation to ensuring access to that substance is not triggered.

11.3. Where the therapeutic efficacy of a medicine is established, that is not the end of the matter. The Regulatory Authority has a duty to protect members of the public from unsafe substances that will have a negative impact on their health.

11.4. In each case, therefore, the Regulatory Authority is required to balance considerations of safety and therapeutic efficacy. Its duty is to ensure that

[5] *Administrator, Cape v Raats Röntgen and Vermeulen (Pty) Ltd* 1992 (1) SA 245 (A) at 254B – E.
[6] *Reitzer Pharmaceuticals (Pty) Ltd v Registrar of Medicines* 1998 (4) SA 660 (T) at 691H – 692B.

the public has access to medicines only where their therapeutic efficacy outweighs any safety concerns.

12. We deal with the issues of access and safety in particular in our discussion of the substantive provisions below. That discussion should be read against this background.

Transparency, Accountability and Communication

13. Transparency and accountability are pillars of effective medicines regulation, as defined by the WHO.[7] The MCC considers transparency and accountability to form part of its obligations.[8] Promoting public access to detailed information about regulatory processes and decisions falls squarely into these commitments, and should be a priority of SAHPRA. This includes information concerning applications for registration, the periods of time for consideration of applications, status of applications and granting or rejection of applications.

14. In December 2014, an application for the registration of sofosbuvir, a curative new drug used to treat hepatitis C, was filed at the MCC. To date, there has been no decision taken by the MCC. For patients needing it, it is impossible to know when the drug will be approved.

15. Similarly, lopinavir/ritonavir pellets, a long-awaited heat-stable formulation for treatment of children with HIV, is currently pending registration, and it is unclear when the medicine will be approved.

16. Obtaining information on the state of registration of these important new drugs or formulations remains dependent on one-to-one discussions with pharmaceutical companies and NDOH officials (which is not always successful), when it should be publicly available to any patient or health care worker.

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[7] Proceedings of the Ninth International Conference of Drug Regulatory Authorities (ICDRA). Berlin, Germany 25-29 April 1999. Access at: http://apps.who.int/medicinedocs/en/d/Js4925e/2.html

[8] Presentation by Dr. Peter Eagles. Chairperson MCC. Access at: http://www.mccza.com/documents/a71edc75CAMs_workshop_Feb2014_IntrotoAct101Prof_Eagles.pdf

17. Registration timelines for all existing procedures, which will be discussed further throughout this document, should be clearly set out in the Draft Regulations and used as one of its performance indicators. Using current information technologies to create a tracking system that allows patients and healthcare providers to follow dossier review advancement should be made a priority. This should be done for both Finished Pharmaceutical Products and Active Pharmaceutical Ingredients. The tracking systems should include details on type of procedure, progress stage, and expected timelines. If the dossier is rejected, the rationale for rejection should be communicated. At the conclusion of the assessment, the assessment report should be made publicly available with the final decision (approval or rejection).

18. Such transparency can be accomplished without contravening business disclosure prohibitions outlined in Section 34 of the Act. The prohibition against disclosing information held by the MCC/SAHPRA is specifically limited to information "relating to the business or affairs of any person". The SAHPRA provide for mechanisms that allow for the disclosure of information in a manner that does not include proprietary business information rather than having a policy of non-disclosure of all information, regardless of the public interest that would be served by its disclosure.

19. Furthermore, the MCC Chairperson, Professor Helen Rees, was quoted as saying the following concerning transparency of the MCC:

> *We are keen to increase the transparency of the work of the MCC including giving more feedback to applicants about decisions made, more opportunities for pre-application discussions with applicants for issues that are unusual and/or of critical public health interest, and more transparency to the broader community about the workings and decisions of Council.*[9] (own emphasis)

[9] Spotlight. Interview with Dr. Joey Gouws "A new dawn for medicines regulation in South Africa" November 2016. Access at: http://www.spotlightnsp.co.za/2016/11/03/new-dawn-medicines-regulation-south-africa/

Transitional provisions and the backlog of registration applications

20. Once the Medicines and Related Substances Amendment Act 72 of 2008 ("2008 Amendment") comes into operation, SAHPRA will replace the MCC as the authority responsible for, inter alia, the registration of medicines, medical devices and IVDs. The Medicines and Related Substances Amendment Act 14 of 2015 ("2015 Amendment") will come into effect immediately after the 2008 Amendment.

