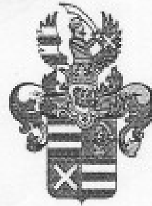


COMMENTS TO THE PORTFOLIO COMMITTEE ON HEALTH ON THE MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL – 2 JUNE 2008

1. I agree with the sections of the *Medicines Bill* for which I provide no comments.

2. The views expressed are my own unless I annotate or state otherwise.

MAIN CONTENTION

3. In light of the large number of statutory changes proposed to health care delivery legislation in South Africa, it is not possible to read the *Medicines Act*[1] in isolation or disjunctively. It must be interpreted jointly with other matching health care legal instruments. The provisions of the *Medicines Act* itself makes it clear that it should be read in addition to and not in substitution for any other law which is not in conflict with or inconsistent with it.[2]

4. The *Medicines Act* was first enacted in 1965. It has been amended on at least fifteen different occasions since then. From 1965 until 1997, the focus of the Act was quality control. In 1997, measures were introduced into the legislation directed towards making medicines more affordable to give effect to the state's constitutional obligation to provide everyone with access to health care services.[3]

5. Chaskalson CJ of the Constitutional Court (at the time) correctly opined that:

> *[2] The newly introduced measures, especially those contained in sections15 A – C, sections 18A – C and sections 22B – H, do not fit comfortably into an Act*

---

[1] Medicines and Related Substances Act 101 of 1965.
[2] Medicines Act section 38. **Operation of Act in relation to other laws.**—The provisions of this Act shall be in addition to and not in substitution for any other law which is not in conflict with or inconsistent with this Act.
[3] Minister of Health and Another v New Clicks South Africa (Pty) Ltd and Others CCT59/04 retrieved

René Doms

FPS Adv Dip (B&A) Blur LL B
Advocate of the High Court of South Africa
Member of the Gauteng Society of Advocates

> *designed to serve other purposes. They pose new problems for those who have to implement them, for those who are directly affected by them as well as for those who have to adjudicate them. The grafted sections make provision for controls to be introduced in respect of the production, importation, distribution and sales of medicines, the relaxation of certain patent restrictions, the promotion where possible of generic substitution of medicines, and the establishment of a Pricing Committee to make recommendations for the introduction of a pricing system for all medicines sold in the Republic.*[4]

6. Professor R W Green Thompson[5] *Report of The Ministerial Task Team on The Restructuring of The Medicines Regulatory Affairs And Medicines Control Council and Recommendations for the New Regulatory Authority for Health Products of South Africa* goes a long way in sorting out the technical issues of the Medicines Act relating to the certification and registration of medicines in South Africa.

7. The *Medicines Amendment Bill 2008* recognises these proposals and incorporates them into its provisions. It does not however address one issue that is a misfit with its main purport specifically, the control of medicine prices and the dispensing fee for pharmacists. The *Medicines Act* is patently '*designed to serve other purposes*'. These commercial and pharmaco-economic issues should be shifted to a more appropriate statute.[6]

8. Interestingly, the first draft of the *Medicines Bill 2008* appeared to recognise this incompatibility in its long title as it proposed the abolition of the Pricing Committee.[7] Unfortunately, section 22G of the *Medicines Act*[8] was not repealed thus negating the long title's

---

[4] *Ibid.*

[5] Special advisor to the Minister of Health.

[6] See footnote *supra*.

[7] Government Gazette No 30985 18 April 2008: - **DRAFT BILL:** To amend the Medicines and Related Substances Act, 1965, so as to provide for the establishment of the South African Health Products Regulatory Authority; for the certification and registration of products which include medicines and certain foodstuffs and cosmetics, the control of Scheduled substances; for the certification and registration of medical devices; for the abolition of the Medicines Control Council and the Pricing Committee; and matters incidental thereto.

[8] **22G. Pricing committee.**—(1) The Minister shall appoint, for a period not exceeding five years, such persons as he or she may deem fit to be members of a committee to be known as the pricing committee.
(2) The Minister may, on the recommendation of the pricing committee, make regulations— on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic;
(b) on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C (1) (a);
(c) on an appropriate fee to be charged by wholesalers or distributors or any other person selling Schedule 0 medicines.

