Comments made by interested parties for which the Dept is in agreement.

Item	Current text or reference to paragraph	Proposed Amendment	Rationale
1	Section 1 Definitions "advertisement" in relation to any 'advertisement', in relation to any medicine, Scheduled substance, medical device or IVD means any written, pictorial, visual or other descriptive matter or verbal statement or reference- *(a)* appearing in any newspaper, magazine, pamphlet or other publication;	"advertisement" in relation to any 'advertisement', in relation to any medicine, Scheduled substance, medical device or IVD means any written, pictorial, visual or other descriptive matter or verbal statement or reference- *(a)* appearing in any newspaper, magazine, pamphlet, other publications or electronic media;	The definition of advertisement only refers to information appearing in newspapers, magazines, pamphlets or other publications. In today's electronic environment electronic media should also be included
2	'medical device' means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article- *(a)* intended by the manufacturer to be used, alone or in combination, for human beings for- (i) diagnosis, prevention, monitoring, treatment or alleviation of disease; (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury; (iii) investigation, replacement, modification, or support of the anatomy or of a physiological process; (iv) supporting or sustaining life; (v) control of conception; (vi) disinfection of medical devices; or (vii) providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and	'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, - (a) intended by the manufacturer to be used, alone or in combination, for humans or animals, for one or more of the specific medical purpose(s) of: (i) diagnosis, prevention, monitoring, treatment or alleviation of disease, (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury, (iii) investigation, replacement, modification, or support of the anatomy or of a physiological process, (iv) supporting or sustaining life, (v) control of conception, (vi) disinfection of medical devices, (vii) providing information by means of *in vitro* examination of specimens derived from the human body; and	The NDOH agrees that the latest updated definition as per the International Medical Device Regulatory Forum (IMDRF) be used. (ref.:GHTF/SG1/N071:2012).

Comments made by interested parties for which the Dept is in agreement.

Item	Current text or reference to paragraph	Proposed Amendment	Rationale
	(b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means; [Definition of 'medical device' inserted by s.1(c) of Act 94 of 1991 and substituted by s.1(g) of Act 72 of 2008.]	(b) which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.	
3	Section 1 Definitions 'IVD' *(In-vitro diagnostic medical device)* means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes;	*'In Vitro Diagnostic* (IVD) medical device' means a medical device, whether used alone or in combination, intended by the manufacturer for the *in vitro* examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.	The NDOH agrees that the latest updated definition as per the International Medical Device Regulatory Forum (IMDRF) be used. (ref.: GHTF/SG1/N071:2012)
4	2A Objective of Authority The objectives of the Authority are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, clinical trials and medical devices and related matters in public interest	2A Objective of Authority The objectives of the Authority are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, Scheduled substances, clinical trials and medical devices and IVDs and related matters in public interest which include regulatory oversight of foodstuffs and cosmetics.	Omission corrected.

Comments made by interested parties for which the Dept is in agreement.

Item	Current text or reference to paragraph	Proposed Amendment	Rationale
5	2B Functions of Authority 1) The Authority must, in order to achieve its objects- (a) Ensure the efficient, effective and ethical evaluation and registration of medicines, medical devices and IVDs that meet defined standards of quality, safety and efficacy	2B Functions of Authority (1) The Authority must, in order to achieve its objects- (a) Ensure the efficient, effective and ethical evaluation and registration of medicines, medical devices and IVDs that meet defined standards of quality, safety and <u>efficacy and where applicable performance</u>	Medical Devices and IVDs need to meet specific performance criteria and not efficacy criteria as in th case of a medicine.
6	2B Functions of Authority 1) The Authority must, in order to achieve its objects- (d) ensure that evidence of existing and new adverse events, interactions, information about pharmacovigilance is being monitored, analysed and acted on.	2B Functions of Authority 1) The Authority must, in order to achieve its objects- (d) ensure that evidence of existing and new adverse events, interactions, information about <u>post-marketing surveillance and vigilance</u> being monitored, analysed and acted on.	Agree to change the wording as post marketing surveillance and vigilance refer to both medicines, Medical Devices and IVDs. The term "Pharmacovigilence" could be regarded restricted to medicine
7	13 Registers 1) The Chief Executive Officer shall keep separate registers for medicines, Scheduled substances, medical devices and IVDs in which he or she shall record- (a) The registration of medicines, Scheduled substances, medical devices or IVDs by the Authority; and	13 Registers 1) The Chief Executive Officer shall keep separate registers for medicines, medical devices and IVDs in which he or she shall record- (a) The registration of medicines, medical devices or IVDs by the Authority; and	Agree to delete reference to Scheduled substances. The Authority will not register Scheduled substances but will only register medicines, Medical Devices and IVDs. The reference to Scheduled substances was included in error.
8	13 Registers 2) The Chief Executive Officer shall publish on the Authority's website the registers referred to in subsection (1) and update those registers every six months	13 Registers 2) The Chief Executive Officer shall publish on the Authority's website the registers referred to in subsection (1) and update those registers <u>when registration is obtained</u>	Agree to amend to allow for greater transparency and to update the electronic registers of the Authority when any medicine, Medical Device ort IVD is registered.
9	15 (a)(iii) is safe, efficacious and of good quality	15 (a)(iii) is safe, efficacious and of good quality and <u>in the case of a medical device and IVD performance as intended</u>	Medical Devices and IVDs need to meet specific performance criteria and not efficacy criteria as in the case of a medicine.

