Accelerating access to new drugs in Japan

Writing in Nature Reviews Drug Discovery, Yasuhiro Fujiwara outlines developments in Japan to reduce the time required for new therapeutic drugs to gain marketing authorisation.

Fujiwara notes that Japan historically has taken longer than the United States and the European Union to give marketing approval for therapeutic drugs. Over the course of the last 20 years approval times have been reduced, through a number of initiatives. These have including the creation of a Pharmaceutical Medical Devices Agency, which mimics the Food and Drug Administration approval model, the prioritisation of budgets for technology evaluation, and more recently, the introduction of the Sagigake review system, which resembles the adaptive patient pathways work in the United States and the European Union. All these changes have contributed to accelerated marketing authorisation approvals.

Whilst these changes are relatively widely adopted and attract little controversy, a more recent initiative is proving more controversial, the Patient-Proposed Health Services (PPHS) initiative. This new model of therapeutic drug authorisation, allows patients to access certain categories of therapeutic drugs and devices which have marketing authorisation outside of Japan but which have yet to be evaluated in Japan. Access to these drugs is managed through an application to a core hospital, which are responsible for managing patient therapy and the evaluation of the therapeutic drug.

Enthusiasm for this apparent patient-led liberalisation of therapeutic drug access is tempered by concerns over both the costs for patients, according to Fujiwara. With PPHS patients become liable both for the costs of the drugs and the costs of trialling the requested drug. Concern has also been raised over the effect of PPHS on Japan's biomedical research capability given this scheme effectively disincentives investment in technology evaluation in Japan.

Although PPHS could be seen as an example of patient empowerment, this empowerment comes with costs, as the work and costs of drug approvals are shifted from industry to Japan's patients and hospitals.

The full article can be accessed at Nature Reviews Drug Discovery.

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