



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: June 15, 2017 – June 28, 2017

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US

FDA taking two new important steps to increase competition in the market for prescription drugs and facilitate entry of lower-cost alternatives

The agency published a list of off-patent, off-exclusivity branded drugs without approved generics, and also implemented a new policy to expedite the review of generic drug applications where competition is limited. To encourage generic drug development, the FDA posted a list of branded drugs that have no listed patents or exclusivities and for which the agency has yet to approve a generic drug application (known as an Abbreviated New Drug Application or ANDA). The agency also intends to expedite the review of any generic drug

application for a product on this list to ensure that they come to market as expeditiously as possible. [FDA](#)

The Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, soliciting written comments on the Healthy People 2030 proposed framework

Drawing on the expertise of a Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030 and public input, Healthy People 2030 will reflect assessments of major risks to health and wellness, changing public health priorities, new knowledge in prevention, and emerging issues related to United States health preparedness. [Federal Register](#)

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Canada

New measures to inform Canadians of the risks of prescription opioids out for consultation

Health Canada is proposing regulations that would make a warning sticker and patient information handout mandatory with all prescription opioids at the time of sale. The sticker would be applied by the pharmacist to the prescription opioid container to warn patients about the potential risks associated with opioid use, including dependence, addiction and overdose. The proposed regulation would require pharmaceutical companies to develop and implement risk management plans for all opioids. Companies would also be required to monitor how their products are being used and undertake actions if harmful effects emerge from using these products. [Health Canada](#)

UK

Regulatory provisions for the government's business impact target to reduce regulation on business

According to the policy, the Department of Health's regulatory bodies must publish an assessment of their impacts on business as part of the government's Business Impact Target (BIT). The policy objectives of the BIT are:

- Reduce regulatory burdens on business and voluntary or community bodies, to free up resources and boost productivity
- Increase transparency around the impact of regulation on business
- Provide greater incentives for regulators to design and deliver policies that better meet the needs of business. [Department of Health. UK](#)

Post-implementation review of the Human Medicines Regulations 2012

The Medicines and Healthcare products Regulatory Agency is reviewing the impact of the Human Medicines Regulations 2012. This is part of a wider exercise within government to test the impact of legislation five years after implementation. The obligation to carry out a post implementation review is set out in regulation 346 of the 2012 Regulations. The agency is seeking feedback from interested stakeholders on 2012 Regulations that introduced the most significant changes:

- The Pharmacovigilance Directive (Directive 2010/84/EU (amending Directive 2001/83/EC);
- Cross Border Prescriptions;
- The repeal of Section 10(7) of the Medicines Act 1968 on Pharmacy wholesale dealing. [MHRA](#)

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Nigeria

FG, May & Baker to produce vaccine in Nigeria

The Federal Government of Nigeria has joined forces with May & Baker Nigeria PLC to resume production of vaccine locally at Federal Vaccine Production Laboratory (FVPL). In addition, May & Baker has appointed Shantha Biotechnics and Bharat Biotech of India as Major Technical Partner for the project. It is expected that ratification of the Joint Venture Agreement between

the Federal Government of Nigeria and May & Baker for the production of local vaccines through Biovaccines Nigeria Limited will ensure a sustained availability of essential vaccines required for the nation's various immunisations programmes. Production is expected to commence between 2017 and 2021 when the current arrangement of sourcing for the vaccines through UNICEF which is heavily subsidised to about 80% by the Global Alliance for Vaccine Initiative (GAVI) is expected to come to an end. [Ministry of Health, Nigeria](#)

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Canada

Government of Canada supports global commercialisation of precision radiotherapy technologies for cancer patients

The Government of Canada is making a 2.06 million CAD investment in the Nova Scotia Health Authority (NSHA) to assist in the development of five radiotherapy technologies. Over the next five years, all six regional development agencies, including Atlantic Canada Opportunities Agency (ACOA), will invest a total of 1.5 billion CAD to strengthen innovation capacity and economic growth in each region of the country. [ACOA](#)

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Kenya

Health PS roots health research in policy development

According to the Principal Secretary (PS) for Health, the National Health Research has allocated a fund of 250 million KSH to support successful research proposals which are submitted through NACOSTI. The PS revealed that guidelines for use of research in policy development have already been developed and various research institutes across sectors among them KEMRI for Health and KARI for Agriculture. [Ministry for Health, Kenya](#)

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WHO

WHO AFRO hosted the inaugural Africa Health Forum

WHO's Regional Office for Africa (AFRO) convened a meeting of global leaders and thinkers to explore Africa's healthcare priorities and challenges and find new ways to achieve better health for all. The Africa Health Forum took place in Kigali, Rwanda on June 27-28 2017. Themes covered at the two-day event included:

- Health financing;
- Health security;
- Health research, innovation and data;
- Universal Health Coverage and the private sector in Africa;
- HIV and the rise of new threats such as non-communicable diseases. [WHO Afro](#)

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