PIASA
Pharmaceutical Industry Association of South Africa
IMPROVING LIVES WITH QUALITY MEDICINES

APPENDIX 2

GAPS ON LEGISLATION RE PERVERSITIES

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GAPS IN LEGISLATION AND ENFORCEMENT TO ENSURE A REDUCTION IN PERVERSITIES IN THE PROCUREMENT, SUPPLY AND SALE OF MEDICINE

This document has been put together and agreed (5th, November, 2007) by the following Trade Associations/Company:

IMSA, NAPM, NAPW, PIASA, SMASA and (IHD) Pharmaceutical Distributors

This grouping supports the presentation of this document to the Department of Health, the Medicines Regulatory Authority and the Professional Councils and other relevant stakeholders in an effort to achieve the effective prevention of perversities and other unacceptable business practices within the medicines and health sector.

A. Section 18A, Medicines and Related Substances Act No 101 of 1965, as amended (Discounts, rebates, incentives)

1. Regulatory gap

S18A is being violated under the guise of a number of so-called "fees". S18A determines that no medicine may be supplied according to a "bonus system, rebate system or any other incentives scheme". The only definition (that of "discounts") is found in the Pricing Regulations, however it was only used to initially establish the SEP. Enforcement also seems problematic, as violations of s18A form part of the offences created by section 29, and is dependent on the MRA Inspectorate.

2. Proposed solution

The following set of regulations could be promulgated to provide clarity on practices which constitute violations of s18A, and delineate acceptable, from unacceptable, practices:

The Minister of Health has, in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), in consultation with the Medicines Control Council, made the regulations in the Schedule, in terms of section 45:

Bonuses, rebates and incentives

1. All suppliers, buyers, intermediaries and persons or organizations influencing the procurement or sale of medicine, may not sell, procure or encourage the sale of any medicine or medicines in terms of a "bonus system, rebate system or any other incentive scheme", as provided for in section 18A of the Medicines and Related Substances Act No 101 of 1965, as amended.

2. "A bonus system, rebate system or any other incentive scheme" include, but is not limited to the following transactions, deals or agreements, which, as defined, constitute unacceptable transactions relating to medicines, and include the involvement, offering, payment and/or acceptance of the following list of transactions, and include instances where such transactions are incorporated into logistics fees:

2.1 unacceptable advertising fees;
2.2 unacceptable credit payments;
2.3 unacceptable data fees;
2.4 discounts;
2.5 formulary listing payments;

2.6 kickbacks and perverse incentives;
2.7 loyalty fees or similar fees or prizes or rewards;
2.8 unacceptable marketing fees and/or co-marketing fees;
2.9 shelf space fees;
2.10 directors' fees, honoraria and similar compensation paid to healthcare professionals for limited or no services provided or work performed;
2.11 fees, enrichment of or benefit provided to a healthcare professional, administrative staff or any business enterprise or healthcare establishment in the healthcare sector, whether for profit or not, including but not limited to healthcare practices, pharmacies, hospitals, medical schemes, scheme administrators; which fee, enrichment or benefit is provided on the understanding that the health establishment or professional will give preference to, or encourage the purchase, sale, prescription, dispensing, use or recommendation of a particular medicine or medicines in return for such fee, enrichment or benefit.

3. The offer, payment of acceptance or appropriate fees for legitimate services, is acceptable and excluded from the ambit of section 18A, provided it does not constitute transactions listed in regulation 1, and such acceptable transactions include, amongst others:
3.1 fees for data, advertising or marketing which is related to the rendering of a bona fide service, commensurate with the value of the services rendered and which are not linked to sales volumes, targets or similar criteria;
3.2 fees paid or to be paid relating to the evaluation of medicine for inclusion in a formulary used by a registered managed care company and/or medical scheme;
3.3 risk-sharing agreements with healthcare insurers, as approved by the Department of Health;
3.4 any other practice, outside of the scope of these regulations, which is found to be acceptable by the Department of Health, and published as being an acceptable trade practice;
3.5 the provision of medicines to the state system through a system of tenders, where discounts are provided as per tender requirements, provided that such discounted price is not accompanied by any perverse incentives or unacceptable fees or payments listed above.

4. All agreements relating to medicines trade practices, as covered by the scope of these regulations, may be subject should be open to scrutiny by the Department of Health and its inspectors, in the event of a complaint relating to section 18A and these regulations.

