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A REVIEW OF THE GOVERNMENT GAZETTE AND NEW DEVELOPMENTS IN LAW

Revision is worth its salt

Amendment act sees significant changes to SA's healthcare regulatory regime

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UNDER SA's current healthcare regulatory regime, some substances or mixtures of substances are subject to compulsory registration as a medicine in terms of the Medicines and Related Substances Act, 1965, by virtue of having been called up for registration by the Medicines Control Council.

Other substances not subject to compulsory registration would become registrable if a person wanted to make marketing claims in respect of such substances which would shift the definition of a medicine for purposes of the medicines act.

For instance, a topical preparation containing camphor would not, in terms of its composition, be subject to compulsory registration as a medicine. If, however, a person wanted to market the preparation in SA as a treatment for ringworm or as a local anaesthetic, the preparation would need to be registered as a medicine with the Medicines Control Council.

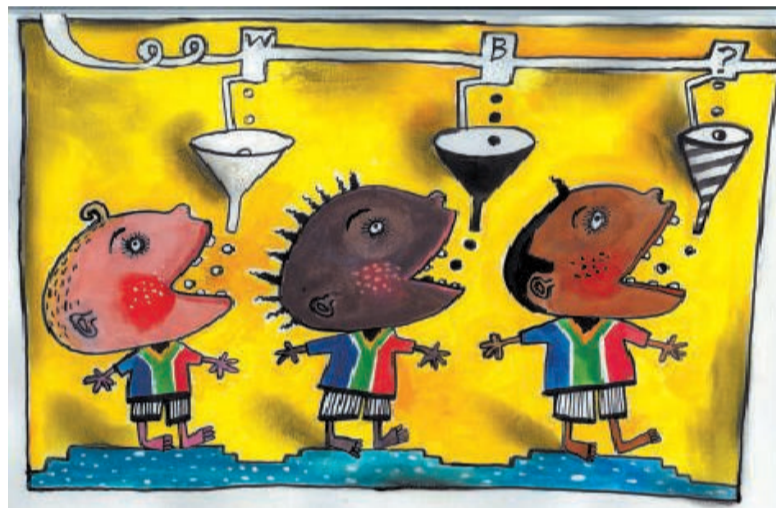
In other words, the medicines act, read with the Foodstuffs Cosmetics

and Disinfectants Act, 1972, currently contemplates and provides for the situation where an article or substance which would otherwise be a foodstuff or a cosmetic in terms of its composition, is in fact a medicine subject to registration on the basis of its medicinal treatment or restorative claims.

On the other hand, certain foodstuffs which contain scheduled substances, but in respect of which no medicinal claims are made, fall within the jurisdiction of the foodstuffs act.

For example, in terms of regulations made under the Foodstuffs Act, foodstuffs such as margarine, jams and marmalade, ice-cream, self-raising premixed powdered cake and bread flours, baking powder, chutney, pre-cooked instant breakfast cereals and food-grade salt are expressly allowed to contain potassium chloride.

Potassium chloride is a metal halide salt consisting of potassium and chlorine. The proper level of potassium is essential for normal human cell function. Among the functions of potassium are regulation of the heartbeat and the function of the muscles. Potassium chloride is a schedule 2 substance under the medicines act (except in certain specific instances where it is dealt with



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as a schedule 0 or a schedule 3 substance). Medically, potassium chloride is used for a number of indications, including in the treatment of hypokalaemia (a condition of abnormally depleted potassium) and to replenish electrolytes in foodstuffs. Potassium chloride is commonly used as a low sodium salt substitute.

The Medicines and Related Substances Amendment Act, 2008 was assented to in April and will come into effect on a date fixed by the president by proclamation.

