Innovative Pharmaceutical Association of South Africa (IPASA)

Submission

on the

General Regulations Relating to Bonusing

Submitted to:

National Department of Health

Director: Pharmaceutical Economic Evaluations Directorate

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IPASA

Innovative Pharmaceutical Association South Africa

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1. Opening Remarks

The Innovative Pharmaceutical Association of South Africa (IPASA) welcomes the opportunity to comment on the General Regulations of the Medicines and Related Substances Act, Act 101 of 1965 (as amended) relating to Bonusing. IPASA is a trade association with representation from 27 of the world's leading global pharmaceutical research and biotechnology companies devoted to inventing medicines that have and continue to contribute to patients living longer, healthier, and more productive lives. With nearly $65.5 billion invested in R&D worldwide in 2016,[1] more than 300 new medicines approved in the last decade, and about 7,000 medicines in development globally our members are world leaders in medical research.[2]

Since the implementation of the Medicines and Related Substances Amendment Act 14 of 2015 on 1 June 2017, scope has been created for the Minister, on consultation with the Pricing Committee, to make general regulations relating to acceptable and prohibited acts in relation to section 18A of the Medicines Act.

In considering acceptable and prohibited activities it is important from a private pharmaceutical market view to recognise that the most highly utilized medicine categories are fragmented with many competitors within a category with significant generic penetration across the market.

IPASA is supportive *of efforts to achieve the effective prevention of perversities and other unacceptable business practices within the medicines and health sector.*

Whilst the gazette published on 1 December 2017 describes prohibited activities, acceptable activities as called for in regulation 18A (2) are not defined. IPASA presents recommended inclusions in this regard.

> *"**Bonusing***
> ***18A.** (1) No person shall supply any **[product]** medicine, medical device or IVD according to a bonus system, rebate system or any other incentive scheme.*
> *(2) Notwithstanding subsection (1), the Minister **may prescribe acceptable and prohibited acts** in relation to subsection (1) in consultation with the Pricing Committee referred to in section 22G."*

2. IPASA Recommended Changes

The below table provides IPASA commentary on identified sections of the draft regulations, together with proposed amendments where applicable, as well as rationale for the proposed amendments.

Sect no	Current text or reference to paragraph	Proposed Amendment	Rationale/ Comment
Definitions	"customer" means any person to whom a medicine, medical device or IVD is supplied or who purchases, prescribes, orders, reimburses or pays (directly or indirectly) for a medicine, medical device or IVD and includes: i. Health care providers, a health establishment, a hospital and a health worker (as defined in the National Health Act) and any health care provider representative association, independent practitioner association, health care provider network and a veterinarian as defined in the Veterinary and Para - Veterinary Professions Act, 1982 (Act No. 19 of 1982);	"customer" means any person to whom a medicine, medical device or IVD is supplied or who purchases, prescribes, orders, reimburses or pays (directly or indirectly) for a medicine, medical device or IVD and includes: i. Health care providers, a health establishment, a hospital and a health worker (as defined in the National Health Act) and any health care provider representative association, independent practitioner association, health care provider network and a veterinarian as defined in the Veterinary and Para - Veterinary Professions Act, 1982 (Act No. 19 of 1982);	
	ii. Health care funders which include medical schemes, managed health care 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 and Health Insurance Products as governed by the Long-Term Insurance and Short Term Insurance.	ii. **Deleted**	ii. The need to include healthcare funders and medical scheme is not required as they are not part of the medicines distribution channel that these regulations intend to govern.
	iii. Health information and data collection companies, data switching entities, practice management companies, including healthcare software support and maintenance companies and health care provider claims administrators;	iii. **Deleted**	iii: Following on the principle of deleting ii; these stakeholders do not form part of the supply chain.
	iv. Medical advisors, medical, pharmaceutical or related advisory committees, patient information service entities or any other related entities; and	iv. **Deleted**	iv: Following on the principle of deleting ii, it then follows that iv should be deleted as these entities are functionaries of ii above.
	v. Consumers, patient advocacy groups and patient representative groups.	v. Consumers, patient advocacy groups and patient representative groups.	