5. The Department of Health must ensure that action is taken in terms of sections 28, 29 and 30 of the Medicines and Related Substances Act No 101 of 1965, as amended, should complaints of alleged conduct in contravention with these regulations, be received.

6. These regulations do not apply to medicines which not subject to the provisions of section 18A and/or the pricing regulations, as amended.

7. Should the transaction at hand involve a person or organization registered, regulated or licensed in terms of the Medicines Act, Pharmacy Act, Health Professionals Act, National Health Act, Medical Schemes Act, the matter, insofar as it pertains to the conduct of such person or organization, may be referred by the Department of Health to such professional or regulated body, for such body to take appropriate steps.

Definitions
In these Regulations, any word or expression defined in the Act and not defined herein bears the same meaning as in the Act and, unless the context otherwise indicates, in these Regulations—

*"**Discounts**"[1] mean any reduction in the price of a medicine that may influence the procurement or sale of a medicine and includes, but is not limited to:*

(a) volume or 'bulk purchase' discounts and other trade discounts including discounts given to customers off the manufacturer or importer's published selling price at the date of the sale, due to purchase of large quantities, as 'favoured' customers or for any other reason;

(b) bonus deals in terms of which additional product units are supplied to customers below the list price or free of charge;

(c) rebates, including payments made to purchasers after the date of sale for achieving certain sales targets, or for any other reasons that relate to influencing the procurement or sale of a medicine;

(d) formulary listing payments including payments made to:

(i) private hospitals, dispensing doctors, independent practitioner associations, provider networks; or

(ii) medical schemes, managed healthcare organisations and administrators of medical schemes as defined or contemplated in the Medical Schemes Act 1998 (Act no 131 of 1998) including the regulations thereto; or

(iii) any other person or organisation including vendors or operators of electronic ordering groups, distributors, independent pharmacies, pharmacy groups and any other individual or organisation purchasing, supplying, selling, prescribing, dispensing, funding or recommending the use of medicines

with the purpose of ensuring that a particular medicine or scheduled substance is included on the relevant formulary used or recommended by any of the persons or organisations listed in (i) – (iii);

(e) other allowances and fees that are aimed to influence the procurement or sale of a medicine;

(f) free services rendered by manufacturers and importers or their agents to other persons selling medicines or scheduled substances;

(g) the purchase or the provision of any equipment by manufacturers or importers or their agents at a reduced cost or for free to other persons selling medicines or scheduled substances; and/or

(h) contributions by manufacturers or importers to salaries or other recurrent expenditure or any other form of payment or inducement to any person or organisation that is aimed to influence the procurement or sale of a medicine.

*"**Kickbacks and/or perverse incentives**" means payments, monetary or in kind, as a flat fee or as a percentage, provided to healthcare professionals, administrative staff and/or healthcare facilities in return for the preferential purchase or sale of a medicine or medicines in exchange for the exercise of decision-making- or recommendation powers in favour of the medicine or medicines, irrespective of the clinical needs, interests or choices of patients;*

*"**Loyalty- or similar fees and prizes or rewards**" mean payment of fees and/or the provision of in-kind goods or services, or accounts or credits, which could be exchanged for goods, services or cash, in return for the supply or prescription of, or for selling, a particular product or range of products;*

*"**Unacceptable advertising fees**" mean fees paid for services which do not constitute legitimate advertising, and which do not relate directly to the provision of an advertising service according to national advertising standard costs and norms, and which agreement is not reduced*

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[1] Definition from Pricing Regulations as amended to ensure that intra vires the Medicines Act. Changes proposed by NAPW.

to writing, and does not include provisions for fees appropriate to the nature, duration and type of advertising and/or which are not directly or indirectly linked to sales value, and/or sales volume, and/or preferential usage or recommendations of any medicine or medicines;

*"**Unacceptable credit payments**" mean the use of credit payments, i.e. payments, whether monetary or in kind, to healthcare providers by companies or organizations such as medical schemes or managed care companies, which credit payments are related to a system of support for prescribing, dispensing or recommending or using a particular medicine or range of medicines obtained from a specific wholesaler or supplier, or which may be listed in a formulary;*

*"**Unacceptable data fees**" mean data fees which are used to encourage or increase the purchase, prescription or use of a medicine or medicines and which data is of no or limited value to the buyer and which is bought solely, or mostly in order to reward or secure a particular purchase, prescription or utilisation behaviour, and which is not reduced to writing and for which the fees are not commensurate with the nature, potential use or type of data, and/or which is linked to sales value and/or sales volume and/or preferential usage or recommendation of any medicine or medicines;*