The amendment act introduces a number of significant changes to the healthcare regulatory regime, includ-

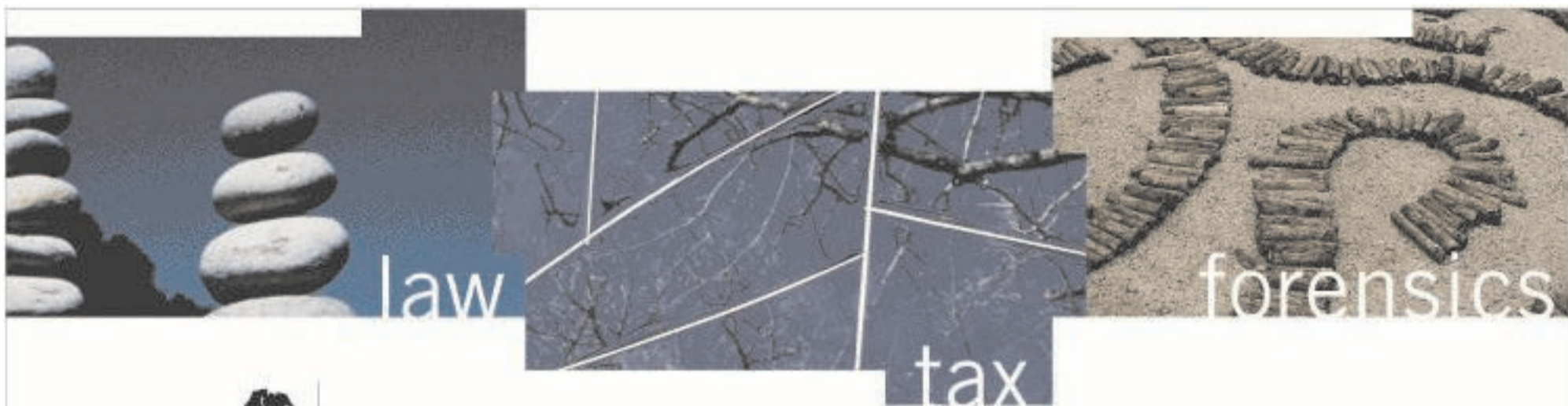
ing the creation of a South African Health Products Regulatory Authority (SAHPRA) — which will replace the Medicines Control Council — the regulation and control of medical devices and in vitro diagnostic medical devices, and the regulation and control of foodstuffs and cosmetics containing a scheduled substance.

In terms of the amended medicines act, medicines, scheduled substances, and foodstuffs and cosmetics (as defined in the foodstuffs act) which contain a scheduled substance fall within the definition of a product. Products will be subject to compulsory registration in terms of the Medicines Act if the regulatory authority (SAHPRA) publishes a declaration to that effect.

Further, products will fall within the prohibitions contained in sections 18A and 18B of the medicines act. This means that foodstuffs or cosmetics containing scheduled substances may not be supplied by any person according to a bonus system, rebate system or any other incentive scheme, and that no free samples of such foodstuffs or cosmetics may be given by manufacturers or wholesalers to healthcare professionals, including pharmacists.

These prohibitions apply to foodstuffs and cosmetics irrespective of whether the products in question have been declared to be subject to regis-

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tration by SAHPRA.

The question which arises is whether it was intended by the legislator that the scope of the medicines act would be expanded to include foodstuffs which contain relatively small amounts of scheduled substances which are currently fully regulated under the foodstuffs act and in respect of which no medicinal treatment or restorative claims are made, or if this is an unintended consequence of the medicines amendment act.

To use the example already discussed, in terms of the amended medicines act, it would appear products such as margarine, jams and marmalade, ice-cream, cake and bread flours, pre-cooked instant breakfast cereals and food-grade salt which contain potassium chloride will fall under the authority of SAHPRA (as opposed to the Health Department, Directorate: Food Control), may be subject to compulsory registration, and may not be supplied or donated in the manners contemplated in sections 18A and 18B of the medicines act.

The amended medicines act does, however, contain a mechanism in terms of which the health minister, on the recommendation of the health authority, may exclude any product from the operation of any or all of the provisions of the medicines act. It is possible this mechanism will be used to ensure foodstuffs and cosmetics of the nature under discussion are not subjected to unintended overregulation.