BIOBUSINESS BRIEFS

REGULATORY WATCH

Crossing the regulatory finish line

The US Food and Drug Administration (FDA) was faster in reviewing applications of novel therapeutics (defined as new molecular entities and novel biologics) than the European Medicines Agency (EMA) and Health Canada in the period 2001–2010, according to a recent report in the *New England Journal of Medicine* (**366**, 2284–2293; 2012). Moreover, many of these novel therapeutics were first to market in the United States. However, compared to the EMA and Health Canada, the FDA approved the lowest proportion of novel therapeutics after one cycle of review only.

The study assessed the review times of approved novel therapeutics for the regulatory agencies from the United States, Europe and Canada in the period 1 January 2001 to 31 December 2010. The data were extracted from publicly available databases, and 510 approved applications were examined, of which 225 were approved by the FDA, 186 by the EMA and 99 by Health Canada. These 510 applications covered 289 novel therapeutic agents, of which 72 were approved by all three regulatory agencies (FIG. 1).

The median length of time for a first review by the FDA was 303 days compared to 352 days for Health Canada and 366 days for the EMA (FIG. 2). This trend was similar when comparing the total time to review (which includes multiple rounds of review): 322 days for the FDA, 366 days for the EMA and 393 days for Health Canada.

Looking more closely, among the 72 novel therapeutics approved by all three agencies, the median length of time for the first review was 254 days for the FDA, 346 days for Health Canada and 356 days for the EMA. However, after one cycle of review, the EMA approved the greatest proportion of new drugs (96.2%; 179), followed by Health Canada (68.7%; 68) and then the FDA (61.8%; 139) (FIG. 2).

Examining first to market, of the therapeutics approved in both the United States and Europe (total 190), 121 were first approved in the United States, with the drugs available a median 96 days earlier in the United States than in Europe. For those approved in both the United States and Canada (total 154), 132 were first approved in the United States, with the drugs available a median 355 days earlier in the United States than in Canada.

The authors acknowledge that there are limitations to the study (for example, they did not attempt to assess the quality of the regulatory decisions), but in general the results indicate that the FDA reviews applications more rapidly than the EMA and Health Canada.

Man Tsuey Tse

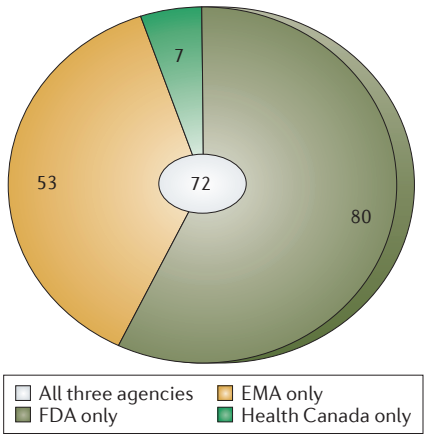

Figure 1 | **Approval of unique novel therapeutics.** The number of unique novel therapeutics approved by the US Food and Drug Administration (FDA), the European Medicines Agency (EMA) and Health Canada in the period 2001–2010 ($n = 289$) is shown. Note that for Health Canada, application approvals were available only from 2005 onwards.

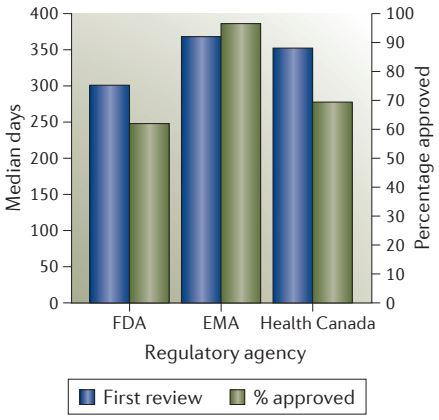

Figure 2 | **Time for first review, and percentage approved after first review.** The median time taken for the first review of applications for novel therapeutics by the US Food and Drug Administration (FDA), the European Medicines Agency (EMA) and Health Canada in the period 2001–2010 is shown, as well as the percentage of applications approved after one cycle of review.