*"**Unacceptable marketing fees or co-marketing fees**" mean payment to a person, company or other entity not providing a legitimate marketing service, and which is not done in terms of a written agreement, and which does not include provision for fees appropriate to the nature, duration and type of advertising and/or which is not directly or indirectly linked to sales value, and/or sales volume, and/or preferential usage or recommendations of any medicine or medicines;*

*"**Shelf space fees**" mean the payment of a fee, in any form, to any purchaser or conduit entity in order to secure shelf or storing space for a particular medicine or medicines, whether in a warehouse, pharmacy, hospital, or medicine storage facility, whether virtual or real*

3. Action steps, role-players and enforcement[2]

3.1 Clarity on definition and scope of perversities/unacceptable trade practices in medicine:

(a) Develop draft definitions of acceptable and unacceptable practices and obtain industry agreement
(b) DoH to incorporate proposed definitions of transactions into a set of regulations (in terms of section 18A) or into the Act, as part of definitions relating to 18A.
(c) DoH to champion other legislative changes and/or recognition of changes in other legislation, as outlined below and above.

3.2 Enforcement

(a) DoH (*Pharmaceutical Policy and Planning / PEE Unit, MRA*) to champion enforcement by means of Section 29 of Medicines Act of 1965, general enforcement takes place through the Inspectorate (contravention of S18A or 18B is an offence).
(b) It is also proposed that other powers, such as those relating to the withdrawal of licences, etc. be exercised, where appropriate.
(c) It is proposed that penalties be graduated in severity depending on the severity of the offence (fines or imprisonment) in terms of section 29.

[2] The bodies and responsible organs have been identified in an attempt to be as clear and helpful as possible. The mis-identification or incorrect assumptions should not be construed as an attempt by industry to be prescriptive towards any person, department or organization.

(d) It is also proposed that compliance with section 18A and 18B be a criteria for new or existing licensing and registration (and withdrawal thereof) in terms of:
- Medicines Act (regulation 43 of General Regulations of 2003 – compliance with section 18A made a condition for registration or continued registration of a medicine) (*PEE Unit and MRA*)
- Health Professions Act and Pharmacy Act (incorporate/recognize specific medicines trade related violations in HPCSA and SAPC codes) (*HPCSA & SAPC*)
- Medical Schemes Act (compliance with this provision criteria for managed care organizations, medical schemes and administrators) (*Council for Medical Schemes*)
- National Health Act (provisions/regulations on Certificate of Need and perverse incentives – one type of perverse incentive should be stipulated to be non-compliance with s18A and its regulations) (*Office of Standards Compliance*)

B. Pricing regulations (logistics fees)

1. Regulatory gap

Two challenges exist with logistics fees, i.e. the licensing of wholesalers and distributors, and the lack of transparency in the logistics fee system, which creates opportunities for the payment of fees which may, or may not, also constitute violations of section 18A. However, as these fees are neither transparent, nor capped/fixed (as per the pricing regulations), it is possible to use such fees as a smokescreen for perversities.

2. Proposed solution

It is recommended that the following definition and provisions be incorporated into all wholesaling and distributing legislation (pricing regulations and section 22C(6) of the Medicines regulation 19 of the General Regulation of 2003).

Prescribed requirements for wholesalers and distributors

1. Provision of logistical services

1.1 Only the legitimate providers of logistical services will be registered in terms of regulation 19

1.2 It is unlawful for any manufacturer or importer to pay logistics fee to any person or organisation who does not perform logistical services.

1.3 No fees may be paid to virtual wholesalers or distributors, i.e. entities who do not fulfil bona fide logistical services.

1.4 The payment of fees for logistical services to an entity not licensed as such as not de facto fulfilling such services constitute an offence in terms of section 29 of the Act.

1.5 Logistics fees mean fixed and appropriate fees paid to licensed wholesalers and distributor for the provision of logistical services, in terms of the provisions of the Pricing Regulations, as amended.

2. Definition of logistical services

2.1 Logistical services mean those services provided by licensed wholesalers and distributors in relation to the supply of medicines, and in order to qualify for licensing and payment of the fixed and appropriate logistics fee, the following services must be rendered:

(a) adherence and conformation to guidelines on good wholesaling and distribution practice;
(b) receiving of bulk;
(c) breaking of bulk;
(d) warehousing;
(e) taking of orders from all customers within the geographic area of operation;
(f) proper record keeping;
(g) batch-tracking and tracing;
(h) maintenance of the cold chain, where applicable and
(i) demonstrate the ability to have and manage a debtors' management system, conforming to accepted accounting norms, and behalf of a principle and/or for the purposes of managing an open debtors' book.

