Is big pharma trying to muscle out the natural medicine industry?

By Daleen Totten

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Pharmaceutical-style regulations are being forced upon natural health products. If a product is proven to have a health benefit, it will then have to be registered as a medicine. The effect of this alone is that the expense to comply will cause small operators to go out of business.

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So what is the issue here really? Products need to be regulated. The consumer needs to be protected. We need to have assurances that the ingredients claimed on the label are actually in the product and that the raw ingredients have been tested for quality, safety and efficacy.

I'm sure everyone agrees that we need regulations. So why are we going on about it and why do we need to make a stand against the new regulations?

Affordability

Multi-million rand air-conditioning and laminar airflow management systems which are required to be installed in all Medicines Control Council (MCC) licensed manufacturing facilities will cause products to become very expensive. The cost of complying with current regulations is prohibitive and will run into millions of rands.

In addition, many applications will fail to satisfy the requirements of the MCC, especially in 'Category A', rendering the products illegal and requiring immediate removal from sale when called up in terms of the roll-out plan over the next few years.

Unfair commercial gain

The cost of compliance allows for unfair commercial advantage to the bigger pharmaceutical manufacturers, loss of diversity, and the removal from the market, of the vast majority of health products not manufactured by drug companies thereby limiting our freedom of choice.

Restriction and low potency

Natural and innovative products are being restricted – something for which there is no evidence to suggest any risk in using them. The products that will remain after 2019 will be low-potency, mostly synthetic nutrient supplements and single substances (without curative or preventative health claims). All unregistered products will also be removed from shelves.

The Allied Health Professions Council of South Africa (AHPCSA) expects high-potency natural medicines to only be allowed to be dispensed by them in terms of their prescribing rights.

But sadly these products may no longer be imported as dispensing is a fraction of the current market-share and then there is the weakening rand... Due to the economies of scale and abovementioned costs to register and comply with the MCC regulations, the AHPCSA won't have the desired products to dispense.

In the end, the new regulations will severely restrict the public's access to natural health products, and manufacturers, wholesalers, retailers, direct marketers, prescribing practitioners and the public will lose. The only winners will be the pharmaceutical industry.

South Africa has recently established an Institute for Regulatory Science at various universities that offers post-graduate degrees in "regulatory medicine", sponsored by the Bill and Melinda Gates Foundation, the European Union and the World Health Organisation.

An envisaged 600 graduates are expected to fill posts at the soon-to-be-established African Medicines Agency and will enable, monitor and enforce the Model Law. Retired regulators from authorities such as the US Food and Drug Administration (FDA) have been recruited to train these students.

African Union Model Law and AMA

According to the new chairman of the Traditional and Natural Health Alliance (TNHA) Anthony Rees: "A newly adopted African Union Model Law and the establishment of an African Medicines Agency (AMA) threatens to undermine the sovereignty of all African Nation-States in their regulation of medicines. This scheme, drafted behind closed doors, will significantly boost big pharma's market share on the continent, and will ensnare traditional and natural health products, foods and cosmetics into a harmonised regulatory framework.

A few days after President Zuma signed the controversial Medicines and Related Substances Amendment Bill into law in January, I stumbled across an online press release stating that the African Union recently ratified a directive (Model Law) that will harmonise all national legislation for medicines administered by 55 regulatory authorities throughout Africa.

This Model Law will benefit pharmaceutical sector development on the continent, and reduce the time taken to register novel and generic drugs, medical devices, and natural health products. This agency will ultimately make decisions for the health of over 1bn people, and we are not aware of any traditional or natural health stakeholders in Africa, who have approved the

inclusion of their products under the Model Law.

How is it that a few people can make unilateral decisions for a whole sector which includes doctors who practise with integrated health strategies, nutritional health practitioners, the manufacturing industry and millions of health-conscious consumers?

The International Coalition of Medicines Regulatory Authorities (ICMRA) was established by global drug regulators in December 2013. Rees says that: “According to local industry insiders, on her return from a meeting held in London in early 2014, Dr Joey Gouws, MCC registrar of medicines reported that ICMRA member countries had agreed that various countries, including South Africa, would follow Health Canada’s lead in bringing natural health products under a quasi-drug-regulatory model, and that these regulatory schemes would become benchmarks for the other countries to follow. South Africa and New Zealand appear to be the first dominos to fall in this global strategy.”

What has already emerged from the ministry of health is a restriction and ban of a substantial number of herbal products and supplements – an attempt to control all forms of medicine under a pharmaceutical stranglehold.

Where is this going to end?

Traditional use of herbal medicine should be accepted. In the EU, the courts have recently ruled on this specific issue (rule of doubt). If a natural substance has been used for over a period of 30 years, it should be accepted as safe, and the authorities should be the ones to do the research and supply scientific evidence that it is unsafe.

ABOUT THE AUTHOR

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