René Doms
South African Registered Pharmacist

FPS Adv Dip (B&A) Blur LL B
Advocate of the High Court of South Africa
Member of the Gauteng Society of Advocates

objective. The second draft of the Bill fixed this oversight and saved the Pricing Committee from its demise. Whether this decision is in line with health policy remains moot.

9. The purpose of the *National Health Act*[9] is to provide a framework for a structured uniform health system within the country by taking into account the obligations imposed by the Constitution and other laws on the national, provincial and local governments concerning health services.[10,11]

10. In particular, the *National Health Act* exacts that its object is to protect, respect, promote and fulfil the rights of the people to the progressive realisation of the constitutional right of access to health care services, including reproductive health care,[12] a safe environment and the stipulation of basic nutritional and health care services for children.[13]

11. The Minister of Health is obligated to achieve these objectives within the limits of available resources by endeavouring to protect, promote, improve and maintain the health[14] of the population and determine the policies and measures necessary to protect, promote, improve and maintain the health and well-being of the population.[15]

12. The Minister, in order to comply with her statutory obligations published an amendment to the *National Health Act*, a second draft

---

(3) (a) The transparent pricing system contemplated in subsection (2) (a) shall include a single exit price which shall be published as prescribed, and such price shall be the only price at which manufacturers shall sell medicines and Scheduled substances to any person other than the State.
(b) No pharmacist or person licensed in terms of section 22C (1) (a) or a wholesaler or distributor shall (c) Paragraph (b) shall not be construed as preventing a pharmacist or person licensed in terms of this Act to charge a dispensing fee as contemplated in subsection (2) (b).
(4) To the members of the pricing committee who are not in the full-time employment of the State may be paid such remuneration and allowances as the Minister, with the concurrence of the Minister of Finance, may determine.

[9] Act 61 of 2003.

[10] Long title to the National Health Act.

[11] Any service, which can contribute to improved health or the diagnosis, treatment and rehabilitation of sick people and not necessarily limited to medical or health-care services.

[12] Any type of services provided by professionals or para-professionals with an impact on health status.

[13] National Health Act section 2.

[14] The state of complete physical, mental and social well-being.

[15] *Ibid* section 3.

René Doms
South African Registered Pharmacist
... of South Africa

FPS Adv Dip (B&A) Blur LL B
Advocate of the High Court of South Africa
Member of the Gauteng Society of Advocates

Bill for consideration and comment.[16] The instrument suggests the addition of a new chapter (10A) to the Act.

13. The object of the new chapter 10A in the *National Health Amendment Bill* – 2 June 2008 (NHAB) is to create a framework that-

   a. enables health care providers,[17] health establishments[18] and medical schemes[19] to-

      (a) negotiate collectively on prices; and

      (b) bargain individually on prices: and

   b. ensures transparency and fairness in the determination of prices.[20]

14. The objects of the Chapter 10A is to provide for a framework to enable health care providers, health establishments and medical schemes ("stakeholders") to negotiate and bargain on prices.

15. 'Prices" mean tariffs, fees or any form of reimbursement for health services[21] rendered, procedures performed and consumable and

---

[16] Government Gazette *supra*.

[17] NHAB section 1: "**health care provider**" means a person providing health services in terms of any law, including in terms of the—
- (a) Allied Health Professions Act, 1982 (Act No. 63 of 1982);
- (b) Health Professions Act, 1974 (Act No. 56 of 1974);
- (c) Nursing Act, 1978 (Act No. 50 of 1978);
- (d) Pharmacy Act, 1974 (Act No. 53 of 1974); and
- (e) Dental Technicians Act, 1979 (Act No. 19 of 1979);

[18] NHAB section 1: "**health establishment**" means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services;

[19] Medical Schemes Act section 1: "**medical scheme**" means any medical scheme registered under section 24 (1);

[20] Section 89B.