2.2 Logistical services can only be undertaken by distributors and wholesalers, whereby:

(a) A distributor acts as warehousing and distributing agent on behalf of a manufacturer, without ownership passing to such distributor, in return for a fee and whereby a distributor is free to deliver products to any customer which qualifies for such service without bias.

(b) A wholesaler buys and sells product and produce revenue and profit of transactional processes, operating either on the basis of a closed or open debtors book.

3. Review and withdrawal of licenses

The Medicines Control Council may review the allocation of licenses awarded in terms of regulation 19, based on information which comes to its attention, and may withdraw such licence based on non-compliance with the criteria set out above, in terms of its powers under regulation 19(10).

3. Action steps, role-players and enforcement[3]

3.1 Incorporation of definition of logistical services, etc (as stated above) in all regulatory frameworks (Department of Health, PEE Unit; MRA; MoH) as part of the "prescribed requirements".

3.2 All licences for wholesaling and distributing to be based on new definitions, review of licences allocated or enforcement of provisions to ensure that wholesaling or distribution is indeed performed by the licence-holder (Department of Health, PEE Unit; MRA/MCC).

3.3 Department to issue notice to all role-players that the provisions will be enforced, i.e. inspections carried out in order to ensure that all license-holders are indeed providing logistical services (Director-General / MoH).

C. Section 36, National Health Act No 61 of 2003 (perversities)

1. Regulatory gap

The acceptance or demand for the provision of medicines in terms of a bonus, rebate or incentive scheme, may not always be understood to constitute a perverse incentives in terms of licensing of health establishments.

[3] The bodies and responsible organs have been identified in an attempt to be as clear and helpful as possible. The mis-identification or incorrect assumptions should not be construed as an attempt by industry to be prescriptive towards any person, department or organization.

Licenses to health establishments (hospitals, practices, etc) may not be awarded, or may be withdrawn, or issued subject to provisions relating to perverse incentives.

2. Proposed Solution

Regulations to be issued in terms of National Health Act, to specify that:

Perverse incentives include, but are not limited to the acceptance, or demand for the provision of medicine in terms of a practice or agreement outlawed in terms of the Medicines Act or any regulation issued in terms of the Act.

The Office of Standards Compliance may investigate allegations relating to perversities, and may co-operate with the relevant units or persons in the Department of Health, in relation to perversities in the field of medicines supply.

3. Action steps, role-players and enforcement[4]

3.1 Promulgation of regulation / criteria relating to health establishment licensing (Department of Health / MoH).

3.2 Enforcement of licensing criteria relating to perversities in supply of medicine (Department of Health, Director-General; Office of Standards Compliance).

D Professional Codes of Practice / Professional Policies

1. Regulatory gap

Only HPCSA has a Code relating to Perverse Incentives and Undesirable Business Practices (relating also to managed care) for medical practitioners, dentists and persons registered at HPCSA. Provisions relating to the supply of medicines, as stipulated above, not explicitly incorporated. Pharmacists have no specific professional code relating to the supply of medicines.

2. Proposed solution

Existing policy documents or professional codes are needed to make violations, from the side of professionals, actionable in terms of the disciplinary councils of such professionals, must be enforced.

Ethical behaviour in terms of the recommendation, procurement and/or supply of medicine

Professionals should refrain from recommending, asking for, or accepting medicines supply or proposed supply in terms of any transaction described as unlawful in terms of the National Health Act and its regulations and/or the Medicines Act, its regulations and registration / licensing criteria.

The above provision applies irrespective of the employment situation of the professional. Professionals are obliged to voice their objection to transactions which constitute violations of the

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stipulated legislative criteria and may be required to submit proof of such objection in cases of disciplinary action.

Professional / statutory bodies should provide guidance to professionals who face dual loyalty challenges in respect of medicine supply.

3. Action steps, role-players and enforcement[5]

3.1 Incorporation of regulatory framework relating to perversities in medicine into ethical codes and policies of statutory councils (HPCSA, SAPC, etc).

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[5] The bodies and responsible organs have been identified in an attempt to be as clear and helpful as possible. The mis-identification or incorrect assumptions should not be construed as an attempt by industry to be prescriptive towards any person, department or organization.