Sect no	Current text or reference to paragraph	Proposed Amendment	Rationale/ Comment
Definitions	None	Inclusion of a definition of activity exemption from 18A ***"exemption" will mean activities that fall outside of 18A due to an exemption granted by the Minister of Health on application for activities that improve patient access to defined specific molecules that cannot attain market access due to factors outside of the behavior of the medicines purchasing and supply chain.***	The rationale for including this is the fact that certain high cost niche molecule faces barriers to patient access due to international pricing issues. The intention of this exemption is solely to improve patient access where the specific molecule cannot attain market access to the benefit of needy patient segments.
Preamble	These regulations are intended to support the attainment of affordable medicines, medical devices and in vitro [diagnostic medical device] diagnostic (IVD)'s and to give effect to the prohibition of activities which have the effect of undermining the transparent pricing system of medicines, medical devices and IVDs and more specifically the activities as envisaged in regulation 18A(1), namely the supply of medicine, medical devices and IVDs according to a bonus system, rebate system or any other incentive scheme.	These regulations are intended to support the attainment of affordable medicines, medical devices and in vitro [diagnostic medical device] diagnostic (IVD)'s and to give effect to the prohibition of acceptable and prohibited activities, the latter of which have the effect of undermining the transparent pricing system of medicines, medical devices and IVDs and more specifically the activities as envisaged in regulation 18A(1), namely the supply of medicine, medical devices and IVDs according to a bonus system, rebate system or any other incentive scheme.	The regulations to be inclusive of acceptable activities as called for per section 18A (2) of Act 14 of 2015 effective 1 June 2017: Bonusing 18A. (1) No person shall supply any [product] medicine, medical device or IVD according to a bonus system, rebate system or any other incentive scheme. (2) Notwithstanding subsection (1), the Minister may prescribe acceptable and prohibited acts in relation to subsection (1) in consultation with the Pricing Committee referred to in section 22G

Sect no	Current text or reference to paragraph	Proposed Amendment	Rationale/ Comment
2,3,4	2. Prohibited Activity 3. Bonus System 4. Rebate System	No proposed changes	
5 Incentive Scheme	Means any practice which encourages or rewards a customer for the use, prescription, purchase, order or reimbursement of a medicine, medical device or IVD which may include but is not limited to: a) a discount;	Means any practice which encourages or rewards a customer for the use, prescription, purchase, order or reimbursement of a medicine, medical device of IVD which may include but is not limited to: a) a discount **but excludes** **i. the free supply to State for donation purposes where the request for donations comes from the State;** **ii. the free supply of medicines for clinical studies and post-trial access as requested by SAHPRA; and**	a) free supply to State in terms of donation and free supply for clinical studies ~~and Section 21 applications~~ indicates pricing of the product is impacted and there is a deviation from the approved SEP. With this section removed from 18B of the Medicines Act, it will need to be covered under section 18A to allow for a deviation from the approved SEP. i. See Appendix I ii. See Appendix II
	b) payment for marketing, promotion, and advertising;	b) payment for marketing, promotion, and advertising **of schedule 2 and above**;	Noting that advertising of schedule 1 and below is permitted and therefore would require payment thereof. Furthermore, S0 is exempt from Section 18A and Section 22G.
	c) fees for shelf space;	c) no changes proposed	
	d) data fees and registry fees but excludes the purchase of health informatics supplied by an independent entity, which entity has no association with a customer and where such data is unrelated to the supply of a medicine, medical device or IVD; and also excludes fees payable for registered clinical trials;	d) **Unreasonable** data fees and registry fees, excluding a fee which is for legitimate local evidence generation and is at fair market value, but excludes the purchase of health informatics supplied by an independent entity, which entity has no association with a customer and where such data is unrelated to the supply of a medicine, medical device or IVD; and also excludes fees payable for registered clinical trials;	Data fees linked to a percentage of sales should be deemed unreasonable and should rather be a fixed fee where an appropriate value can be determined for the data received. The data purchased should add value to the purchaser and should be utilized to analyze performance/results.

Sect no	Current text or reference to paragraph	Proposed Amendment	Rationale/ Comment
5 Incentive Scheme	e) loyalty fees or similar fees; f) directors' fees or shareholder fees, honoraria and similar compensation paid to a customer, excluding a fee, honorarium or compensation which is for a legitimate educational activity and at fair value; g) entertainment costs, meals and disbursements including congress and conference attendance in excess of acceptable practices of any marketing code approved and or endorsed by the regulator; h) payment or contribution by a supplier towards any recurring expenditure of a customer which includes salaries or any subsidy of staff costs of personnel or contractors of a customer;	e), f), g) h) No changes proposed	
	i) free services rendered by suppliers or their agents to customers which has the effect of (h) above;	i) free services rendered by suppliers or their agents to customers which has the effect of (h) above **but excludes free servicing of administrative medical devices which is needed to ensure safe and effective delivery of medicines;**	Administrative medical devices are required to ensure safe and effective delivery of a medicine. These devices in most cases are serviced for free by the company placing the device to ensure safe and effective delivery of the medicine with no additional cost to the patient. See Appendix III.

