HCLS Pulse – A bi-weekly update on regulations impacting the healthcare and life sciences industry

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KPMG in South Africa

Scope of coverage: **Africa** *(South Africa, Botswana, Ethiopia, Ghana, Rwanda, Uganda, Libya, Kenya and Nigeria)*; **North America** *(the US and Canada)*, **Europe** *(the UK)*, **ASPAC** *(Australia)*, **International agencies** *(WHO and OECD)*

Time period: May 18, 2017 – May 31, 2017

In This Issue:

South Africa

Minimum data specifications with regard to Crohn's Disease and Ulcerative Colitis published

The managed care working group completed work towards putting in place the measurement of the quality, outcomes, and the value proposition of managed care interventions. The initiative is focused on the impact of managed care insofar as the techniques relating to funding of benefits

for medical scheme beneficiaries. The introduction of entry level criteria, process indicators and clinical outcome measures for chronic disease conditions will enable the Council of Medical Schemes to asses, guide, monitor and promote the measuring of value of managed care interventions to beneficiaries. Medical schemes will henceforth be required to report on these process indicators and outcomes achieved in the annual statutory returns. *CMS*

National Public Health Institute of South Africa Bill
The National Public Health Institute of South Africa Bill aims to provide for the setting up of the Public Health Institute. The institute would seek to conduct disease and injury surveillance and to provide specialised public health services, public health interventions, training and research directed towards the major health challenges affecting South Africa's population. *Sabinet*

National Health Laboratory Service Amendment Bill
The National Health Laboratory Service Amendment Bill intends introducing amendments to the National Health Laboratory Service Act in order to make the Preferential Procurement Policy Framework Act applicable to the National Health Laboratory Service (NHLS). The proposed legislation also aims to adjust the objects and duties of the service and strengthen the governance and funding mechanism of the NHLS. *Sabinet*

Draft dispensing fees for pharmacists published for comment
The proposed dispensing fees include:

Single exit price less than R107.15 – R11.00 plus 46% of the price;
Single exit price between R107.15 and R285.80 – R24.30 plus 33% of price;
Single exit price between R285.80 and R1000.32 – R74.00 plus 15% of price; and
Single exit price of R1000.33 and above – R173.00 plus 5% of price.

According to the notice, the dispensing fees are reviewed on an annual basis taking considerations such as availability and affordability, the inflation rate and information supplied by pharmacists into account. All invoices for purchased medicines must show the dispensing fee charged and the single exit price. *Sabinet*

Draft dispensing fee to be charged by doctors, dentists and nurses for comment
The proposed dispensing fees include:

- Single exit price less than R120.00 – the dispensing fee must not exceed 30% of price; and
- Single exit price equal to or greater than R120.00 – the dispensing fee must not exceed R36.00 of price. *Sabinet*

Proposed annual single exit price adjustment for medicines and scheduled substances for 2018
The proposed formula that may be taken into consideration when recommending the next annual adjustment cycle is 70% (South African CPI) + 30% (foreign exchange rate) = % adjustment. *Sabinet*

Copyright Amendment Bill 2017
Some of the revisions to the previous Bill include:

Allow reproduction of copyright work;
Protection of copyright in artistic work;
Accreditation and registration of Collecting Societies;
Access to copyright works by persons with disabilities;
Establishment of the Intellectual Property Tribunal;
Prohibited conduct in respect of technological protection measures;
Management of digital rights. *Sabinet*

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Australia

Consultation: Comparable overseas regulators - medical devices
This includes proposed criteria to identify comparable overseas regulators and mechanisms to allow consideration of such overseas marketing approvals when deciding whether a medical device should be approved for the Australian market. The consultation is specifically looking for feedback on criteria for identifying:

Comparable overseas regulators to allow consideration of their market authorisation decisions; and
Overseas designating authorities that are comparable to the TGA to allow confidence in the third parties they designate. *TGA*

Guidance on GMP requirements when manufacturing compounded medicines
The guidance clarifies the PIC/S Guide to Good Manufacturing Practice (GMP) for Medicinal Products PE-009 requirements for the manufacture of extemporaneously compounded medicines. This document is only applicable to licensable manufacturers, although may be used as guidance for pharmacists performing compounding that are considered exempt from licensing under the Therapeutic Goods Regulations 1990. *TGA*

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Canada

Improving the licensing of production of cannabis for medical purposes
Health Canada is implementing the following measures:

Increasing the department's capacity to review and process applications by allocating additional resources;
Undertaking some stages of the review of the application concurrently;
Permitting licensed producers to manage production on the basis of their vault capacity;
Authorizing longer validity periods for licenses and security clearances in accordance with the regulations;
Streamlining the review and approval of applications to modify or expand a production facility for licensed producers with a record of good compliance with the ACMPR. *Health Canada*

Government of Canada took action on Anti-Microbial Resistance (AMR)
Health Canada introduced new rules for veterinary drugs that will protect Canadian against AMR.
Changes to food and drug relations include:

- Restricted importation of certain veterinary drugs for food-producing animals;
- Stricter guidelines to make companies ensure quality of pharmaceutical ingredients;
- Annual reporting of sales of medically important anti-microbial drugs to Health Canada for better surveillance; and
- Introduction of flexible and risk appropriate framework. *Health Canada*

