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 23, 2017 – April 5, 2017

In This Issue:

Regulatory Developments

South Africa

CMS ready to monitor compliance on Demarcation Regulations

Per the regulation, insurers would not be allowed to provide primary healthcare insurance policies and hospital indemnity products. These health cover can only be provided by providers that apply for the exemption from the CMS. The Exemption Framework grants a two year exemption to providers of primary healthcare insurance policies, while the development of a Low Cost Benefit Option (LCBO) framework is in development. Providers that do not apply for the exemption by April 1, 2017 would face enforcement action as a result of the amended definition. *CMS*

CMS issued a circular on evaluation of contribution increase assumptions

The Council for Medical Schemes issued a circular on evaluation of contribution increase assumptions submitted by Medical Schemes as provided in the benefit review submissions to increase transparency of the scheme's pricing decisions. This has been primarily done to limit the inappropriate cost increases to beneficiaries. This circular helps analyze the contribution increase assumptions into standard cost items and cost variables and their utilization stratified by the type of scheme they are linked with. *CMS*

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The UK

MHRA issued guidance on notifying MHRA about clinical investigation of a medical device

The guidance issued by the MHRA includes the procedure to carry out clinical investigation for a CE marking for the required medical device.

Specific conditions when it is not necessary to notify MHRA of a clinical investigation is:

- When the medical device has been manufactured in the house for its own patients with no objective to introduce it in the market.

Specific condition when it is necessary to notify MHRA of a clinical investigations is :

- When one wants to provide a medical device to another organization that up until now has been manufactured in-house for patients for data to support safety and performance of a commercial product. *MHRA*

Department of Health issued a guidance on the Yellow Card scheme

The Yellow Card scheme records all the adverse events that have taken place due to medicine and medical devices and help MHRA monitor the safety of all health care products to ensure that they are acceptable to be used by all the patients. New medicines and vaccines that would require additional monitoring have an indicative inverted black triangle (▼) this has been introduces and the black triangle scheme. E-nursing modules for nurses have also been developed. *Department of Health*

Government for Health issued a guidance note on ADRs

The government for health issued a guidance note which would help the marketing authorization holders learn to use the E2B messaging system which is mandatory. This messaging standard is used to exchange information on adverse drug reactions (ADRs) which would be reported by the patients and health professionals. The information would be received in a single format known as individual case safety report (ICSR). *Department of Health*

Department of Health released a policy paper on innovation in regulations

In response to the government's productivity plan the regulatory bodies in the department of health published documents that support their progress in the field of innovation. These

documents portray the efficiency of the regulatory framework in order to support innovation and disruptive business models this is being done to deliver work more efficiently. *Department of Health*

Government for Health issued a guidance note on clinical trials for medicines

As per the guidance note issued by the government of health submissions for clinical trials can be made through the Common European Submission Portal (CESP) which would be available from Heads of Medicines Agencies (HMA). The purpose of introducing this system is to:

- Provide a secure method of communicating with regulatory agencies via one platform
- Allow submission of an application once to reach all required agencies
- Reduce the burden for both industry and regulators of submitting/handling applications on CD-ROM and DVD. *Department of Health*

Government of Health issued a guidance note on Common issues identified during clinical trial applications

Medicines and Healthcare products Regulatory Agency (MHRA) receives clinical trial authorization (CTA) applications for investigational medicinal products (IMPs) every year. These applications require additional information to be submitted before they are considered approvable. Many of the requests for further information or 'grounds for non-acceptance' (GNA), are common and are avoidable if available guidance is followed or if a satisfactory justification for not following the applicable guidance. This guidance aims to assist applicants in understanding the common reasons for MHRA requiring additional information and provides direction to where further information and guidance can be found. *MHRA*

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Australia

Australian Government appointed new mental health advisory panel

The Primary Health Network Advisory Panel on Mental Health to be appointed will work closely with the Government on its plan to deliver more frontline mental health services in Australia. The primary objectives of the panel would be :

- To review and provide guidance on the mental health plans developed by the Primary Health Networks (PHN)
- The review and provide advice on Mental Health commissioning guidelines that will be provided to the PHNs
- Provide advice on strategies that will help PHNs effectively carry out their mental health commissioning responsibilities
- Provide recommendation on the ongoing governance and coordination of the commissioning procedure of the mental health services performed by the PHNs. *Department of Health*

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WHO

WHO issued ethics guidance to protect rights of TB patients

The World Health organization launched ethics guidelines which would ensure that sound ethical standards are maintained to protect the rights of the people suffering from Tuberculosis by countries that are implementing the end TB strategy. The new WHO ethics guidance will address issues related to isolating the patients, rights of the patients in prison and discriminatory policies. Five key policies emphasized are:

- To provide patients with the social support they need to fulfil their responsibilities

- To refrain from isolating TB patients before exhausting all options to enable treatment adherence and only under very specific conditions
- To enable "key populations" to access same standard of care offered to other citizens
- To ensure all health workers operate in a safe environment
- To rapidly share evidence from research to inform national and global TB policy updates. *WHO*