Sect no	Current text or reference to paragraph	Proposed Amendment	Rationale/ Comment
5 Incentive Scheme	j) the placement or the provision of any equipment, medicine, medical device or IVDs by suppliers or their agents at a reduced cost, nominal cost or for free to customers whether directly or indirectly, related to or unrelated, to the supply of a medicine, medical device or IVD and includes consignment stock and loan sets;	j) the placement or the provision of any equipment, medicine, medical device or IVDs by suppliers or their agents at a reduced cost, nominal cost or for free to customers whether directly or indirectly, related to or unrelated, to the supply of a medicine, medical device or IVD and includes consignment stock and loan sets; **excluding the free supply of administrative medical devices which are needed to ensure safe and effective delivery of the medicine;**	Specific administrative medical devices are required to ensure safe and effective delivery of a medicine. These administrative devices are given/loaned to the healthcare establishment/prescriber/patient at no additional cost to the healthcare establishment/prescriber/patient or funder. See Appendix III.
	k) unjustified credit payments which have the effect of an inducement;	k) No changes proposed	
	l) formulary and protocol listing payments to any customer or any person who is able to influence such a listing	l) formulary and protocol listing payments to any customer or any person who is able to influence such a listing, **this includes incentive schemes to pharmacies and pharmacists which may influence a decision/advice to patients for a particular product.**	Pharmacy groups should not be allowed to incentivise Pharmacies / Pharmacists to dispense medicines according to a Formulary as opposed to a prescription (generic switching). This should be classified as inappropriate as it creates an opportunity for a Pharmacist to dispense a product which is influenced by an incentive, rather than by giving patients objective, unbiased advice. Some Pharmacies are making use of incentive programs for the Dispensing Pharmacist or pharmacist assistant in which the Dispensing Pharmacist or assistant gets a financial incentive from the relevant pharmaceutical company / Pharmacy Owner when sticking to an agreed formulary. This practice competes with the patient's right to objective advice.

Sect no	Current text or reference to paragraph	Proposed Amendment	Rationale/ Comment
5 Incentive Scheme	New	n) pharmacists or pharmacy assistants switch from one generic to another based on an incentive scheme	As per Good Pharmacy Practice in South Africa, Good Pharmacy Practice Requirements… (d) an integral part of the pharmacist's contribution to health care is the promotion of rational and economic prescribing and optimal use of medicines. … (f) … (vii) the philosophy underlying practice must be professionally rather than commercially orientated.
	New	o) funders contacting patients and advising on a cheaper product when the HCP is the prescriber.	As per the current "Drug Utilisation Review (DUR)" process.
	New	p) In response to 6.2, hospital listing/de-listing on formularies and pharmacists regarding dispensing.	In response to 6.2, we recognise this might open up an unwanted scenario where Managed Healthcare Company pay pharmacies to collect evidence that a product should NOT be included on a formulary, thereby impacting on the rights of a patient to decide themselves what product they want to use. In essence it would come over as bias if the party paying for the evaluation is also set to benefit from the outcome. A Pharmacist must remain objective when offering advice to patients.

Sect no	Current text or reference to paragraph	Proposed Amendment	Rationale/ Comment
New **6. Acceptable Activity**	***New insertion*** **6. Acceptable Activity**	**Acceptable Activity** **<u>New text below</u>** The offer, payment or acceptance or appropriate fees for legitimate services, is acceptable and excluded from the ambit of section 18A. Such acceptable transactions include, amongst others: 1. acceptable / appropriate fees for data, advertising or marketing which is related to the rendering of a <u>bona fide</u>, actual service, commensurate with the value of the services rendered and which are not linked to sales volumes, targets or similar criteria; 2. acceptable / appropriate 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 to cover the lawful and legitimate costs that might be incurred in such evaluation.	Include a section on acceptable activities to support the attainment of affordable medicines as per regulation 18A(2) Therefore, new insertion as Section 6 and move Penalties to Section 7. Commencement would then become Section 8. Refer to 5d Marketing and advertising of S1 and below is permissible. If these activities are conducted, they should be at arms-length – the fee should be in line with an external third party. This process should be objective and supported by the Pharmacoeconomic Analysis Regulations.