[21] "**health services**" means—
- (a) health care services, including reproductive health care and emergency medical treatment, contemplated in section 27 of the Constitution;
- (b) basic nutrition and basic health care services contemplated in section 28 (1) (c) of the Constitution;
- (c) medical treatment contemplated in section 35 (2) (e) of the Constitution; and
- (d) municipal health services.

René Doms
South African Registered Pharmacist
Fellow of the Pharmaceutical Society of South Africa

FPS Adv Dip (B&A) Blur LL B
Advocate of the High Court of South Africa
Member of the Gauteng Society of Advocates

disposable items utilised by health establishments, health care providers or health workers.[22]

16. There is a difference in the meaning between the words "negotiate" and "consult". The court's view:[23]

> *By using the word, 'negotiate' the Minister purported to require something in addition of mine managers than merely to ascertain the wishes of the employees. According to The Oxford English Dictionary vol VII, the word, when used in the transitive sense, means*
>
> > *'to hold communication or conference (with another) for the purpose of arranging some matter by mutual agreement; to discuss a matter with the view to some settlement or compromise'.*
>
> *The process contemplated by the requirement of negotiation means that, if the employees' organisations concerned express needs and preferences at variance with what the manager considers reasonable or essential, or if various employees' organisations on a mine have different needs and preferences, the manager should endeavour to reach agreement with those organisations. He must enter into debate with them, and, if he thinks it necessary, endeavour to persuade them to change their attitudes. He should give consideration to whether he should not depart from a position already taken for the expediency of achieving compromise. The duty imposed in 'negotiate' means that the interchange should proceed until agreement or deadlock is reached...*
>
> *I think there is a clear distinction between negotiation and simple consultation or conference. The duty to negotiate is far more onerous than the duty to consult or confer. If nothing more is required of the manager than to sound out the employees' organisations concerned about his proposals, he need not endeavour to come to terms with them if they do not accept his ideas. He can at once put his plans into effect, and quick and decisive action is possible.*

17. The parties may only negotiate and bargain[24] on prices after the Department of Health has published the reference price lists. These lists must serve as a price reference for the parties during the negotiations process.[25]

---

[22] "**health worker**" means any person who is involved in the provision of health services to a user, but does not include a health care provider.

[23] Minister of Economic Affairs And Technology V Chamber of Mines Of South Africa [1991] 4 All Sa 52 (T).

[24] Negotiate the terms of an exchange.

[25] **Negotiating and Bargaining**
89F (1) The Minister must within 60 days of publication of the reference price lists (RPL) contemplated in section 90(1)(v), by notice In the Gazette, invite health care providers,

René Doms
South African Registered Pharmacist
Fellow of the Pharmaceutical Society of South Africa

FPS Adv Dip (B&A) Blur LL B
Advocate of the High Court of South Africa
Member of the Gauteng Society of Advocates

18. The parties to the negotiations are health care providers, health establishments and medical schemes. Negotiations may only commence once the Director General has published the reference price lists as described above.

19. The provisions of this Chapter do not apply to the sale of medicines. According to the explanatory memorandum on the objects of the amendment bill, the clause exempts medicines from the provisions of the new chapter because medicines' prices are already regulated in terms of other legislation.

20. This exemption includes the dispensing fee that a pharmacist may charge over and above the single exit price established in term of the provision. In other words, the professional dispensing fee chargeable by a pharmacist (health care provider) is also excluded from the *National Health Amendment Bill's* scope and still controlled by the Pricing Committee.

21. The "reference price list" means a list of items and reference prices utilised by categories of health establishments, health agencies, health care providers or health workers, including rules for the use of the reference price list in billing for such health services, procedures, consumable and disposable items.[26]

22. Director-General must, annually by notice in the Gazette, source from any stakeholder information relating to health financing, the pricing of health services, business practices within or involving health establishments, health agencies, health workers or health care providers for the development and publication of the reference price list. The Director-General may hear representations from or enter into

---

health establishments and medical schemes (hereinafter jointly referred to as "the parties") to negotiate on prices
(2) The parties may-
(a) negotiate collectively in instances where the parties are represented by representative organisations or associations; and
(b) bargain individually in instances where the parties represent themselves as individual entities.
(3) The parties to both collective negotiations and individual bargaining-
(a) may conduct such negotiations or bargaining separately according to their specific area of interest, and
(b) must use the RPL as a source of reference for negotiations and bargaining.

