		physical or mental state or the symptoms thereof in humans; or *(ii)* restoring, correcting or modifying any somatic or psychic or organic function in humans, and (*b*) includes any veterinary medicine; **'medical device'** means any instrument, apparatus, implement, machine, appliance, implant, [*in vitro*] reagent for *in vitro* use [or calibrator], software, material or other similar or related article, **including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973) —** *(a)* intended by the manufacturer to be used, alone or in combination, for humans [beings] or animals, for one or more of the following: [-] (i) diagnosis, prevention, mönitoring, 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 *(b)* which does not achieve its primary intended action [in or on the human body] by pharmacological, immunological or metabolic means, in or on the human **or animal** body, but which may be assisted in its intended function by such means; ['**product**' means a medicine, a Scheduled substance or a cosmetic or foodstuff which contains a scheduled substance;]

Comment [BL3]: Sandwich provision not properly reflected in 2008 Amendment Act. Technical correction.

		(2) The Authority may— *(a)* liaise with any other regulatory authority or institution and may, without limiting the generality of this power, require the necessary information from, exchange information with and receive information from any such authority or institution in respect of— (i) matters of common interest; or (ii) a specific investigation; and *(b)* enter into agreements to co-operate with any regulatory authority in order to achieve the objects of this Act. (3) The Authority is responsible for advising the Minister on policy and regulatory matters relating to— *(a)* cosmetics; **and** *(b)* foodstuffs**[; and]** **[*(c)* Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973)].** **2C Composition of Board** (1) The Board of the Authority consists of not less than 10 but not more than 15 members appointed by the Minister. (2) Subject to section 2D, the Minister must appoint as members of the Board— *(a)* not more than 10 persons who have expertise in the fields of medicine, medical devices, IVD, pharmaco-vigilance, cosmetics and foodstuffs regulatory, clinical trials, good manufacturing practice, public health or epidemiology; *(b)* one person on account of his or her knowledge of the law; *(c)* one person on account of his or her knowledge of good governance; *(d)* one person on account of his or her knowledge of financial matters and accounting; *(e)* one person on account of his or her knowledge of information technology; and *(f)* one person on account of his or her knowledge of human resource management. (3) The Chief Executive Officer is by virtue of his or her office a member of the Board but with no voting rights. **2D Appointment of members of Board** (1) The Minister must, before appointing the members contemplated in section 2C(2), by notice in the *Gazette* and in two or more nationally circulating newspapers in the Republic, invite all interested persons to nominate, within the period specified in the notice, persons who in the opinion of such interested persons are fit to be so appointed, stating the grounds upon which such opinion is based. (2) If the Minister receives no nominations or an insufficient number of nominations within the period specified in the notice referred to in subsection (1), the Minister may either readvertise or in any other