Market Barriers & Innovation in The Pharmaceutical Industry

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Abstract

Background: Although there has been significant growth in investment in the Research and Development (R&D) sector of the pharmaceutical industry, productivity in terms of drug approvals has not been rising accordingly. In 2014 the estimated cost of developing a prescription drug that gains market approval was $2.6 billion, a 145% increase since 2003. However, recent studies have shown that the number of new compounds being approved have stagnated demonstrating flat productivity. Furthermore, the number of New Molecular Entities (NME) dropped significantly in 2016, reflecting the lowest rate of small-molecule Food and Drug Administration (FDA) approvals in almost five decades.

Aims: To collate data on drug approvals from FDA and European Medicines Agency (EMA) between November 2016 to April 2017, to analyse key market barriers in the pharmaceutical industry.

Methodology: Data was extracted from the regulators' websites and classified based on indication, drug and disease then subjected to thematic analysis.

Results & Discussion: In the investigated time frame, 374 drugs were approved by the FDA and 49 by the EMA. Since data from the EMA was limited to only 'centralised' drug approvals, numbers for the EMA were less in comparison to the FDA. Some factors contributing to decreased productivity are post-approval market barriers such as: Health Technology Assessments (HTA); increased R&D costs; selectivity of drug companies; and variations in authorisation decisions between the regulatory bodies. Potential solutions include: increasing publicity of particular therapy areas to increase demand for new drugs; and using Mutual Recognition Agreements (MRA) to harmonise decisions between the FDA and EMA.

Conclusion: Arguably the real implications of these market barriers is felt by the patient for whom access to new and innovative treatments is subsequently limited. Further research, with a broader scope, to include other routes of approval, needs to be carried out.

Images

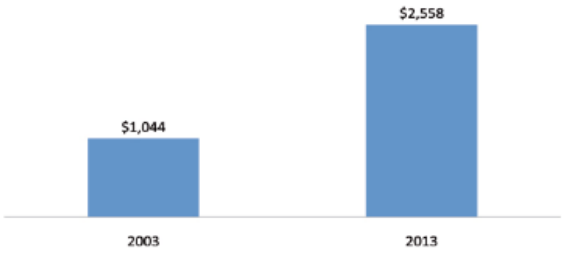


Figure 1 Cost of a new drug in 2003 and 2013 (DiMasi, Grabowski & Hansen, 2016)

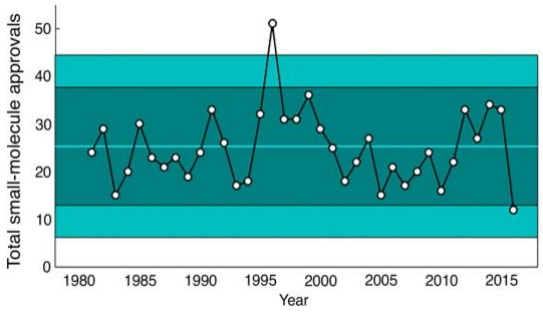


Figure 2 Total small-molecule approvals and biological drug approvals by the FDA from 1975 to 2015 and the five-year running averages (Griesenauer and Kinch, 2017)

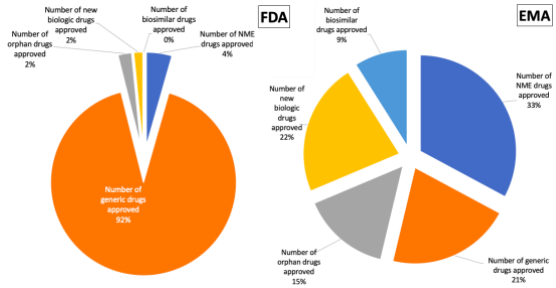


Figure 3 Comparison of drug approvals between FDA and EMA according to drug classifications i.e. NMEs, generics, orphans, new biologics and biosimilars (in percentages of total number of drugs approved by each regulatory body)

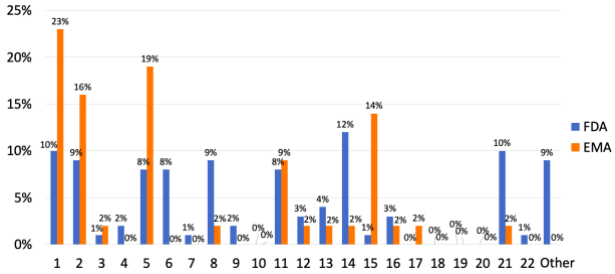
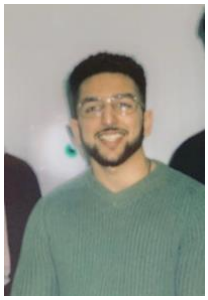


Figure 4 Comparison of drug approvals between FDA and EMA according to disease classification e.g. skin diseases, diseases of circulatory system, neoplasms etc (in percentages of total number of drugs approved by each regulatory body)

Publications

1. DiMasi, J., Grabowski, H., & Hansen, R. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. *Journal Of Health Economics*, *47*, 20-33.
2. Kaitin, K. and DiMasi, J. (2010). Pharmaceutical Innovation in the 21st Century: New Drug Approvals in the First Decade, 2000–2009. *Clinical Pharmacology & Therapeutics*, 89(2), pp.183-188.
3. Griesenauer, R., & Kinch, M. (2017). 2016 in review: FDA approvals of new molecular entities. *Drug Discovery Today*, *22*(11), 1593-1597.



Biography

Amardeep is a passionate and driven individual looking to progress in the field and make an impact in the Pharmacy arena. Having graduated from University of Hertfordshire, Amardeep currently works as a pre-registration pharmacist in West London and looks forward to working as a qualified pharmacist later this year. Author of *A Pharmacy Student's Perspective on Digital Health* (featured in The Pharmaceutical Journal) and *Market Barriers and Innovation in The Pharmaceutical Industry* (featured on the British Pharmaceutical Students' Association website).

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