21. Given the change over from the MCC to SAHPRA, it is essential that adequate provisions be put in place to ensure a smooth transition that continues to prioritise the right of access to medicines that comply with the standards of safety, quality and therapeutic efficacy.

22. The transition from the MCC to the SAHPRA is governed by section 26 of the 2015 Amendment. These transitional provisions include the following:

    22.1. The MCC will continue to perform its functions until the day before the first meeting of the Board appointed by the Minister of Heath in terms of section 2C of the Act.

    22.2. Anything done by the MCC that could have been done by the SAHPRA in terms of the Medicines Act will be regarded as having been done by SAHPRA.

    22.3. Medicines, medical devices and IVDs that are registered on the date of commencement of the 2015 Amendment will be regarded as having been registered by the SAHPRA, and will be entered in the relevant register.

    22.4. All employees will be transferred from the MCC and some from the National Department of Health to SAHPRA, with no interruption and no consequences for the purpose of tax law or labour law.

22.5. Registration applications and appeals that are pending before the MCC at the commencement of the 2015 Amendment must be dealt with by the Regulatory Authority as if the 2015 Amendment had not come into effect.

23. We understand the transitional provisions discussed in paragraph 22.5 above are intended to guard against interruptions and delays in pending registration and appeal processes as well as ensuring sufficient human resources. While we welcome this step, we submit that the Draft Regulations do not provide adequate detail to address what we understand is a substantial backlog in pending registrations and appeals.

24. In our discussion of the specific provisions below, we highlight the need for clear time frames for considering applications in Draft Regulation 5.

25. We submit that in addition to this, there should be clear time frames applicable to registrations and appeals that are already pending before the MCC, to give effect to the transitional provisions in the 2015 amendment. In other words, the Draft Regulations should provide for a window period in which all existing backlogs are addressed.

26. We understand that one of the key roles of the SAHPRA will be to address a substantial backlog in registrations and appeals, and that the SAHPRA will be able to fast track those matters pending before the MCC at the time of the transition.

27. In order to achieve this objective, and to ensure an accountable Regulatory Authority, we submit that clear time frames for this fast-tracking process should be provided.

28. Moreover, we emphasise the importance of compliance with all time periods to ensure that the backlog is not further increased.

COMMENTS ON SPECIFIC PROVISIONS OF THE DRAFT REGULATIONS

Time frames for considering applications

29. Draft Regulation 5 deals with time frames for considering applications for the registration of medicines, medical devices and IVDs. The Draft Regulation requires the SAHPRA to –

    29.1. As soon as practically possible, inform an applicant for registration or receipt of the application; and

    29.2. As soon as practically possible, inform an applicant on the acceptance of an application for evaluation.

30. While we welcome these provisions as a step towards accountability, we emphasise the need for specific time frames for the consideration of applications, including time frames within which SAHPRA is to inform an applicant of further information required and time frames for the communication of SAHPRA's decision.

31. Given the commitment to ensure a more efficient regulatory body, SAHPRA should also commit to a standard to which it can be held by stakeholders and the public. This is a critical element of ensuring access to medicines in the public interest. Where there are no clear time frames setting out when the outcome of an application for registration may be determined, the constitutional guarantee of access to medicines may be undermined.

Expedited and standard registration process for medicines for human use

32. The Registrar of the MCC in a recent interview stated that the MCC was working to target timeframes for registration of medicines - 36 months for new chemical entities (NCEs) and 24 months for products where one source is already registered in the country (known as "multisource products") – however, these

timelines have not been finalised.[10] Thus there are currently no specific time frames in any official MCC document, nor provision made in the Draft Regulations.

33. The current General Regulations,[11] which will be repealed once the Draft Regulations come into force, contain an expedited registration process for medicines on the Essential Drug List, or other medicines considered essential for national health. The MCC is currently required to take a decision on the registration of a medicine falling into this category within nine months of receipt of the application.

34. Since 2005, the MCC has experienced significant backlogs in the processing of standard and expedited registration applications[12]. Attempts to promote wider availability of generic products and improve affordability of medicines had unforeseen consequences, as the resulting substantial increase in multisource product applications was not met with an increase in the MCC's human resources capacity, leading to registration times of up to five years.