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Updates from other African countries

Health gets KSh54.9 billion budget and tax exemption for medical equipment (Kenya)
Per Cabinet Secretary, Henry Rotich the allocation will go towards implementation of programs aimed at promoting health; addressing health needs of children, mothers and adolescents; enhancing social health protection; improving health infrastructure and strengthening norms, standards and health regulations. The exemption of medical equipment and apparatus from VAT is expected to motivate investors to focus their resources towards the health sector and address some of the challenges that the sector faces. *Ministry of Health, Kenya*

Govt. lays strategies to reduce health disparity (Kenya)
Per Health Cabinet Secretary Cleopa Mailu, the government is keen on having medical training institutions across the counties to reduce prevalence of chronic diseases, anticipated disease outbreaks, and meet the sustainable development goals. According to Dr. Mailu healthcare cost is a major driver of poverty in Kenya with out of pocket expenditure comprising more than a quarter of the total health expenditure. High healthcare costs also bars 13 percent of Kenyans to access healthcare facilities. He opined a need to leverage joint initiatives and formulate dynamic policies to address these disparities across the counties. *Ministry of Health, Kenya*

Govt. to launch five-day polio vaccination campaign on April 1 (Kenya)
The campaign will be conducted in Bungoma, Busia, Elgeyo Marakwet, Garissa, Homabay, Isiolo, Kakamega, Kisumu, Lamu, Mandera, Marsabit, Nairobi, Nandi, Samburu, Siaya,Tana River,Trans Nzoia,Turkana,Uasin Gishu, Vihiga, Wajir and West Pokot counties. Vaccination teams will move across residential areas and other designated places like schools, churches and transit points to ensure that no eligible child is missed. Those seeking treatment in health facilities for other disease conditions will also receive the vaccine. *Ministry of Health, Kenya*

New partnership to strengthen healthcare (Kenya)
Health Cabinet Secretary, Dr. Cleopa Mailu opined strengthening Private-Public-Partnership as a compelling strategy to address a wide range of health care system needs. The partnership is expected to include employing synergy in service delivery, exchanging leadership and technical competences in human resources, improving decision making through better access to information, employing technology in management of medicines and combined resource mobilization. He added that for the partnership to be effective in addressing poverty, equity, quality and cost components considerable work needs to be done in terms of developing accountability, transparency, regulatory framework and mutual trust. *Ministry of Health, Kenya*

Ministry fosters partnership for non-communicable disease financing (Kenya)
The investment case, which is being developed with support from the World Bank, will outline the country's NCDs financial burden and provide a platform to guide cost-effective interventions aimed at preventing and controlling NCDs. It will also identify a set of priorities for accelerating NCD prevention and control in Kenya in line with the findings of the 2016 Stepwise Survey on NCDs. According to the Health Principal Secretary, Dr. Nicholas Muraguri the government is seeking technical assistance from the World Bank Group to advance the profile of the NCD

burden to state and non-state actors and to complement the robust policy framework which the Ministry of Health has established for the nationwide interventions, to curb the rise of NCDs. *Ministry of Health, Kenya*

EU grants Kenya Shs.32M specialized equipment to mitigate chemical, biological, radiological and nuclear risk (Kenya)

The CBRN Centers of Excellence is an initiative of EU, jointly implemented by the United National Interregional Crime and Justice Research Institute and the European Commission Joint Research Center. The aim is to create regional and national initiatives dedicated to improving national policies and international cooperation in CBRN risk mitigation. The countries served by the Nairobi Secretariat are Burundi, the Democratic Republic of Congo, Ethiopia, Ghana, Kenya, Malawi, Rwanda, Seychelles, Tanzania, Uganda and Zambia. Regional Secretariats are used by the member states to share information; assess national needs and develop national action plans, which are used by respective countries to identify priority areas for development of project proposals on CBRN risk mitigation, with support from the EU Development Cooperation and other development partners. *Ministry of Health, Kenya*

Minister of Health gives update on Lassa Fever Outbreak (Ghana)

Per the Minister of Health, Alex Segbefia the ministry has initiated the necessary measures to enhance surveillance, public awareness for prevention, early detection as well as the treatment of the disease. According to him the MOH has directed health workers at all levels, to intensify public awareness, education and provide regular updates on the disease. The Ministry has also recommended suspected cases of Lassa fever to be managed in specific isolation conditions, with adherence to regular infection prevention and control measures. Meanwhile the governments of Benin and Togo have initiated response measures and interventions including field investigations, enhanced surveillance, case management, infection prevention and control, contact tracing and follow-ups, as well as social mobilization and risk communication, to contain the situation. *Ministry of Health, Ghana*

The Health Minister urged the sates to increase the health budget (Nigeria)

The Federal Ministry of Health would work with the State Ministry of Health (SMOHs) towards institutionalizing the State Health Account (SHA) studies to fast track the process of achieving universal coverage and sustainable development goals. The creation of budget line for health financing in the various state health budget with the SHA as a sub- head would encourage state investment case for the health as well as develop the financing policy and strategy in the health sector.

