



# 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:** March 9, 2017 – March 22, 2017

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### Regulatory Developments

#### South Africa

##### Medicinal dagga guidelines out for comment

The Medicines Control Council (MCC) published draft guidelines for the cultivation and processing of cannabis for medical use. Interested parties have until 31 March to comment on

the guidelines that were published yesterday in the Government Gazette. The guidelines set out the standards researchers and manufacturers will need to meet to ensure patients get a product that is safe and reliable, and contain extensive details on the security requirements for sites growing or processing medical marijuana. They also say cannabis cannot be grown on the same site as hemp, in order to protect the integrity of the plants. Prospective cannabis growers will have to obtain a license from the MCC, as well as a permit from the Department of Health. There is no limit on the number of licences the MCC will grant for the production of cannabis for medical purposes, but the overall quantities grown in SA cannot exceed the quota set by the International Narcotics Control Board.

[Full Business Day report \(subscription needed\)](#)

### **CMS issued a circular for Demarcation Exemption Framework**

The CMS in consultation with the Financial Services Board, National treasury and Department of Health concluded an exemption framework which would serve as a guideline to providers of indemnity products that conduct business of a medical scheme and want to apply for exemption in terms of Medical Schemes Act. The exceptional framework is a transitional arrangement whilst the department of Health leads the development of a low cost benefit option type of product for medical scheme. The exemption framework grants a two year exemption. [CMS](#)

### **Task team to examine mental health centers**

The Office of Health Standards Compliance (OHSC) has announced plans to step up its inspections of government mental health facilities in the wake of the scandal over the deaths of more than 100 mentally ill patients in Gauteng, says a Business Day report. In the 2015-16 fiscal year, the OHSC did not inspect a single psychiatric hospital, according to an inspection register previously provided to Business Day. OHSC acting CEO Bafana Msibi said task team has now been established to look more closely at state mental health facilities. It was also piloting an assessment system for state psychiatric hospitals and aimed to put all of them through their paces by September, he said. OHSC board chairperson Lizo Mazwai said the organisation was investigating the scope for probing mental healthcare services in the community.

[Full Business Day report](#)

### **CMS issued a circular on benefit definition submissions for lung cancer and palliative care**

The Council for Medical schemes (CMS) called for submissions regarding benefit definitions for the following conditions

- Lung cancer [such as](#) Mesothelioma, Small cell- lung cancer, Non- small cell lung cancer
- Palliative care. [CMS](#)

### **Government of Health released summary of the National Public Health Institute of South Africa bill**

The Minister of Health showed his intent to introduce the National Public Health Institute of South Africa bill in the National Assembly shortly. The explanatory summary was hence published in accordance with the rules of the National Assembly. The bill provides for the establishment of the National Public Health Institute of South Africa in order to coordinate and where appropriate 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 the population of the Republic and to provide for matters connected therewith. [Sabinet](#)

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## The US

### **FDA approved drug to treat Parkinson's disease**

The U.S. Food and Drug Administration today approved a drug as an add-on treatment for patients with Parkinson's disease who are currently in a phase where the prescribed medications are not efficient. It is a relevant step as the disease is incurable and half a million people in America are affected. This step reflects the considerable amount of care shown by the Government for people with chronic diseases. [FDA](#)

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## The UK

### **Performance agreement signed between the World Health Organization (WHO) and the Government of UK and Northern Ireland**

The performance agreement will specifically cover joint areas of collaboration between the UK and the WHO. These include:

- **Strengthening of health systems:** In 2017, the UK will encourage WHO to continue to play a leadership role in health systems strengthening, adopting an approach to all its work and collaborating with others in a way that promotes systems strengthening behaviors and providing evidence-based guidance to countries.
- **Antimicrobial Resistance (AMR):** In 2017, the UK will continue to provide international influence on AMR. We will press WHO to ensure successful follow-up to the United Nations High Level Meeting on AMR and the delivery of objectives through international partnerships and frameworks such as the Global Health Security Agenda and the G20.
- **Tuberculosis (TB):** In 2017, the UK will press the case for greater focus on TB, including through a successful outcome-focused Ministerial Conference in Moscow in November 2017 and a UN General Assembly event in 2018. We will encourage WHO to update the TB research roadmap and use it to drive global research priorities.
- **Neglected Tropical Diseases (NTDs):** In 2017, the UK will press WHO to organise a successful 5th anniversary event of the London Declaration of NTDs in April 2017 that results in a sustainable financial package for NTDs going forwards. This should include ensuring a focus on increasing endemic country financial and non-financial commitments to increasing coverage of NTD prevention and treatment activities. The UK shall also press for an expansion of coverage with proven cost effective interventions, including a focus on reaching the poorest.
- **Family planning:** In 2017, the UK will strongly encourage WHO to engage at the highest policy and technical levels to help achieve the global FP2020 targets of reaching an additional 120 million women and girls with voluntary family planning.
- **Polio:** In 2017, the UK will push for completion of eradication and the successful transitioning of polio eradication assets and infrastructure for other global goods.
- **Pan-Africa focus:** In 2017, the UK will work through multilateral and bilateral programmes to further our health development programmes, particularly building on our strong relationship with WHO Regional Office for Africa (WHO AFRO).
- **Better allocation of limited resources for health:** In 2017, the UK will press WHO to provide technical guidance and support to countries to enable them to make fair, transparent and evidence-informed resource allocation decisions.

