



## HCLS Pulse

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

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**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 04, 2017 – May 17, 2017

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### South Africa

#### Governance compliance instrument guidelines

The Council for Medical Schemes (CMS) in collaboration with The Global Platform for Intellectual Property (TGPIP) has developed the Governance and Compliance Assessment

Instrument (GCI) for medical schemes. The GCI is intended to be the mechanism for a complete, credible and standardised process that facilitates better governance and compliance management by the Board of Trustees (BoT) and promote transparency and accountability towards the scheme beneficiaries and the CMS. The CMS is in the process of developing a questionnaire on the GCI platform to provide guideline and clarity to stakeholders. [CMS](#)

### **The National Health Insurance (NHI) is still a top priority for the health department**

The department of health's aim of having a functional National Health Insurance (NHI) Fund by 2019/20 forms a big part of its medium-term targets. The department aims to have the draft NHI Bill gazetted for public comments during 2017/18 and a functional NHI fund with the ability to purchase services on behalf of the population from accredited and contracted providers during 2019/20. [Sabinet](#)

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## **Australia**

### **TGA announces changes to advertising for medicines containing codeine**

The Therapeutic Goods Administration (TGA) announced changes to the advertising for medicines containing codeine, which will be effective from February 1, 2018. According to the new rule, all medicines containing codeine will become prescription medicines and will no longer be able to be advertised to the public. In the interim, all advertisements to the public for medicines containing codeine must comply with the Therapeutic Goods advertising requirements. [TGA](#)

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## **Canada**

### **NRC develops a pulmonary endarterectomy (PEA) surgery simulator**

The National Research Council of Canada (NRC), in association with Bayer, developed a pulmonary endarterectomy (PEA) surgery simulator that would allow doctors to train more effectively to perform surgery in cases of Chronic Thromboembolic Pulmonary Hypertension (CTEPH). This new 3D device will allow PEA surgery simulator addresses an imperative training need for this technically complex surgery for which only a few surgeons in Canada currently have expertise. The first simulator is now in operation at the Toronto Western Hospital, creating a training Centre of Excellence for surgical residents. [Department of Health](#)

### **New Canadian guideline provides advice to physicians to avoid overprescribing of opioids**

The updated guideline, released in the Canadian Medical Association Journal, recommends that patients with chronic non cancer pain first try non-opioid options to manage pain before considering a trial of opioid therapy. The guideline also offers specific recommendations for tapering opioids for patients on high doses, if that is something a prescriber chooses to do collaboratively with his or her patient. As with all medications, prescribers will continue to assess the individual needs of their patients on a case-by-case basis, as part of the practice of medicine. [Health Canada](#)

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## **The US**

### **Draft revisions to the Food And Drug Administration blueprint for prescriber education for extended-release and long-acting opioids**

The blueprint is part of the FDA Risk Evaluation And Mitigation Strategy (REMS) for Extended Release (ER) and Long-Acting (LA) opioid analgesic medications (ER/LA Opioid Analgesics REMS). The FDA is considering modifications to the existing blueprint in light of the recommendations from the May 2016 Advisory Committee meeting. The draft revisions would broaden the blueprint to include information on pain management, including the principles of acute and chronic pain management; non-pharmacologic treatments for pain; and pharmacologic treatments for pain (both non-opioid analgesic and opioid analgesic). FDA is seeking comment on the draft revisions to the blueprint and has added sections of draft revised blueprint to the background materials for the public workshop scheduled for May 9-10, 2017. [Federal Register](#)

### **Three-month extension of certain tobacco product compliance deadlines related to the final deeming rule**

This guidance is intended to assist persons who manufacture, package, sell, offer to sell, distribute, or import for sale and distribution within the United States newly regulated tobacco products, roll-your-own (RYO) tobacco, and cigarette tobacco in complying with the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), and FDA regulations. [Federal Register](#)

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## The UK

### **MHRA issues guidance for reporting ADRs**

The Medicines and Healthcare products Regulatory Agency (MHRA) issued guidance for marketing authorisation holders while communicating information on adverse drug reactions (ADRs). MHRA uses the E2B messaging standard to send and receive information on adverse drug reactions (ADRs) reported by patients and healthcare professionals. [MHRA](#)

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## Other African Countries

### **Govt. launches a new ARV drug for HIV negative people and innovative HIV self-testing to revitalize HIV prevention (Kenya)**

