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CENTRE FOR THE AIDS PROGRAMME OF RESEARCH IN SOUTH AFRICA

CAPRISA IS A UNAIDS
COLLABORATING CENTRE
FOR HIV PREVENTION RESEARCH

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Attention: Ms Vuyokazi Majalamba

Dear Ms Majalamba

Submission and Request to Present – Medicines and Related Substances Amendment Bill (Bill 44 of 2008)

The Centre for the AIDS Programme of Research in South Africa (CAPRISA) welcomes the opportunity to provide input on the Medicines and Related Substances Amendment Bill (Bill 44 of 2008), currently before the Portfolio Committee. CAPRISA also request an opportunity to give an oral presentation of this input on either 5 or 6 August 2008.

CAPRISA is an internationally funded and recognized research institution. It conducts HIV prevention and treatment research and is also involved in the provision of services to patients infected with HIV in collaboration with the Department of Health. CAPRISA has extensive experience in the use of unregistered medicines in clinical trials and is currently conducting pivotal studies that will contribute to the registration of new treatment and prevention modalities.

Yours sincerely,

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CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

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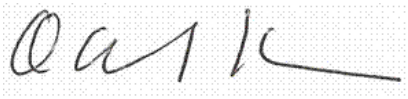

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Substantive input

In developing this input, CAPRISA has been guided by the recommendation of the Ministerial Task Team on the Restructuring of the Medicines Regulatory Affairs and Medicines Control Council and their recommendations for the new Regulatory Authority for Health Products of South Africa (hereinafter referred to as the "Task Team report").

The recommendations provided follow the numbering of the Bill before the Committee.

1. Definition of a health product

CAPRISA supports the intention of the legislation in regard to ensuring that all products that make a medicinal claim become subject to appropriate regulation. However, the definitions as provided for in the Bill are problematic.

The three linked definitions are proposed to read as follows:

- ***'cosmetic'*** *means a cosmetic as defined in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), in respect of which a medicinal claim is made*
- ***'foodstuff'*** *means a foodstuff as defined in the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), in respect of which a medicinal claim is made*
- ***'product'*** *means medicine or medical device, or any cosmetic or foodstuff in respect of which a medical claim is made*

The definitions of "cosmetic" and "foodstuff" would appear to contradict what was enacted last year in the Foodstuffs, Cosmetics and Disinfectants Amendment Act (Act 39 of 2007), which made the following changes:

- **'cosmetic'** means any article, preparation or substance (except a **[drug]** medicine as defined in the **[Drugs Control]** Medicines and Related Substances Act, 1965 (Act No. 101 of 1965)) intended to be rubbed, poured, sprinkled or sprayed on or otherwise applied to the human body, including the epidermis, hair, teeth, mucous membranes of the oral cavity, lips and external genital organs, for purposes of cleansing, perfuming, correcting body odours, conditioning, beautifying, protecting, promoting attractiveness or improving or altering the appearance, and includes any part or ingredient of any such article or substance
- **'foodstuff'** means any article or substance (except a **[drug]** medicine as defined in the **[Drugs Control]** Medicines and Related Substances Act, 1965 (Act No. 101 of 1965)) ordinarily eaten or drunk by **[man]** a person or purporting to be suitable, or manufactured or sold, for human consumption, and includes any part or ingredient of any such article or substance, or any substance used or intended or destined to be used as a part or ingredient of any such article or substance

It is clear from this Act that the most important definition is that of a "medicine", as provided for in the Medicines and Related Substances Act (Act 101 of 1965, as amended). This interpretation was recently confirmed by Zondi J in his findings in the Rath case (at para 96):

> *"The question whether or not a substance is a medicine is determined with reference to the provisions of the Medicines Act dealing with the meaning of a "medicine" and whether the substance makes medicinal claims about itself. A substance which falls within the definition of "medicine" cannot be classified as foodstuff in terms of the Foodstuffs Act."*[1]

What would appear to be required is a clear definition of "medical claim", to accompany the definition of a "medicine", the interpretation of which was also confirmed by Zondi J. More importantly, it would seem prudent to include clear definitions for both "complementary" and "traditional" medicines in the Act itself, rather than to leave these for subordinate legislation (either Regulations or Guidelines to be issued by the new Authority).

2. Creation of the South African Health Products Regulatory Authority

The Task Team report provided extensive evidence of the failings of the current medicines regulatory system in South Africa. While it recommended moving to a system based on decision-making by full-time employees of the Authority, as opposed to part-time members of the Medicines Control Council, it also expressed concerns about

[1] Treatment Action Campaign and Another v Matthias Rath and Others. As yet unreported decision of the Cape of Good Hope High Court in case no. 12156/05 (13 June 2008).

the potential cost of such a move. Thus, although the Task Team report proposed that the new Authority be funded on the basis of "partial cost recovery from fees" (on a 50% cost recovery basis), in order to reduce "pressure on the fiscus, enable affordability, cost effectiveness and sustainability", it warned that "[t]he projected financial assumptions detailed in Chapters 12 and 15 show that this is feasible but the calculations will be firmed up should the recommendations be approved". In this regard, the Bill before Parliament would seem premature.

Two human resource projections have been made by the Task Team. An "ideal" model would entail the employment of 482 full time equivalent (FTE) staff, and the cost would be R197.96 million per annum. Some of these would be external appointments. The "lower cost" model would involve 285 FTEs and cost R117.44 million in human resources costs alone. However, a large proportion of these FTEs would be at a senior level, in order to replace the skills currently relied upon in the form of expert committee and Council members. In either case, this would entail a massive increase in staff. The current Medicines Regulatory Affairs cluster employees 138 staff and is supported by a total of 145 members of Council and the expert committees. The total budget for 2007/2008 was R30.55 million No indication of the feasibility of attracting so many highly skilled persons, drawn mainly from full-time academic and research positions, has been presented. Thus, while the proposal is indeed in line with international practice, it may not represent a feasible option in a developing country with scarce human resources.