[26] GNR.681 of 23 July 2007: Regulations Relating to the Obtainment of Information and the Processes of Determination and Publication of Reference Price List (Government Gazette No. 30110)

correspondence with an interested party to evaluate the information submitted in response to the notice.[27]

23. Information is submitted according to the guidelines which include:

   a. pricing methodology, for the determination of reference prices for items;

   b. procedures for addition, deletion or change of items; and

   c. calculation of responsibility values. Responsibility value means the increased responsibility for providing a service relative to a standard service for providers and is calculated by taking into account experience and knowledge, judgement and mental effort, skill and physical effort as well as risk and stress to the patient.

24. The Director-General then develops the draft reference price list. In preparing the reference price list, he must take the following into account:

   a. the advice of an advisory committee;[28]

---

[27] *Ibid* regulation 2.

[28] **NOTICES**

GN 398 of 11 April 2008: Advisory Committee: Reference Price Lists (Government Gazette No. 30947)

NATIONAL HEALTH ACT, 2003

The Minister of Health has, in terms of section 91 (1) of the National Health Act (Act No. 61 of 2003) ("the Act") appointed the following persons as members of an advisory committee on reference price lists ("the Committee"):

1. Dr Reno Morar (Chairperson)
2. Prof Heather Mcleod
3. Mr Marothi Ledwaba
4. Ms Mizeria Nyathi
5. Prof David Buso
6. Mr Stephen Harrison
7. Prof Indres Moodley
8. Ms Nandisile Mokoena (as an observer)

Functions of the Committee

The Committee—

(a) advises the Director-General generally on the determination of reference price lists, starting with the 2009 reference price lists, as contemplated in section 90 (1) (v) of the Act, and in particular, on the verification of information submitted to the Director-General in terms of regulation 5 of the Regulations Relating to the Obtainment of Information and the Processes of Determination and Publication of Reference Price Lists, the regulations made in terms of the Act;

(b) may request the Director-General that research be undertaken into any area falling within these terms of reference;

b. the need for private health establishments and health agencies to have a return on investment;

c. the need for health care providers to earn an income;

d. the need for certainty, sustainability, affordability and stability within the medical schemes environment and among private sector consumers;

e. the need to improve and maintain efficiency and quality in the delivery of health care services as well as to increase and ensure access to such services for medical scheme beneficiaries;

f. the need to eliminate perverse incentives, unethical business practices and unprofessional conduct from the health care industry;

g. relevant information already in possession of the Department submitted in terms of any law;

(c) may establish subcommittees comprising its members to perform such functions of the Committee as the Committee may determine.

Term of office and Remuneration

1. Members of the Committee are appointed for a period of three years.
2. Members of the committee who are not in the full-time employment of the State shall be paid, in accordance with the Treasury Regulations made in terms of the Public Finance Management Act, 1999 (Act No. 1 of 1999), such remuneration and allowances in respect of any expenses incurred in the performance of the functions of the Committee, as may be determined by the National Department of Health.

Meetings and Procedures

The Committee:

(a) must at its first meeting:
(i) note the appointment of the Chairperson;
(ii) select one of its members as deputy Chairperson; and
(iii) note that the National Department of Health's Financial Planning and Economics Directorate shall provide secretariat services to the Committee.
(b) must meet at such times and places as may be determined by the Chairperson in consultation with the Director-General. The Committee shall meet at least three times a year and on a frequency to be determined by the Chairperson.
(c) shall, in consultation with the Director-General, make rules governing its meetings and such rules shall include:
(a) the procedures for such meetings;
(b) recommendations arising out of those meetings;
(c) duties of committee members during and outside those meetings;
(d) reporting by the Committee; and
(e) interaction with the media.

h. the need to promote competition within the private health care industry; or

i. the need to promote and ensure access to membership of medical schemes for employed persons and their dependants.[29]

