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: June 01, 2017 – June 14, 2017

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Quarterly statutory returns submission

The following signed documentations must be physically submitted to the Council for Medical Schemes (CMS) to ensure a complete submission:

Two quarterly return documents indicating final date;

Two sets of monthly management accounts; and
Detailed investment schedules, including a breakdown of all the underlying assets per institution.

The principal officer, chairperson, and one other trustee signatory must sign the above mentioned documents in line with section 39, of the Medical Schemes Act. *CMS*

Comments invited on draft regulations relating to human gamete banks

The regulations only apply to the withdrawal, storage and distribution of gametes from living persons. The notice include matters related to:

Application of the regulations;
Screening of donors for removal or withdrawal of gametes;
Gamete donor files, availability of information and destroying of gametes;
Deletion of names from database;
Prohibition of disclosure of certain facts; and
Offences and penalties. *Sabinet*

Allied Health Professions Council of South Africa ruling on unprofessional conduct with regard to acupuncture

According to the notice, practitioners are required to observe at all times the safety requirements associated with the use of needles and to use needles only in accordance with the manufacturer's recommendations and to dispose of them in an appropriate manner. The use of blade needles in acupuncture will also constitute unprofessional conduct until they are included in the scope of practice for acupuncture. *Sabinet*

Strategic Plan for the Prevention and Control of Non-Communicable Diseases (NCDs) 2013-2017 presented in parliament by the department of health

The strategic plan involves the implementation of multi-sectoral responses including the private sector and civil society, the reduction of risk factors, strengthening national policies and health systems and increasing research and development. The department also outlined its proposed new policy framework on the prevention and control of NCDs.

The department's plan on management and control of NCDs has been marked as urgent with a proposed approval by March 2018. *Sabinet*

South African Pharmacy Council invited comments on proposed amendments to its rules relating to good pharmacy practice

The draft amendments focus on minimum standards for the selling of HIV screening test kits. The notice deals with proposed amendments and additional minimum standards that includes accessibility of HIV self-screening test kits and the sale of HIV self-screening test kits by pharmacists. The Council also published amendments related to:

The minimum standards including the collection of medicines from the pharmacy and transportation for the delivery of medicines;
Rules relating to the services for which a pharmacist may levy a fee and guidelines for levying such a fee or fees; and
Fees payable to the Council under the Pharmacy Act including registration fees of R5 863.27, and annual fees of R1 509.98 for a remote automated dispensing unit. *Sabinet*

Healthcare service providers urged to continue to treat COMMED beneficiaries as members of the scheme

The Council for Medical Schemes (CMS) issued a notice in response to a communique advising private hospitals and pharmacies to treat beneficiaries of the Community Medical Aid Scheme (COMMED) as private patients, following the placement of the scheme under provisional curatorship. Though this notice, CMS has advised all healthcare service providers to continue to treat COMMED beneficiaries as members of the scheme, and not as private patients. The CMS also urged any beneficiary affected in this regard to bring the matter to the attention of the scheme with immediate effect. *CMS*

CMS has noted Constitutional Court judgement on Genesis

The significance of this judgement lies in the fact that members of medical schemes are not entitled to earn interest on the portion of the money in the Personal Medical Savings Accounts (PMSA), which according to the judgement, belongs to the medical scheme once such funds are deposited into the scheme's account. An equally noteworthy implication is the huge bearing on what happens to members' contributions in a situation where a scheme is declared insolvent. The implication of the judgement is that the members' PMSA cannot be ring-fenced from being accessed by creditors should a scheme become liquidated. *CMS*

CMS published Demarcation Exemption Framework

Applicants whose exemption have been granted would be required to submit a substantive application in terms of Stage 2 of the exemption framework within 30 days of being notified. The CMS will also in due course publish a list of all providers who are exempted from the provisions of the act. Product providers who continue to offer indemnity products that fall within the classification of a business of a medical scheme but have not received exemption would be in violation of the demarcation act and appropriate regulatory measures would be undertaken by CMS to enforce compliance. *CMS*

