First WHO-prequalified hepatitis C rapid test opens door to expanded treatment

A great number of people with chronic hepatitis C live without knowing they have the infection and miss the opportunity to be cured. WHO has just prequalified its first hepatitis C virus (HCV) rapid diagnostic test, a tool that will aid diagnosis of HCV in low- and middle-income countries and significantly improve access to treatment for those most in need. Read more >

Taking the panic out of emergencies

Emergency preparedness was one of the hot topics of ICDRA 2016, the international conference of drug regulatory authorities that takes place every two years. Recounting their experiences of the West Africa Ebola epidemic, regulators who had been in the eye of the storm outlined the lessons they learned and sketched out some of the ways we can progress to be better prepared for the next epidemic. Read more >

New method developed to measure antimicrobial consumption to help countries address resistance

WHO in consultation with key national and regional partners has developed a methodology for monitoring antimicrobial consumption and will be piloting surveys in 20 countries in Africa, Asia and the Pacific. Thanks to that methodology, countries should be able to retrieve valuable information on overall use of antimicrobials (including antibiotics, TB, malaria and HIV medicines) and which classes of antimicrobials are used. Read more >

Work towards global access to quality medical products
At least 30% of NRAs globally have limited capacity to perform core regulatory functions. Underfunding, understaffing and weak policies are hampering national regulatory authorities’ capacity to advance access to quality medical products and safeguard patient safety, particularly in developing countries. A meeting in Cape Town on the 29 November 2016 – 2 December 2016 gave regulators the chance to discuss common challenges and how collectively they can make a difference.

Press release >
Fact sheet >

New: School of INN Video

In many countries, different brand names are used for the same medicine. The International Nonproprietary Name (INN) programme was set up to provide a common and an official generic name for each and every medicine. In a highly globalized world, the use of INNs, rather than medicines brand names, are critical for health care professionals as well as patients.

View video HERE! >

In Vitro Diagnostics (IVDs) for Zika accepted for procurement

WHO has developed an Emergency Use Assessment and Listing (EUAL) procedure to accelerate the availability of IVDs needed in public health emergency situations. The first Zika test was listed in August and WHO has recently added a second product to the list. These IVD kits are designed to detect Zika, Dengue and Chikungunya infection in patients.

Read more >

New financial arrangement to improve sustainability, quality and global reach of WHO prequalification of medical products

WHO, industry groups and key partners have agreed on a new financing arrangement to ensure the financial sustainability and quality of WHO’s prequalification programme in the coming years. The arrangement is based on an improved fee structure that aims to make the programme better equipped to address current global quality challenges in the medical products area, to lay the ground for strengthening and expanding services provided, and to improve financial predictability and transparency.

Read more >

Good regulatory practices in the pipeline
Back in 2014, the Sixty-seventh World Health Assembly recognized that “effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes”. The guidelines for good regulatory practices (GRP) provide a means for establishing sound, affordable and effective regulation of medical products. The tool is intended to assist Member States in the implementation of GRP and provides both orientation to foundational principles and guidance for developing, maintaining and evaluating a regulatory framework for the control of medical products. Read more >

Guidelines for changes to approved biotherapeutic products

Biotherapeutic products are an increasingly important component of global healthcare. Such products have had a highly successful record in treating many life-threatening and chronic diseases but their cost has often been high and they represent an increasing proportion of healthcare expenditure. The guidelines on procedures and data requirements for changes to approved biotherapeutic products provide guidance for national regulatory authorities and market authorization holders. Review of preliminary draft guidelines and comments have been received and are under the 1st round of public consultation. Read more >

New head of RHT

Ms Emer Cooke was appointed Head of Regulation of Medicines and other Health Technologies (in HIS/EMP). Ms Cooke is from Ireland and until recently held the role of Head of International Affairs at the European Medicines Agency in London. She worked at the Agency since 2002, during which time she also served as Head of International and European Cooperation and Head of Inspections.

Happy holiday season to all!

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