Additionally, the document also details four broad priority areas where the UK feels the WHO must improve. These are: risk and financial management, value for money budgets focused on key priorities outlined above, collaborative and effective leadership at a global level and lastly a robust emergency management function. [Government of Health](#)

### **MHRA released regulations for E-cigarettes consumer products**

Medicines and Healthcare products Regulatory Agency (MHRA) released Preliminary guidance on how to get an e-cigarette on the market in the UK, including the notification scheme and reporting problems with e-cigarettes. The Tobacco Product Directive (TPD) introduced new rules and regulations that set out requirements for E-cigarettes and refill containers. The rules ensure:

- Minimum standards for the safety and quality of all e-cigarettes and refill containers (otherwise known as e-liquids)
- That information will be provided to consumers so that they can make informed choices
- An environment that protects children from starting to use these products. [Department of Health](#)

### **Government of Health issued a guidance note notifying to register for the EU common logo**

Falsified medicines are a major threat to public health and safety. Anyone selling medicines to the public via a website has been asked to be registered with MHRA and display an EU common logo on every page of the website offering medicines for sale. The aim of the EU common logo is to help members of the public to identify websites that can legally sell medicines. [Government of Health](#)

### **Coding and import regulations for human tissue and cells**

The European Union (EU) published 2 new commission directives on the coding and import of tissue and cells for human application. There are 2 consultation documents and 2 sets of consultation questions for the following

- The Human Fertilization and Embryology (Quality and Safety) Regulations 2017, about reproductive cells
- The Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2017 about all other types of human tissue and cells. [Government of Health](#)

### **New essential Orange and Green Guides 2017 published**

The Medicines and Healthcare products Regulatory Agency launched its latest guide of UK pharmaceutical regulations, EU directives and guidance. The new 2017 edition of the Orange Guide has been updated to incorporate changes and additions made to the detailed European Community guidelines on Good Manufacturing Practice (GMP) and the revised EU Guidelines on Good Distribution Practice (GDP). There are new sections on:

- GMP for excipients
- Guidance on revised Annex 16 of GMP
- Data Integrity definitions and guidance for industry

The new 2017 edition of the Green Guide provides a single source of guidance to, and legislation for, the distribution of medicines in Europe and UK. There are new sections on:

- The guidelines on principles of Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01)
- Matters relating to unlicensed medicines
- Sourcing and exporting medicinal products – non-EEA countries
- Data integrity
- The EU regulation on safety features for medicines [Department of Health](#)

### **Changes in regulatory fees for providers confirmed**

Following a public consultation that was conducted last year, the Care Quality Commission (CQC) outlined the fees that providers of health and adult social care in England will be charged

from April 2017 to recover the costs of their regulation. Government policy requires CQC to move towards full chargeable cost recovery (FCCR) for all health and adult social care providers in England that it regulates. [CQC](#)

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## Australia

### **Department of health released colorectal cancer guidelines for public consultation**

Cancer Council Australia released the draft Clinical practice guidelines for the prevention, early detection and management of colorectal cancer for public consultation. Cancer Council Australia will be seeking NHMRC approval of these guidelines under the National Health and Medical Research Council Act. [NHMRC](#)

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## Updates from other African countries

### **Second Generation Health Extension intends quality service (Ethiopia)**

The Ministry of Health has disclosed that the Second Generation Health Extension Program, which is on the pipeline to be implemented in the short run, is mainly intended to create quality in health services and infrastructures that are realized during the prior program. Assistant Director of Health Extension and Primary Health Services under the Ministry, Temesgen Ayehu, told Walta Information center (WIC) that the second generation health extension program is intended to sustain the achievements gained through the prior program and meet the growing demand for health services in the country in a further adequate and qualified manner. The professional status of health extension workers shall be upgraded from level three to level four in order to implement the program in such a qualified manner. [Ministry of Health](#)