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Australian Industrial Chemicals Reform
The new Australian Industrial Chemicals Introduction Scheme (AICIS) will replace the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). The Bills deliver on the government's commitment to introduce reforms to reduce regulatory burden. The legislation will implement a new scheme which better reflects the level of risk to human health and safety and the environment. To ensure the ban does not adversely impact industry, a transition period is required to allow for adequate time to adjust and understand the new obligations. This transition period will align with the further consultation on the AICIS that will be undertaken prior to the legislation coming into effect on July 1, 2018. *Assistant Minister for Health*

Regulatory requirements for in-house IVDs
The transition period for in-house IVDs ends on 30 June 2017. Laboratories must comply with the regulatory requirements and notify the TGA of their Class 1-3 in-house IVDs by 1 July 2017. The IVD regulatory framework has the following features:

- IVDs must comply with a set of essential principles for the quality, safety and performance of the IVD.
- A risk-based classification scheme requiring different levels of regulation for each class of device.
- There are a choice of procedures (known as conformity assessment procedures), based on the risk classification, to be applied by manufacturers to demonstrate initial and on-going compliance with the essential principles.
- Compliance with recognised standards is used as a means to demonstrate that the essential principles and conformity assessment procedures have been met.
- It includes provisions for post market activities, including monitoring and adverse event reporting. *TGA*

TGA notification of a new proprietary ingredient
The role of the 'Notification of a new proprietary ingredient' form is to allow the TGA to enter formulation details and other relevant information relating to a proprietary ingredient into the Proprietary Ingredient Table in TGA Business Services. If a proprietary ingredient is to be used in a listed medicine, all ingredients within the formulation must be included in the Therapeutic Goods (Permissible Ingredients) Determination (the Determination) and meet the requirements of that Determination. Any ingredients not included in the Determination must be evaluated for use by the Complementary and Over the Counter Medicines Branch (COMB). The Determination is updated quarterly. *TGA*

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FDA issued notice for validation data requirements for certain reusable medical devices in premarket notifications
The Food and Drug Administration (FDA or Agency) has determined that it is necessary for manufacturers of certain reusable medical devices to include in their premarket notifications (510(k)s) instructions for use which have been validated and validation data regarding cleaning, disinfection, and sterilization, for which a substantial equivalence determination may be based. This notice includes a list of these reusable devices that will require validated instructions for use and validation data in their premarket notification. FDA is publishing this list in accordance with the requirements established by the 21st Century Cures Act. *Federal Register*

Centers for Medicare & Medicaid Services (CMS) seeks public input on reducing the regulatory burdens of the Patient Protection and Affordable Care Act
Centers for Medicare & Medicaid Services (CMS) issued a Request for Information (RFI)

seeking recommendations and input from the public on how to create a more flexible, streamlined approach to the regulatory structure of the individual and small group markets. The goal is to identify and eliminate or change regulations that are outdated, unnecessary, or ineffective; impose costs that exceed benefits; or create inconsistencies that otherwise interfere with regulatory reform initiatives and policies. This new rule will place downward pressure on premiums, limit special enrollment period abuses, and help to improve choices; while also reducing regulatory burden. The RFI will be open for public comment for 30 days. *CMS*

Humanitarian Use Devices; 21st Century Cures Act; Technical Amendment
The Food and Drug Administration (FDA) is amending regulations to reflect changes recently enacted into law by the 21st Century Cures Act. Specifically, certain requirements related to humanitarian device exemptions (HDEs) and institutional review boards (IRBs) for devices have changed. This action is being taken to align the regulations with the Federal Food, Drug, and Cosmetic Act (the FD&C Act) as amended. This rule is effective June 7, 2017. *Federal Register*

Revision of the nutrition and supplement facts labels
The Food and Drug Administration (FDA or we) is amending its labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices. The final rule

- Updates the list of nutrients that are required or permitted to be declared;
- Provides updated daily reference values and reference daily intake values that are based on current dietary recommendations from consensus reports;
- Amends requirements for foods represented or purported to be specifically for children under the age of 4 years and pregnant and lactating women and establishes nutrient reference values specifically for these population subgroups; and
- Revises the format and appearance of the Nutrition Facts label. *Federal Register*

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Plain Language Labelling Regulations come into force for non-prescription drugs
The regulations provide key safeguards, such as:

- Clear, understandable and plain language;
- Standardized table format for outer labels (similar to nutrition labels on food packaging) to Help users find and understand important information;
- Mandatory contact information so that users can report problems and adverse drug reactions; and
- Requirement for manufacturers to provide mock-ups of labels for review by Health Canada.