Federal Ministry of Health

The Minister of Health assured Nigerians on Meningitis (Nigeria)

According to the Minister of Health, the ministry has already started collaborating with all the affected states in areas of awareness and sensitization, laboratory investigation and analysis, documentation and disease surveillance techniques through the National Centre for Disease Control and National Primary Health Care Development Authority (NPHCDA). He further added that the government is also in constant discussion with World Health Organization (WHO), UNICEF, E-health Africa and other international health agencies for supplies of vaccines and injections. *Federal Ministry of Health*

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Market Updates

The US

Antibody mediated rejection in kidney transplantation; public workshop; request for comments

This public workshop is intended to provide information for and gain perspective from individuals, industry, health care professionals, researchers, public health organizations, patients, patient care providers, and other interested persons on various aspects of clinical development of medical products for prophylaxis and/or treatment of AMR in kidney transplant recipients, including clinical trial design and endpoints. The input from this public workshop will also help in developing topics for future discussion. *Federal Register*

Food and drug administration/xavier university medical device conference (MedCon)

The 3-day public conference includes presentations from key FDA officials and industry experts with small group break-out sessions. The conference is intended for companies of all sizes and employees at all levels. *Federal Register*

FDA approved first treatment for a rare form of skin cancer

The U.S. Food and Drug Administration (FDA) granted accelerated approval to Bavencio for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC), including those who had not received prior chemotherapy. This is the first FDA-approved treatment for metastatic MCC, a rare, aggressive form of skin cancer. These advancements are leading to therapies where treatment earlier was limited or did not exist. *FDA*

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The UK

Good laboratory practice (GLP) for safety tests on chemicals

The guidance provides information on good laboratory practice (GLP) regulations that any test facility which conducts, or intends to conduct must comply with when carrying out safety tests on pharmaceuticals, agrochemicals, veterinary medicines, industrial chemicals, cosmetics, additives for human food and animal feed and biocides in the UK. The test facility should belong to the UK GLP compliance monitoring program and must be run by the UK GLP Monitoring Authority. The new update included membership update of the UK GLP compliance program. *Department of Health*

MHRA introduced a new way to make payments

Medicines and Healthcare products Regulatory Agency (MHRA) announced a new way of payment for medicines licences, clinical trials and clinical investigations. A new pay on invoice payment has been introduced instead of the advance payment method to reduce regulatory burden and improve the payment process for applying for a new license. It will remove the adverse effects of the complex fees structure and will reduce the chance for the applications being rejected incase the payment details are given incorrectly. It will aim to save time and money. *MHRA*

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OECD

OECD conducted a workshop on Enhancing traditional research and clinical development for Alzheimer's disease

The findings and conclusions of the workshop conducted by the OECD on enhancing the research dimensions and improving the clinical development procedures for Alzheimer's were as follows:

- Patient and public engagement: Increase involvement of the public through government policies like strengthening the public trust increase transparency and conduct clinical trial platforms to deepen involvement of the public
- Driving the paradigm shift: The need to develop Integrated cross-disciplinary strategies to identify potentially novel processes that capture the clinical benefit and stages of the disease
- Prevention and symptomatic treatment: The main aim is to develop disease-modifying therapies that alter disease progression or ultimately provide a cure
- Research incentives and risk-sharing: The growing need for governments, funders and the pharmaceutical industry to co-ordinate research investments in a systematic way.
- Open science and smart data: The need to develop a Global Clinical Trials Platform with a future Central Clinical Database in Alzheimer's disease would offer the required international outreach and leverage synergies. *OECD*

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UNICEF

UNICEF pledged its support for the Health Sector (Nigeria)

UNICEF aims to improve maternal and child health, strengthen the levels of immunity and uplift the primary healthcare system in the country. The immunization component will aim to support the fight against Polio. Minister of Health, Prof. Isaac Adewole urged the UNICEF to also support capacity building of Health Extension Workers working at the primary healthcare system centers, in order to achieve the objective of Saving One Million Lives Program. *Federal Ministry of Health*

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WHO

All African countries united themselves to tackle threat of polio

Polio vaccinators across west and central Africa united to immunize children over the next week, which would help Africa tackle the last remaining stronghold of polio on the continent. The synchronized vaccination campaign is one of the largest of its kind ever implemented in Africa and taken up as a part of the urgent measures to permanently stop polio on the continent. All children under five years of age in 13 African countries will be simultaneously immunized in a coordinated effort to raise childhood immunity to polio across the continent. *WHO*

WHO launched global effort to reduce medication related errors by 50 percent

WHO launched a global initiative to reduce severe and avoidable medication-associated harm in all countries to half over the next 5 years. The Global Patient Safety Challenge on Medication Safety aims is spread awareness on the weaknesses of the health systems due to which severe harm is caused to the public and medication error take place. It will lay out ways to improve the way medicines are prescribed, distributed and consumed, and increase awareness among patients about the risks associated with the improper use of medication. As per WHO an organizational culture that routinely implements best practices and that avoids blame when mistakes are made is the best environment for safe care. *WHO*

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