### **Govt. to roll out PrEP in April (Kenya)**

The Government will next month roll out the new HIV intervention measure dubbed Pre-exposure Prophylaxis (PrEP). The intervention seeks to lower the country's HIV transmission rate by administering oral antiretroviral medication (ARVs) to HIV negative individuals who face a substantial risk of contracting HIV. Kenya became the second country in Africa, after South Africa, to roll out PrEP. However, it is widely used in developed countries. [Ministry of Health](#)

### **The President addressed the nations on having fulfilled national health agenda promise (Kenya)**

Four years ago, the President promised to upgrade public hospital facilities, provide free primary healthcare for expectant mothers and increase access to affordable healthcare. Across the country, government policies have significantly improved access to health care, the affordability of care, and the quality of care since 2013. The government also secured equipment and expertise from India to establish a cancer centre at a Hospital in Kenya. [Ministry of Health](#)

### **The Cabinet Secretary for Health inaugurated pharmacy board of management (Kenya)**

The Pharmacy and Poisons Board of Management has been inaugurated. The Cabinet Secretary for Health inaugurated the eight members Board on Tuesday to oversee all aspects of governance, contract management and service development. He advised the Board to focus on the health of the public by ensuring no substandard medicines get to the country, only appropriate medicines and outlets registered, encourage good manufacturing practices and investment in local industries to control prices of medicines. [Ministry of Health](#)

### **Kenyan Government to hire 500 doctors to improve quality care (Kenya)**

The Cabinet Secretary for Health claimed that the Government is operating within the law to hire the doctors from Tanzania who shall be distributed across the country to boost the doctor patient ratio and improve the quality of care for Kenyans. “I want to emphasize that the medics will not require double registration since countries within the EA carry out joint inspection of training schools and even registration and can therefore work in either of the countries,” said the Cabinet Secretary. Speaking during a fact finding tour of a National Hospital on Monday the Cabinet Secretary also revealed that plans are underway to hire specialized doctors from Cuba to ease the suffering of Kenyans especially in the area of cancer care. [Ministry of Health](#)

#### **UNICEF pledged support for health sector (Nigeria)**

The United Nations International Children Education Fund (UNICEF) renewed its commitment to support the Nigerian health sector towards improving maternal and child health, strengthening immunization and revitalization of Primary Healthcare system. The Minister urged the UNICEF to support in building capacity of Health Extension Workers working at the Primary Health Care centers in the communities, this according to him would help in achieving the objective of Saving One Million Lives Programme for Result Initiative aimed at improving the health of mothers and children. [Federal Ministry of Health](#)

#### **Federal government launched use of mobile phone for nutrition (Nigeria)**

Determined to improve health and nutrition of pregnant women in Nigeria, the Federal Government has launched the use of mobile phone to circulate nutrition information in the country.

The Programme tagged “mNutrition” is a process of using mobile technology to send text messages to Nigerians with a view to expanding access to health and nutrition services. [Federal Ministry of Health](#)

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### **Market Updates**

#### **The US**

##### **Secretary of HHS is committed to greater Medicaid flexibility for States**

Health and Human Services Secretary issued a statement today committing the U.S. Department of Health and Human Services (HHS) to using its regulatory authority to create greater flexibility in the Medicaid program for states. The Administration has announced a three-pronged approach to repealing and replacing Obamacare – which includes HHS providing essential regulatory relief. [HHS](#)

##### **Department of HHS issued a media release on offering states flexibility to increase market stability and affordable choices**

The Department of Health and Human Services (HHS), in partnership with the Department of the Treasury, suggested ways to help foster healthcare innovation by giving states greater flexibility. “States need the flexibility to develop innovative healthcare models that will improve patient access to care, increase affordability and choices offered, lower premiums, and improve market stability,” said Health and Human Services Secretary, “Today’s letter highlights State Innovation Waivers as opportunities for states to modify existing laws or create something entirely new to meet the unique needs of their communities.” [HHS](#)

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#### **The UK**

### **'Regulator ready' stem cell lines now available for clinical development**

The UK Stem Cell Bank (UKSCB) at the National Institute for Biological Standards and Control (NIBSC) is releasing its first stem cell lines suitable for development into novel cell-based medicines to researchers wishing to bring new and innovative therapies to clinical trial. The stem cell lines are produced and quality-controlled under European regulation and are therefore suitable for use as starting materials in manufacturing therapies for clinical trials, saving researchers precious time and effort. [Department of Health](#)

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## **Australia**

### **TGA announced the submission of comments on bio vigilance responsibilities of sponsors of biologicals**

The Therapeutic Goods Administration (TGA) announced the submission of comments from interested parties on draft guidance on Bio vigilance responsibilities of sponsors of biologicals - Australian requirements and recommendations. This consultation was related to two concurrent consultations on guidance on risk management plans for medicines and biologicals and the adoption of a European Union guideline in Australia. The guidance sets out requirements and recommendations for detecting and reporting adverse events and serious threats to public health that may arise in relation to the use of any class of products regulated by the TGA under the biologicals framework. [TGA](#)