Kenya became the first country to launch self-testing and second country in Africa, after, South Africa, to officially roll out Pre-exposure Prophylaxis (PrEP). PrEP is a pill taken once daily by HIV negative persons at high risk of HIV such as negative partners in discordant relationships, individuals with history of recurrent or frequent STIs or condom bursts and people with multiple sexual partners among others, who are at a continuous ongoing risk of being infected. PrEP will be provided for free in selected health outlets and facilities but if one wishes to purchase then it will cost approximately 3600 KES per month. The HIV self-test will initially be available in the private sector at a cost of between 850-950 KES but the Ministry of Health will work to make self-testing available in the public sector for free in the near future. [Ministry of Health, Kenya](#)

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## Australia

### **Prostheses reforms to deliver better value for private health insurance**

The Australian Government continues to work with the private health insurance industry to make premiums more affordable for Australians. In February 2017, the Government delivered price reductions to around 2,400 medical devices which will deliver around 500 million AUD of savings over six years to patients and private health insurance members. The Prostheses List Advisory Committee (PLAC) in its approach for targeted prostheses reviews has set out a process to review devices and benefits on the prostheses list. The outcomes of these reviews, together with the collaborative approach with industry, will inform options to improve the prostheses arrangements and potential savings. The PLAC will commence targeted reviews of the hip, knee, cardiac and spinal categories. [Ministry of Health, Australia](#)

### **Australian government announces 68 million USD funding for the establishment of Australia's first Proton Beam Therapy facility**

Australian government announced that it will 68 million USD to support the establishment of Australia's first Proton Beam Therapy facility at the South Australian Health and Medical Research Institute in Adelaide. This major investment is a significant boost for Australian health and medical research, and for patients across the country who are set to benefit from this cutting-edge technology. Proton Beam Therapy (PBT) is radiation therapy that uses heavier particles (protons) instead of x-rays, which are used in conventional radiotherapy. [Australian Department of Health](#)

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## Other African Countries

### **Government of Uganda to expand infectious disease research and training (Uganda)**

The Ministry of Health has signed an agreement with the Government of the United States to

further their collaboration on infectious diseases research and training. This new agreement will strengthen and expand the relationship between the two Governments for training and research on HIV/AIDS, Malaria and other emerging diseases. The Permanent Secretary of Ministry of Health, Dr. Diana Atwine and U.S. Ambassador to Uganda, Deborah R. Malac signed the agreement which will enable further biomedical research cooperation between the two countries in preventing, diagnosing and treating the heavy burden of diseases in Uganda. [Ministry of Health](#)

### **Health CS assures Kenyans suspension of US Aid will not affect lifesaving health services (Kenya)**

Procurement of life saving commodities such as ARVs, HIV test kits, nutritional supplements, family planning products and lifesaving equipment have not been affected by the suspension, which the Ministry expects to be temporary. According to the Cabinet Secretary, the suspension only affects programme administrative support and does not affect health service delivery to Kenyans. The Ministry is also in constant engagement with development partners to keep them abreast of the developments and has shared with the National Treasury the measures undertaken to strengthen financial management systems and address internal control weaknesses. [Minister of Health, Kenya](#)

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## **WHO**

### **WHO to begin pilot prequalification of biosimilars for cancer treatment**

The WHO will launch a pilot project for prequalifying biosimilar medicines to make some of these expensive treatments for cancer more widely available in low- and middle-income countries. In September, the WHO will invite manufacturers to submit applications for prequalification of biosimilar versions of two products in the WHO Essential Medicines List: rituximab (used principally to treat non-Hodgkin's lymphoma and chronic lymphocytic leukemia), and trastuzumab (used to treat breast cancer). The decision comes after a two-day meeting in Geneva between WHO, national regulators, pharmaceutical industry groups, patient and civil society groups, payers and policymakers to discuss ways to increase access to biotherapeutic medicines. The WHO also plans to explore options for prequalifying insulin. [WHO](#)

### **Zambia improves real-time tracking of vaccines, reduces stock outs**

The system uses mobile phones and internet to allow supply chain managers in the country's national, district and provincial vaccine warehouses and stores monitor vaccine stocks, use, and expirations minute-by-minute. The system also monitors the cold chain to ensure vaccines are kept at the correct temperature at all times. With additional funding from UNICEF, the system has now been scaled up to 115 facilities in every district in Zambia, each with at least one trained staff to manage it. As a result, nearly all facilities are reporting on-time each month to the Ministry of Health and nearly all are correctly stocked so vaccines do not go unused. In the future, the Ministry of Health is looking to expand the system to see how it can be used for other essential medicines and tracking disease outbreaks. [WHO Afro](#)

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