35. Expedited registration timelines are not adhered to, even when there is a significant public health imperative to make products available. For example, an application to register generic linezolid (an antibiotic that can be used for the treatment of drug-resistant tuberculosis[13]) was still pending 16 months after the application was fast-tracked in 2013, leaving patients with limited treatment options unable to afford the originator product on the market.[14]

36. The current expedited process is over-saturated with generic applications, many of which may have limited added value for improving access and do not always

[10] Spotlight. Interview with Dr. Joey Gouws "A new dawn for medicines regulation in South Africa" November 2016. Access at: http://www.spotlightnsp.co.za/2016/11/03/new-dawn-medicines-regulation-south-africa/
[11] GNR 510 in Government Gazette 24727 of 10 April 2003.
[12] Leng HMJ, Sanders D, Pollock Ap. Pro-generics policies and the backlog in medicines registration in South Africa: implications for access to essential and affordable medicines. GaBI J 2015; 4(2): 58-63.
[13] MSF. Linezolid Fact Sheet. Access at: http://www.msf.org/sites/msf.org/files/linezolid_fact_sheet.pdf
[14] Treatment Action Group. Letter to the Registrar of Medicines. 20 October 2014. Access at: http://www.treatmentactiongroup.org/sites/g/files/g450272/f/201411/MCC%20linezolid%20letter.pdf

result in significantly reduced prices.[15] Supply security can be better guaranteed when multiple sources are available—if one company faces production challenges in manufacturing active pharmaceutical ingredient (API) or finished pharmaceutical products (FPP), other sources can be called upon to fill supply gaps. It is also important to have multiple product sources registered, as competition facilitates price reductions.

37. However, studies show that beyond a certain number of sources available in the market, the addition of a new source has no impact on decreasing the price. There is currently no cap in South Africa on the number of sources that can be registered for a given medicine, and no mechanism to prioritise registration of products for which a limited number of sources exist, or where there is an imperative for price reductions[16].

38. We understand that this expedition process was intended to expand access to medicines given a special status as a result of their role in treating certain conditions. However, this expedited process has been omitted from the Draft Regulations, with the result that medicines on the Essential Drug List or considered essential for national health will no longer receive priority consideration for registration.

39. There is also no provision in the Draft Regulations to include other measures, such as a cap on the number of generics which may be registered, particularly through the expedited process, or a prioritisation mechanism of some kind, in order to avoid a continuation of the current backlog faced. While we understand plans are in place to implement these measures, we submit that it is important for the measures to be explicitly stated in the Draft Regulations.

[15] SA Drug Producers urge patients to Demand Generics (Business Day) https://www.businesslive.co.za/bd/national/health/2017-04-25-sa-drug-producers-urge-patients-to-demand-generics/

[16] Leng HMJ, Sanders D, Pollock Ap. Pro-generics policies and the backlog in medicines registration in South Africa: implications for access to essential and affordable medicines. GaBI J 2015; 4(2): 58-63

40. Further measures that could be used to expedite standard registration procedures are that of an Abbreviated Medicine Review Process, and a Priority Request Mechanism.

41. The Abbreviated Medicine Review Process could allow products which are already registered by an authority with which SAHPRA aligns itself and products prequalified by the WHO a shorter time period of review due to data already collected by other authorities (such as Swissmedic, the US Food and Drug Administration or the European Medicines Agency).

42. The Priority Request Mechanism is another process that can be used, on decision by the Minister of Health in consultation with SAHPRA, to exclude any medicine, medical device or IVD from the operation of any provision of the Act.[17] This can and should be used, inter alia, in cases of emergency—as it was in 2015 to find an alternative source for abacavir, when National Department of Health suppliers experienced production failures.

43. The mechanism can also be used to prioritise the review of amendments to applications for antiretroviral (ARVs), tuberculosis (TB), malaria, reproductive health and oncology products on public tender.[18] In 2015, priority requests made up more than 29% of all processed amendments. When applications for amendments have not been prioritised in the past, clinics have experienced medicine stock outs of ARVs.

44. We submit that omission of the expedited process and other named measures would undermine the right of access to medicines, and therefore recommend that they be included in the Draft Regulations. In this regard we highlight that although the Draft Regulations are intended, inter alia, to expedite the ordinary registration process, which we endorse, this should not be at the expense of giving priority to

[17] Section 36 of the Medicines and Related Substances Act.

