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Clinical Research NEWS letter
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1. Medical regulations transform in Australia to provide faster access to medicines and devices

The Government of Australia will adopt majority of the recommendations made by an independent review of medicines and medical devices, which will expedite the drug approval process and ultimately enable the Aussies to gain faster access to new drugs and medical products. This independent review was published in 2014 with an objective to eradicate any unnecessary or ineffective regulations regarding the safety or quality of medicines.

Australia's drug regulator 'Therapeutic Goods Administration (TGA)' will effectively reform these recommendations gradually over the next 18 to 24 months with regulatory pathways for some medicines within 12 months.

Australia is deprived of certain lifesaving and innovative medicines and medical devices, which are approved in other markets; implementation of new regulations will expedite the drug approval process, especially for approved products in other countries. It is expected that the cancer patients will have access to certain medicine at least 2 years earlier as compared with today with these regulations. The health ministry of Australia expects Australia to be aligned with other international regulators, and a faster registration of breakthrough medicines with these reforms.

These regulations also encourage the sponsors to publish the data supporting their products on their website so that will help consumers to compare complementary drugs. Additionally, advertising for medical products will be simplified with these regulations; however, ambiguous advertising will get stricter penalties.

Source: theguardian.com

DRUGS: DEVELOPMENT & CLINCIAL TRIALS

- Merck & Co. & Pfizer's ertugliflozin meets endpoints in a Phase 3 trial
- Novartis' Zykadia meets endpoints in Phase 3 ALK+ NSCLC trial
- FDA's fast track designation to malaria vaccine
- Exenatide XR and dapagliflozin combination shows benefits in diabetes in a Phase III trial

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

- Lawsuit filed by Sanofi against Merck for patent infringements
- FDA rule clarifies pharma patent process to reduce unnecessary litigation

TECHNOLOGY/ NDDS NEWS

- FDA approves YOSPRALA with new drug delivery system
- Simple saliva test to diagnose asthma
- FDA approves Obalon Balloon System for weight loss

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