25. Once the Director-General has determined the draft reference price list, he must publish it in the Gazette for at least four weeks for public comments. After the comment, he must prepare the final reference price list and publish it in the Gazette before the end of September of the preceding year.[30]

26. The reference price list is a public document that may be freely used by any interested person. The document rests in the public domain.[31]

27. Where information is not submitted despite an invitation by the Director-General or where information is submitted after the deadline set in the notice and the Director-General is prevented from preparing a reference price list, he must make a determination on the reference price list taking into account the CPIX. [32]

28. Where disputes arise during price negotiations, these may be referred to an arbitrator agreeable to both parties to resolve the dispute.[33]

29. Pharmacists are defined as "health care providers" in terms of the *National Health Act* and arguably fall within the scope of the proposed Chapter 10A provisions and not in terms of section 22G of

---

[29] *Ibid* regulation 7.
[30] *Ibid* Regulation 8.
[31] *Ibid*.
[32] *Ibid* regulation 8: "**CPIX**" means the consumer price index excluding interest rates on mortgage bonds for the historical metropolitan and other urban areas.
[33] **Arbitration, resolution of disputes**
891. (1) A pa$ or parties to the bargaining process or the Facilitator may in the prescribed manner refer a dispute arising from the bargaining process to the Minister.
(2) The Minister shall within 30 days of receipt of the notice or the dispute, refer the dispute to an arbitrator agreeable to both parties and appointed by the Minister.
(3) Where the parties fail to agree on the appointment of the arbitrator, the Minister shall, after consultation with the Minister of Justice and Constitutional Development, appoint the arbitrator.
(4) The arbitrator shall make a determination on the dispute within 30 days and inform the parties, the Facilitator where the dispute was referred to the Facilitator and Minister of such determination.
(5) The costs of arbitration shall be borne by the parties to the dispute, with the arbitrator having the power- to make an appropriate cost order having taken into account the conduct of the parties during arbitration.

the *Medicines Act* that is prescriptive and prevents pharmacists from negotiating directly with the Pricing Committee or collectively with users of their professional services. This puts pharmacists at a considerable disadvantage in relation to other health care providers as they are precluded from using the alternate dispute resolution procedures envisaged in Chapter 10 A.[34] This is simply not fair and discriminatory towards the pharmacy profession.

30. The Pricing Committee and the pharmacist have now been in dispute for four years. The spat has travelled from the High Courts, Supreme Court of Appeal to the Constitutional Court. A further action is pending in the Pretoria High Court. This is a clear reflection, four years later that the parties cannot agree on fundamental principles. The issue is the determination of an appropriate dispensing fee for pharmacists.

31. The recent court papers reveal that:[35]

    a. The applicants[36] are determined to prevent or stall as long as possible the implementation of an appropriate dispensing fee to be charged by pharmacists;

    b. Applicants are not interested in establish a dispensing fee that is fair to pharmacists and the public;

    c. Determination to frustrate the process;

    d. Parties are acting in bad faith, ulterior motives or on spurious grounds;

    e. Negative attitude toward the country and its democratic values;

    f. Contempt by the applicants of the deliberations of the pricing committee and its conclusions;

    g. That the applicants are disingenuous;

[34] "**health care provider**" means a person providing health services in terms of any law, including in terms of the—
(a) Allied Health Professions Act, 1982 (Act No. 63 of 1982);
(b) Health Professions Act, 1974 (Act No. 56 of 1974);
(c) Nursing Act, 1978 (Act No. 50 of 1978);
(d) Pharmacy Act, 1974 (Act No. 53 of 1974); and
(e) Dental Technicians Act, 1979 (Act No. 19 of 1979);

[35] Case No 41743/06 – High Court of South Africa – Transvaal Provincial Division.

[36] PSSA, SAPPA and USAP.

René Doms
South African Registered Pharmacist

FPS Adv Dip (B&A) Blur LL B
Advocate of the High Court of South Africa
Member of the Gauteng Society of Advocates

h. Alleged abuse of the applicants

32. I pass no comment on the accuracy or otherwise of the statements but they do display a complete breakdown of the trust relationship between the parties. The fact that they seek satisfaction in the courts speaks for itself. This does not auger well for a long-term relationship that is vital for the continued enduring supply of affordable medicines to all, the people of our country. If what is stated in the papers is factual then such conduct from both parties cannot be condoned nor tolerated in the interest of all.