Sect no	Current text or reference to paragraph	Proposed Amendment	Rationale/ Comment
New **6. Acceptable Activity**	***New insertion*** **6. Acceptable Activity**	3. risk-sharing agreements between pharmaceutical manufacturer's and healthcare insurers that directly benefit patients in both a clinical and possibly a financial sense as well as the financial upside to an insurer and which are aligned with internationally-acceptable models of risk-sharing, as approved by the Department of Health;	Risk sharing agreements which directly benefits the patient, only addresses clinical risk. Should we include risk sharing to manage financial risk of budget overspending as carried by the scheme. I.e. risk sharing agreements may or may not benefit the patient directly. Offsetting cost in one area of a populations intervention (i.e. decrease in overall hospital cost) in exchange for funding of better pharmaceutical prevention may not benefit a specific patient directly but does it for the Medical scheme in totality.
		4. the provision of medicines to the public health system where discounts are provided as per state tender requirements, provided that such discounted price is not accompanied by any perverse incentives or unacceptable fees or payments listed above;	Products should be made available to the public health system, even if not on tender, at a negotiated price, in an attempt to increase access to quality healthcare to a broader population.
		5. any other practice, outside of the scope of these regulations, which are found to be acceptable by the Minister of Health and published as being an acceptable trade practice in the Government Gazette.	

3. Further Clarity Requested

Medical Devices and IVDs

It should be noted that, due to the legislative nature of the pharmaceutical industry, where prices for pharmaceutical manufacturers are capped by means of the Single Exit Price (SEP), the separation of acceptable and unacceptable practices might look different for medical devices and IVDs, where price regulation is not in existence, and where competition law currently separates what is lawful, and what is not, in terms of discounts, bonuses and similar deals.

As per the Medicines Control Council, now the South African Healthcare Products Regulatory Authority (SAHPRA), exemption published in the Government Gazette 41362 dated 29 December 2017, medical devices and IVDs are exempt from the Act for a period of one year, however the draft regulations issued on 1 December 2017 do include medical devices and IVDs. This needs to be clarified.

4. Concluding Remarks

IPASA welcomes the opportunity to comment in this regard. IPASA is supportive of efforts to achieve the effective prevention of perversities and other unacceptable business practices within the medicines and health sector.

The regulations proposed in GN 1321 of 01 December 2017 are far reaching in the National Department of Health's (NDoH) stated ambition of achieving a transparent system for medicines and scheduled substances. Matters addressed in this government notice go to the heart of areas of uncertainty which have clouded the goal of transparency for a prolonged period.

The proposed regulations and our suggested amendments comprise a regulatory transformation to existing practices. If correctly implemented these changes can have a significant impact on the ultimate price paid for medicines by patients in South Africa and consequently improved access. IPASA, through its membership and its product offering, wishes to reinforce its stated aim of being recognised as a partner to assist the NDoH to improve the health of all South Africans

While complying through submitting this document for comments on the general regulations relating to bonussing, the issues touched on require a greater interaction to explain fully and to ensure clarity how these changes will benefit patients.

In making this submission we request, in a spirit of collaboration, an opportunity to meet with the Pharmaceutical Economic Evaluations Directorate to discuss in greater detail than can be covered here regarding our response to issues raised in the notice. There are important practical considerations that need to be considered.

Details pertaining to the recommended refinements to the proposed regulations set out in GN 1321, as well as a number of inclusions have been detailed above, providing rationale.

In summary, IPASA has made critical proposals regarding section 18A as well as potential exemptions from the regulations. IPASA, with regard to the former, strongly recommends the inclusion of both ***acceptable*** and prohibited activities in line with Section 18A of the Medicines and Related Substances Act, 1966 (Act No. 101 of 1965). With regard to these proposed exemptions we have provided both a definition and examples. We have also reviewed the definitions of "customer" and made important adjustments to these.

We look forward to a fruitful and constructive engagement on this important piece of proposed legislation which will contribute to ultimately securing transparency in the supply chain.