[18] Section 21 of the Medicines and Related Substances Act.

essential medicines, as long as all safety efficacy and quality conditions of a medicine are met.

Pre-Registration Importation Waiver provisions

45. Section 21 of the Act permits the MCC to authorise sale of an unregistered medicine in the country. While this is typically used to access products for which no registered source exists, the Section 21 mechanism has been used on various occasions to access unregistered generic products when a registered product in the country was priced out of reach of patients or healthcare providers. However, MCC practice around providing such authorisation has been inconsistent.

46. MSF used the Section 21 mechanism in the early 2000s to import generic ARVs and treat people living with HIV. However, in 2013, the MCC rejected an application by MSF to import a generic version of linezolid approved by a stringent regulatory authority to treat patients with drug-resistant tuberculosis.[19] One of the reasons given by the MCC for the linezolid decision was that a registered source existed in South Africa—however, at a cost of over R700 per pill, MSF could only afford to treat a limited number of patients with the originator product. After appealing the decision and initiating litigation, authorisation was finally granted—but the process took over six months, while patients in need of the drug went without it.

47. While we are encouraged to note that the application process for Section 21 waivers is clarified in draft Regulation 34A, we submit that, in order to clarify the application of the section, the criteria for its granting are also clarified in the Regulations and it is made explicit that these apply to unregistered products even when a registered version may exist in the country.

[19] MSF. Linezolid Fact Sheet. Access at: http://www.msf.org/sites/msf.org/files/linezolid_fact_sheet.pdf

Vigilance

48. Draft Regulation 37 deals with vigilance and provides a framework for dealing with adverse drug reactions. This provision requires an applicant for the registration of a medicine, the holder of a certificate of registration, or the holder of a license in terms of section 22C(1)(b) of the Act, to report new existing safety concerns (including adverse drug reactions) as well as the risk minimisation and risk mitigation activities adopted.

49. In terms of Draft Regulation 37(2), a health care provider, veterinarian or any other person “should” inform SAHPRA of any suspected adverse drug reactions or new or existing safety concerns occurring as a result of the use of a medicine.

50. This Draft Regulation is similar to Regulation 17 of the Medical Device and IVD Regulations, which deals with adverse event reporting and vigilance for medical devices or IVDs.

51. These vigilance provisions are critical to an ongoing evaluation of safety, quality and therapeutic efficacy, to inform the determination of whether the availability of a particular medicine, medical device or IVD continues to be in the public interest. Adequate vigilance is therefore essential to enable SAHPRA to comply with its obligations arising from section 27 of the Constitution.

52. It may happen that SAHPRA is alerted to an adverse event or a suspected adverse drug reaction, but that it does not have sufficient information to be able to re-evaluate whether the continued availability of the medicine is in the public interest. As a result, members of the public could be exposed to a medicine whose safety threats outweigh its therapeutic efficacy, or the public could be deprived of a medicine of a high therapeutic efficacy due to unfounded safety concerns.

53. As such, we propose that the Draft Regulations be amended to mirror Regulation 17 of the Medical Device and IVD Regulations, to the extent that Regulation 17

addressed this. We propose that, following Draft Regulation 37(2), the following should be included as Regulation 37(3):

Any person referred to in subregulation (1) must –

(a) Whenever requested by the Authority, conduct a concise critical analysis of the safety and performance of the medicine or Scheduled Substance and submit the results thereof to the Authority within a specified time frame;

(b) In the case where, after the receipt of the results referred to in paragraph (a), the Authority determines that the medicine or Scheduled Substance may not be safe to use, submit to the Authority, if required to do so –

(i) Case reports of adverse events or suspected or actual adverse drug reactions in respect of the medicine or Scheduled Substance;

(ii) Where applicable, the usage figures of the medicine or Scheduled Substance, as well as periodic safety update reports and performance studies; and

(iii) Any other data requested by the Authority; and

(c) Keep and maintain or have access to records of the adverse event data in respect of his or her or its medicines or Scheduled Substances.

54. This would require the current Draft Regulation 37(3) to be changed to 37(4), and to make reference to subregulations (1), (2) and (3), which should all apply to unregistered medicines used in terms of the relevant provisions of the Act.

55. The Draft Regulations recognise the important role of health care providers and health care users in furnishing SAHPRA with information regarding safety concerns, including adverse events and actual or suspected adverse drug reactions. We welcome this, and recognise that complete reliance on applicants for registration or holders of certificates of registration or licenses for this information has its inherent limitations.