33. The blame for the impasse, in my view rests squarely with the lack of appropriate procedures and transparency that is indispensable to resolve fairly disputes between the parties cost effectively and expeditiously. Such mechanisms do not exist in terms of section 22G of the *Medicines Act*. Aggrieved parties must seek relief in the civil courts. A long and expensive process that is not justifiable in a dynamically changing market place where negotiations are expected to take place regularly. The present scheme is malfunctioning and fundamentally flawed. It should be scrapped.

34. A suitable system that meets all the sought after criteria does exists and has now been formalised in the suggested amendments as outlined in Chapter 10A of the *National Health Amendment Bill*.

35. The document prepared and published by the Health Financial Planning and Economics Directorate of the Department of Health (Mr S. Jikwana)[37] is sound. It overcomes most if not all of the technical hurdles for pricing transparency when establishing professional fees for health care providers. It addresses most, if not all the issues that the pharmacists have raised during their deliberations with the department. The underlying principle of the Department of Health's approach to reference pricing is that the cost of providing the particular service must be made explicit, and it is this cost that forms the basis of the reference price. In order to apply this principle certain preconditions must be met:

    a. A standard nomenclature to identify the service being priced; and

[37] GNR.681 of 23 July 2007: Regulations Relating to the Obtainment of Information and the Processes of Determination and Publication of Reference Price List (Government Gazette No. 30110)

René Doms
South African Registered Pharmacist

FPS Adv Dip (B&A) Blur LL B
Advocate of the High Court of South Africa
Member of the Gauteng Society of Advocates

b. An agreed upon methodology to determine the reference price associated with a particular service.

36. These fundamental principles were not achieved previously to find an equitable solution for the determination of an appropriate dispensing fee for pharmacists.

SUBMISSION

37. It is my submission that:

a. The Department of Health remove from the roll the pending court hearing in the Pretoria High Court in anticipation of the suggestions of the Portfolio Committee on Health and the finalisation of the *Medicines and National Health Amendment Bills*; and

b. Section 22G 2(b)[38] is repealed in favour of Chapter 10A procedures for pharmacists.

CONCLUSION

---

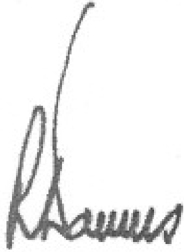
[38] **22G. Pricing committee.**—(1) The Minister shall appoint, for a period not exceeding five years, such persons as he or she may deem fit to be members of a committee to be known as the pricing committee.
(2) The Minister may, on the recommendation of the pricing committee, make regulations—

(a) on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic;
(b) [on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C (1) (a);]
(c) on an appropriate fee to be charged by wholesalers or distributors or any other person selling Schedule 0 medicines.

(3) (a) The transparent pricing system contemplated in subsection (2) (a) shall include a single exit price which shall be published as prescribed, and such price shall be the only price at which manufacturers shall sell medicines and Scheduled substances to any person other than the State.
(b) No pharmacist or person licensed in terms of section 22C (1) (a) or a wholesaler or distributor shall sell a medicine at a price higher than the price contemplated in paragraph (a).
(c) Paragraph (b) shall not be construed as preventing a pharmacist or person licensed in terms of this Act to charge a dispensing fee as contemplated in subsection (2) (b).
(4) To the members of the pricing committee who are not in the full-time employment of the State may be paid such remuneration and allowances as the Minister, with the concurrence of the Minister of Finance, may determine.

38. It appears that a solution exists that may satisfy both parties in moving forward positively. Only minimal tweaking of the *Medicines Act* is necessary. The proposed system meets all requirements for fairness and equality by treating all health care professionals in the same way.

Yours sincerely



René Doms
Thursday, 17 July 2008

René Doms
South African Registered Pharmacist

FPS Adv Dip (B&A) Blur LL B
Advocate of the High Court of South Africa
Member of the Gauteng Society of Advocates