The regulations will be effective from June 13, 2017. By June 30, 2021, labels and packaging of all non-prescription drug products on the market will reflect the new requirements. *Health Canada*

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HHS announces over 70 million USD in grants to address the opioid crisis
These funds will be made available through the following three grants:

- Medication-Assisted Treatment and Prescription Drugs Opioid Addiction: Up to 28 million USD to 5 grantees to increase access of medication-assisted treatment for opioid use disorder. Medication-assisted treatment combines behavioral therapy and FDA-approved medication.
- First Responders: Up to 41.7 million USD over 4 years available to approximately 30 grantees to train and provide resources for first responders and members of other key community sectors on carrying and administering an FDA approved product for emergency treatment of known or suspected opioid overdose.
- Improving Access to Overdose Treatment: Up to 1 million USD over 5 years to one grantee to expand availability to overdose reversal medications in healthcare settings and to establish protocols to connect patients who have experienced a drug overdose

with appropriate treatment. *HHS*

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Canada

Canadian youth & mental health patients to benefit from new support for research collaborations
Government of Canada announced 4.8 million CAD in funding for three new networks under the International Knowledge Translation Platforms (IKTP) initiative of the Networks of Centres of Excellence (NCE). This funding will support international collaborations for youth mental health and addiction services, prisoner mental health services and best practices in health care supply chains. Project recipients also include the International Collaboration for Excellence and Innovation in Mental Health in Corrections (I-CEIsMIC), and the Supply Chain Advancement Network in Health (SCAN Health). Recipients will each receive 1.6 million CAD in funding over the next four years. *Health Canada*

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Kenya

ICTs have potential to enhance healthcare , CS Mailu
The cabinet secretary disclosed that all the ministry agencies and departments are focused on using ICTs for service delivery and commended the Pharmacy and Poisons Board for actively participating in the implementation of the wider Government of Kenya development policies that embrace the implementation of the Vision 2030 Strategy. He said the board has set up robust systems that ensure the increase in efficiency of service delivery in-line with the regulatory framework guidelines. These systems are widely accessible via any device that is convenient to the user and have been simplified to enhance user experience. *Ministry for Health, Kenya*

Principal Secretary Health hosts High Commissioner of India to discuss bilateral health ties
The meeting was a follow up of the state visit last year, where India donated a Bhabhatron Cancer equipment for the Kenyatta National Hospital. As a result of the cooperation 11 Kenyan Oncologists have benefited from training in India and five more are scheduled to begin training later this year. Kenya is also set to receive more equipment worth one million USD from India and medicines for Cancer and ARVs. *Ministry of Health, Kenya*

Health ministry fast tracks efforts for a generation born free of HIV by 2021
The Government of Kenya launched an ambitious targets and a new framework to eliminate mother to child transmission of HIV and Syphilis on June 13. With this framework, the government commited to be validated globally for pre- elimination of mother to child transmission of HIV and Syphilis by 2021. Key strategic shifts include enhanced shared responsibility of both parents in the prevention of transmission, intensified community and county led programming, private sector participation in public health agendas and an increased focus on adolescent girls and young women due to the high rate of new infections among this age group. *Ministry of Health, Kenya*

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WHO

WHO updates Essential Medicines List with new advice on use of antibiotics, and adds medicines for hepatitis C, HIV, tuberculosis and cancer
New advice on which antibiotics to use for common infections and which to preserve for the most serious circumstances is among the additions to the WHO Model list of essential medicines for 2017. Other additions include medicines for HIV, hepatitis C, tuberculosis and leukaemia. The updated list adds 30 medicines for adults and 25 for children, and specifies new uses for 9 already-listed products, bringing the total to 433 drugs deemed essential for addressing the most important public health needs. The WHO Essential Medicines List (EML) is used by many countries to increase access to medicines and guide decisions about which products they ensure are available for their populations. *WHO*

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