### **COAG conducted an Independent Review of Food Labelling Law and Policy**

The public consultation period conducted by COAG is an important opportunity for people to provide the Review Committee with specific information about ways to improve food labelling in Australia and New Zealand. The Food Labelling Review Issues Consultation Paper summarises the issues that have been raised in the first round of submissions to the Review, as well as issues in the literature and media in recent years. This Paper elaborates on the Review's Terms of Reference and has been prepared to stimulate thinking and debate. The next step in the Review process should be taken and the range of solutions and ideas to improve food labelling should be considered. Members of the public have been asked to respond to the consultation questions, and to attend one of the public meetings that will be held across Australia and New Zealand. [Government of health](#)

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## **Canada**

### **Government of Canada released a media statement on public reporting of drug shortages and discontinuances**

The government of Canada made the public reporting of drug shortages and discontinuances mandatory to report. Regulations are brought into force that requires drug companies experiencing shortages and discontinuances to publicly report them. Drug manufacturers are now required to report the following on the independent government run website.

- An anticipated drug shortage
- A discontinuation of a drug six months in advance
- Any previously unreported shortage within five days of learning about it.

The new website features enhanced notification features and a mobile application. As well, it provides updated information for health care providers and patients, including tools and guidance to help manage shortages. [Health Canada](#)

### **Government of Canada Announces \$6 million in Emergency Funding to Combat Opioid Crisis in Alberta**

The Government of Canada announced an additional \$6 million in urgent support to the Province of Alberta to assist with its response to the growing effects of the significant crisis in the province of Alberta. Canada's opioid crisis is multifaceted. First, the overdose crisis has been driven by the emergence of fentanyl and other powerful illicit opioid drugs, which has led to unprecedented number of deaths among users of illegal drugs. And second, high levels of addiction to legal opioids across Canada have been caused, in part, by inappropriate prescribing practices and poor education about the risks associated with opioids. The government's Opioid Action Plan, including the new resources announced has addressed both of these aspects of the crisis. [Health Canada](#)

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## OECD

### **Sustainable access to innovative therapies - Online consultation**

The French Ministry of Health asked the OECD to act as the Secretariat for a new initiative to promote an international and high-level dialogue between stakeholders on access to innovative pharmaceuticals and sustainability of pharmaceutical spending. The initiative was endorsed by OECD member countries and by Health Ministers at the G7 Health Ministerial meeting in Kobe. The overall objective is to improve patient access to innovative treatments and ensure the sustainability of health spending as well as continued innovation that meets patient needs.

[OECD](#)

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## WHO

### **WHO highlighted the Global health sector strategy on viral hepatitis**

The Global Health Sector Strategy on Viral Hepatitis is the first of its kind and, when implemented, will contribute to the achievement of the 2030 Agenda for Sustainable Development. The Strategy outlines a Vision, Goals and Targets, Frameworks for Action, and 5 critical Strategic Directions to eliminate viral hepatitis as a public health threat by 2030. A dedicated portal has been developed for the first ever Global Health Sector Strategy on Viral Hepatitis. [WHO](#)

### **UN announced interagency group to coordinate global fight against antimicrobial resistance**

The United Nations today announced the establishment of an Interagency Coordination Group on Antimicrobial Resistance, which will be co-chaired by Deputy Secretary-General Amina Mohammed and World Health Organization (WHO) Director-General. WHO chief said antibiotic resistance is already prolonging illness worldwide, and the political declaration was a vital commitment to help tackle the scourge globally. She said the inter-agency group would support governments across the world, as well as advising on the "use and abuse" of antibiotics for people, and livestock. [UN](#)

### **RD calls for renewed approaches to health in Nairobi**

The meeting was addressed by Dr Matshidiso Moeti, WHO Regional Director for Africa, who acknowledged Africa's various health challenges and lessons learnt but called for good governance, leadership and stewardship. She said these would ensure that the right and comprehensive policies and strategies were in place if Africa was going to attain the sustainable development goals. She noted that lessons learned from the Millennium Development Goals had shown that investments in health by governments and health partners had not been optimal. Challenges in the health system had included:

Health services in many countries being grossly underfunded, leading to sub-standard quality of care.

Health care was often inaccessible geographically and financially for disadvantaged and marginalized populations.

Inequities in access for health were compounded by a critical shortage of human resources which are unequally distributed and biased towards urban areas. [WHO](#)

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