News

India: Biosimilar Approvals under Debate in India

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Herceptin: Roche Products (India) Private Limited v. Drugs Controller General of India (Delhi High Court; CS (OS) No. 355/2014)

http://lobis.nic.in/ddir/dhc/MAN/judgement/26-04-2016/MAN25042016S3552014.pdf

Avastin: Roche Products (India) Private Limited v. Drugs Controller General of India (Delhi High Court; CS (COMM) No. 540/2016)

http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=131419&yr=2016

Trastuzumab – a breast cancer drug manufactured by Roche and Genentech Inc., is imported and marketed in India by Roche Products (India) Private Limited under the brand names Herceptin, Herclon and Biceltis. It dominates the market, however following Roche's decision to allow the Indian patent on Herceptin to lapse in 2013, generic drug manufacturers have launched biosimilars. Approved versions include Biocon's and Mylan's CANMAb and Hertraz respectively.

Biosimilar versions (two at last count with another in the pipeline) of Avastin – used to treat a range of advanced cancers – are also on the Indian market.

Biosimilar regulatory approvals in India are governed by the Drugs & Cosmetics Act, 1940 supplemented by the Guidelines on Similar Biologics, 2012 (the 'Guidelines'). Until 2012 biosimilar approval criteria was less stringent involving an abbreviated version of the regulatory pathway applicable to new drugs. Current Guidelines however outline robust pre-clinical and clinical data requirements to establish similarity with the reference drug. Approval processes look set to become even more rigorous in the days ahead as proposals exist to include post marketing phase IV studies – to ensure safety and further reduce residual risk of biosimilars – in the regulatory process.

The Avastin lawsuit is currently being heard by the court on maintainability, however, an interim ruling was passed recently in the Herceptin case (filed in 2014) and that has garnered a lot of attention.

On April 25, 2016, the court while balancing public access to cheaper generic drugs without compromising the reputation of the innovator ruled in favour of Roche to hold that marketing approvals granted to CANMAb and Hertraz were indeed not in adherence with the Guidelines. However, Biocon and Mylan were allowed to continue manufacturing, marketing and advertising their products provided the 'biosimilar tag' was removed and the INN name –trastuzumab – was not used on a stand alone basis. The court also restrained the two companies from using safety and efficacy data of the innovator drug until the biosimilarity issue was decided. Significantly, to the question whether data for metastatic breast cancer could be extrapolated to two additional indications

(metastatic early breast cancer and metastatic gastric cancer), the court held that regulatory compliance was a pre-requisite. This was found missing in the present case as approval has been granted following an abbreviated pathway that fell foul of the Guidelines and one that had omitted consideration of data from phase I and phase II clinical studies. Further, on the question of data exclusivity, the court acknowledged that data in the public domain may be relied upon in the absence of any policy on data exclusivity in India; however, in contradiction to extant policy, the judge surprisingly opined that unless the government frames a data exclusivity policy, the regulatory authority must neither disclose nor rely upon the first applicant's data at the time of granting marketing approval to the subsequent applicants.

Biocon has appealed the interim order and it remains to be seen whether it will successfully reclaim its biosimilar tag.

As matters stand, the interim order has shown the way to innovators to stave off brand-based competition in the Indian market. In its wake regulatory approvals and statutory compliances for biosimilars are likely to face stricter checks. And for the many biosimilars already approved through abbreviated regulatory pathways, it will be interesting to see whether other innovator companies walk Roche's path.