56. We submit, however, that the wording of subregulation (2) should be stronger, to compel health care providers to report adverse events or real or suspected adverse drug reactions. Health care practitioners also carry important obligations

arising from the right to health, and a failure to report these matters to SAHPRA would undermine these obligations and could lead to inaccurate data as to the quality, safety and therapeutic efficacy of a particular medicine.

57. Once SAHPRA has all of the relevant information, it will be in a position to analyse and determine whether the continued availability of the medicine or scheduled substance in question is in the public interest.

RECOMMENDATIONS

58. The establishment of SAHPRA should be accompanied by a **substantial increase in human resources** to accomplish timely review of application dossiers. This includes increasing the number of in-house experts and limiting the current heavy reliance by the MCC on external experts. Increasing capacity will be particularly important given the expanded mandate of SAHPRA to review not only medicines, but other medical products including medical devices and IVDs.

59. Similarly, the MCC has long operated on an insufficient budget to accomplish its many responsibilities. It is essential that SAHPRA is equipped with a budget that will enable it to carry out its duties. We recommend that the MCC **budget is fully re-assessed** and that SAHPRA is allocated a more significant budget so that it may increase its capacity, skills and technological ability sufficiently to meet the public health needs of the country.

60. Developing clearer processes and **guidelines for prioritisation of dossiers** would also allow the Authority to more adequately respond to pressing public health needs, and promote security of supply. SAHPRA should track the number of API and FPP sources for medicines registered in South Africa, and monitor market analyses and public health relevance in consultation with the National Department of Health when deciding on the relevance of a multisource product application for expedited review.

61. Regarding prioritisation in the regular registration procedure, products that should be given priority, with a decision timeline of **no more than 24 months** after submission, are:

    61.1. Any FPP or API used for treatment of public health priorities that have between two and five previously registered and accessible sources. This will help to promote both supply security and price reduction.

    61.2. Products that should benefit from a fast-track decision timeline of **no more than nine months after submission** should be restricted to:

        61.2.1. NCEs that address a previously unmet medical need (eg sofosbuvir);

        61.2.2. New formulations that have a significant advantage for patients as compared to previously registered formulations (eg lopinavir/ritonavir (LPV/r) pellets for children); and

        61.2.3. Any FPP or API used for treatment of public health priorities that have no (or only one) previously registered and accessible sources.

62. Regarding an Abbreviated Medicine Review Process, for products registered by one of the authorities with which the MCC aligns itself and products prequalified by the WHO, a decision timeline **of no more than three months after application submission** should be applied. This should include products, of established public health interest to South Africa, that have benefited from expedited approval pathways such as the Conditional Approval (European Medicines Agency) or the Accelerated Approval (US Food and Drug Administration).

63. Regarding Priority Request Mechanisms, a clear and transparent **prioritisation process should apply to any amendments that threaten supply of tendered products**. Any applicants who plan to apply for an amendment while

discontinuing the previous version of the product should alert the NDOH and MCC, and apply for the amendment with sufficient time to avoid supply interruption.

64. Regarding pre-registration import waivers, SAHPRA can play a positive role in promoting access and more affordable pricing practices by making explicit provision that **Section 21 authorisation may be extended to quality products** that are not registered in South Africa, when barriers to access exist (such as price), while also ensuring expedited approval of application dossiers for such products.

65. On the subject of transparency and accountability, we make the following three recommendations:

    65.1. Regular opportunities for **public consultation** should allow for patients, communities and health care workers, in conjunction with the NDOH to advise on the allocation of products into the different priority groups and registration timelines.

    65.2. An easy-to-use search tool on a public website should allow accessing a **database with all registered products**, the basis of their registration when generic (bioequivalence, comparator, etc.) and detailed information on their registration date, applicant, indication and price. Such a database could also track progress of application progress, without disclosing sensitive business information.

    65.3. A **forum should exist** where all concerned parties can question the regulatory body's decisions and receive answers within an acceptable and predefined time period.

CONCLUSION

66. SECTION27, MSF AND TAC welcome the efforts of the National Department of Health through these Draft Regulations to meet their constitutional obligations to

ensure that the medicines regulator is streamlined and can meet its objective to protect public health.

67. SECTION27, MSF AND TAC are available for further consultations. For more information, please contact the following:

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