In addition, we would suggest that far more detailed Bill is required which details the relationship between the full-time staff of the Authority and the necessary advisory committees (and not just an enabling provision as per section 3 of the Bill.[2] Such provisions would also require a revision of section 34 of the Act, which would appear to be in conflict with the new constitutional order and the requirements of the Promotion of Administrative Justice Act (Act 3 of 2000).[3]

3. Registration of medicines

CAPRISA's greatest concern is with the proposed two-stage registration process, involving certification by the Authority and then registration by the Minister.

In particular, CAPRISA notes that the involvement of the Minister in the form proposed was not recommended by the Task Team. Instead, the Task team recommended the following (emphasis added): "A new South African Regulatory Authority for Health Products is recommended, as an Agency within the Department of Health. The full time Head of the regulatory authority, as the CEO will be the Accounting Officer, subject to the PFMA and will report directly to the Minister of Health. **The regulatory authority will regulate all Health Products through independent operating divisions or components**."

In public utterances since the publication of the draft Bill, senior government officials have given varying accounts of the way in which section 15 of the amended Act would operate. This provision has been described as a means of protecting emerging local industry and also as a "4th hurdle", based on cost-effectiveness analyses to be conducted by the Pricing Committee. It is noted that the draft Bill initially provided, at least in the long title, for the abolition of the Pricing Committee.

CAPRISA is supportive of the use of pharmacoeconomic data in the selection of medicines for inclusion on the Essential Medicines List or reimbursement by medical schemes. CAPRISA is also supportive of government intervention to improve the affordability of medicines. However, neither of these two processes should be confused with the **registration** of medicines. Provisions made in other legislation in respect of both of these processes have yet to be implemented fully. Examples include the international benchmarking of medicine prices, as provided for in the Pricing Regulations, and the proposed regulations on the selection of essential medicines and medical devices,

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[2] "The Chief Executive Officer may, subject to the approval of the Minister, appoint committees, as it may deem necessary, to investigate and report to it on any matter within the purview of the Authority in terms of this Act.''.

[3] Section 34 currently reads as follows:

"34. Preservation of secrecy
No person shall, except for the purpose of the exercise of his powers or the performance of his functions under this Act, or for the purpose of legal proceedings under this Act, or when required to do so by any competent court or under any law, or with the written authority of the Director-General, disclose to any other person any information acquired by him in the exercise of his powers or the performance of his functions under this Act and relating to the business or affairs of any person, or use such information for self-gain or for the benefit of his employer."

Zondi J has stated (at para 54 of the recent judgment in the Rath case, vide supra): "It is clear that the MCC performs an administrative function when it considers applications for registration of medicines. Its decision must comply with the provisions of section 33 of the Constitution which provides that everyone has the right to administrative action that is reasonable and procedurally fair. The decision of the MCC must be reasonable within the meaning of the Promotion of Administrative Justice Act No.3 of 2000 ("PAJA")."

provided for in the National Health Act (Act 61 of 2003). However, the system described in section 7 of the Bill is ill-defined. In particular, the factors to be considered by the Minister in deciding whether or not to register a product are not easily interpreted.[4] These considerations run counter to the purely scientific factors that have always underpinned medicines regulation – efficacy, safety and quality. The central nature of this principle is seen in the wording of section 1(3) of the current Medicines and Related Substances Act (Act 101 of 1965) (emphasis added): "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". As drafted, the Bill would place this important administrative function, which should be based on scientific principles, at risk of inappropriate political interference.

4. Other tasks assigned to the Minister

The inappropriate involvement of the Minister in the day-to-day operation of what purports to be an independent regulatory authority is also demonstrated in section 19 of the Bill, which would replace section 21 of the Act with the following:

> **"21.** (1) The Authority may in consultation with the Minister in writing authorise any person to sell during a specified period to any specified person or institution a specified quantity of any particular product which is not certified or registered."

The issuing of a section 21 permit, either for compassionate use or for the use of unregistered medicines in clinical trials, is a purely technical act, which would not seem to justify political oversight in the manner described above.

The same applies to section 41 of the Bill, which would replace section 36 of the Act as follows:

> **"36.** The Minister may, on the **[unanimous]** recommendation of the **[members present at any meeting of the council]** Authority, by notice in the *Gazette* exclude, subject to such conditions as he or she may determine, any **[medicine]** product from the operation of any or all of the provisions of this Act, and may in like manner amend or withdraw any such notice."

The existing Act recognises that exclusion of a medicine from one or more of the provisions of the Act should be step taken carefully. The amendment would remove the carefully devised safeguard of a unanimous vote of the Council, and vest decision-making to an inappropriate extent in the hands of the Minister.

5. Recommendations

It is recommended that this Bill be withdrawn and resubmitted at a later date, after extensive redrafting. As presented, it is a premature attempt to put into place the recommendations of an extensive Task Team report, but with important and potentially crippling deviations from those recommendations. If passed in its current form, it has the potential to destroy the scientific basis for medicines registration in South Africa, and place at risk the international standing of the medicines regulatory authority.

[4] "In determining whether it is in the public interest to register a product, the Minister shall take the following into account:
(i) Public health interests including national epidemiological trends;
(ii) economic interests in relation to health policies;
(iii) whether the product is supportive of national health policy and goals in the long term;
(iv) whether the product is likely to significantly improve access to health care for vulnerable groups within society;
(v) the experience of other countries concerning the marketing, distribution and use of the product; and
(vi) generally, whether the public would be best served by such registration."