Regulation of patented drug prices
Minister of Health is focused to improve affordability, accessibility and appropriate use of prescription drugs. The regulatory framework that guides the work of the Patented Medicine Prices Review Board (PMPRB) will be modernized. This will be done by making amendments to the regulations. Potential amendments include:

Revise the list of comparator countries for which patentees must provide drug price information;
Introduce new economics-based factors so that willingness and ability to pay can be taken into consideration in assessing whether the price of a patented drug is excessive; and
Update the information required from patentees. *Health Canada*

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Other African Countries

Guidance on GMP requirements when manufacturing compounded medicines (Kenya)
In response to Kenya's commitment to the global action plan on antimicrobial resistance and the resolution WHA68, the country has completed developing the National Policy and Action Plan on the Prevention and Containment of Antimicrobial Resistance. The country is currently gearing towards the operationalization of the plan and mobilize resources both domestic and external funding to support the implementation of the priority areas identified in the National Action Plan, which include research and development, increasing and sustaining awareness of and knowledge on antimicrobial resistance among the public and health professionals. *Ministry of Health, Kenya*

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US

FDA approves first cancer treatment for any solid tumor with a specific genetic feature
The U.S. Food and Drug Administration today granted accelerated approval to a treatment for patients whose cancers have a specific genetic feature (biomarker). This is the first time the agency has approved a cancer treatment based on a common biomarker rather than the location in the body where the tumor originated. *FDA*

Secretary's Ventures Fund announce upcoming projects
Health and Human Services (HHS), Secretary announced the selection of five entrepreneurial projects for investment by the Secretary's Ventures Fund (HHS Ventures). The projects were chosen from across HHS as part of the latest round of funding and support designed to advance the innovation agenda. The following projects will be taken up:

Fight against Zika: leveraging health information technology
Optimize cyber-molecular surveillance of Viral Hepatitis;
Internet devices to improve animal care;
Electronic signature capture and data transfer; and
Streamline acquisition of lab supplies. *HHS*

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Canada

Government of Canada announces funding for Lyme disease research
The Government of Canada released the federal framework on Lyme Disease. The framework, which is intended to help guide a way forward in areas where the federal government has a role, is built around three pillars: surveillance; guidelines and best practices; and education and awareness. Progress will be reported on an ongoing basis. This framework will support the continued collaboration and work between the federal and provincial and territorial governments in addressing Lyme disease. *Health Canada*

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WHO

Unprecedented new organizational reforms for WHO in the African region announced
The World Health Organization's (WHO) Regional Director for Africa announced four new flagship programs for the region over the next two years, including a major push on adolescent health and the creation of regional emergency hubs. She also announced that WHO country offices in the African region will be held accountable to a mandatory set of performance deliverables over the next two years as part of the next phase of Transformation Agenda reform program which begun in 2015 in the wake of the Ebola crisis in West Africa. As part of its new Adolescent Health Flagship programme, WHO-AFRO will support countries to develop strategies and implement evidence-based interventions. Globally, such interventions include improving immunization coverage, tackling substance abuse, treating mental health, offering reproductive and sexual health services, and preventing accidents and injuries. A second flagship program will establish sub-regional emergency hubs over the next two years. Each hub would house a team of emergency experts who would be geographically closer to emergencies and able to respond more quickly to support member countries in their region. *WHO*

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Kenya

Kenya submits funding request application to global fund
Kenya has this week, submitted a Funding Request of 355,631 million USD to Global Fund to support HIV, Tuberculosis, Malaria and Resilient, Sustainable Health Systems for Health interventions, for the period 2018 to 2020. Most of the grant will be used to procure Commodities and lifesaving medicines for HIV, TB and Malaria.The Funding Request application was jointly developed by an all-inclusive funding request secretariat and writing teams with representatives from National and County Governments, civil society organizations, persons living with or affected by HIV, TB and Malaria, key population, adolescents and young people, development and implementing partners among other stakeholders. *Ministry of Health, Kenya*

Kenya and Cuba sign MOU in health
Kenya and Cuba signed a Memorandum of Understanding (MOU) on health cooperation which will enable Kenya to build capacity and acquire skills in specialized areas such as

Biotechnology, Oncology, Nephrology, Critical care, Cardiovascular Surgery, Drug manufacturing, Equipment and device registration. The MOU will also open avenues for the two countries to collaborate in the pharmaceutical sector to explore the opportunities for investment within the Kenyan health sector especially in the manufacture of anti-retroviral medicines, anti-malarial, vaccines, medical gases and devices. *Ministry of Health, Kenya*

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Nigeria

FG inaugurates board of health institutions

The Councils/Boards inaugurated include: Nursing and Midwifery Council of Nigerian (N&MCN), Radiographers Registration Board of Nigeria (RRBN), Dental Technologists Registration Board of Nigeria (DTRBN), Institute of Chartered Chemist of Nigeria (ICCON), Institute of Public Analysts of Nigeria (IPAN) and Dental Therapist Registration Board of Nigeria (DTHRBN). The main function of the Councils/Boards was to provide oversight on the management to ensure smooth implementation of government policies, effective and efficient utilization of resources, the observance of extant laws and regulations as well as ensuring accountability of funds and high-level performance. *Ministry of Health, Nigeria*

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