Comments made by interested parties for which the Dept is in agreement.

Item	Current text or reference to paragraph	Proposed Amendment	Rationale
10	22C. Licensing (1) Subject to the provisions of this section- (a) the Director-General may on application in the prescribed manner and on payment of the prescribed fee issue to a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, a licence to compound and dispense medicines, on the prescribed conditions;	22C. Licensing (1) Subject to the provisions of this section- (a) the Director-General may on application in the prescribed manner and on payment of the prescribed fee issue to a medical practitioner, dentist, practitioner, veterinarian, nurse or other person registered under the Health Professions Act, 1974, a licence to compound and dispense medicines, on the prescribed conditions;	Veterinarians compound and dispense veterinary medicines. Experience has shown that veterinarians lack knowledge on compounding and dispensing of medicine although previously it was claimed that the pre graduate Curriculum for veterinarians include training on compounding and dispensing
11	22C. Licensing (b) the Authority may, on application in the prescribed manner and on payment of the prescribed fee, issue to a medical device or IVD establishment, manufacturer, wholesaler or distributor of a medicine, scheduled substance, medical device or IVD a licence to manufacture, import or export, act as a wholesaler of or distribute, as the case may be, such medicine, scheduled substance, medical device or IVD upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the Authority may determine.”;	22C. Licensing (b) the Authority may, on application in the prescribed manner and on payment of the prescribed fee, issue to a medical device or IVD establishment, manufacturer, wholesaler or distributor of a schedule 1 and higher medicine or scheduled substance, medical device or IVD a licence to manufacture, import or export, act as a wholesaler of or distribute, as the case may be, such medicine, scheduled substance, medical device or IVD upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the Authority may determine.”;	Acknowledge that some distributors such as “Makro” and “Cash and Carry” deals exclusively with unscheduled medicines. Not required that these type of distributors comply with all the SA Pharmacy requirements or obtain a license from MCC as they operate as so called retailers dealing with bulk products.
12	22C. Licensing (6) No manufacturer, wholesaler or distributer referred to in subsection (1) (b) shall manufacture, import, export, act as a wholesaler of or distribute, as the case may be, any medicine unless he or she is the holder of a licence contemplated in the said subsection.	22C. Licensing (6) No manufacturer, wholesaler or distributor referred to in subsection (1) (b) shall manufacture, import, export, act as a wholesaler of or distribute, as the case may be, any medicine unless he or she is the holder of a licence contemplated in the said subsection.	Correction of typographical error

Comments made by interested parties for which the Dept is in agreement.

Item	Current text or reference to paragraph	Proposed Amendment	Rationale
13	36 Exclusion of any medicine, Scheduled substance, Medical Device or IVD from operation of the Act (2) Notwithstanding subsection (1), the exclusion of any medicine or Scheduled substance from the operation of Section 22G shall be on the recommendation of the Pricing Committee	36 Exclusion of any medicine, Scheduled substance, Medical Device or IVD from operation of the Act (2) Notwithstanding subsection (1), the exclusion of any medicine or Scheduled substance from the operation of Section 18A and 22G shall be on the recommendation of the Pricing Committee to the Minister.	In agreement. Current practise is for the MCC to consider the request for exemption. MCC mandate is quality, safety and efficacy not pricing.
14	18A. Bonussing (1) No person shall supply any product, 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)	18A. Bonusing (1) No person shall supply any medicine, Scheduled substances, 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	Mandate of the Pricing Committee is to pronounce on marketing, bonusing and pricing matters and advise the Minister accordingly.