

Availability of new medicines – Characterising the factors influencing drug roll out to six mature markets

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Introduction

Every marketed medicine undergoes a rigorous evaluation from a regulatory agency to ensure that the benefits of the medicine outweigh the risks and as such become a valuable asset in the treatment of diseases. The development of new medicines is long, expensive and risky with only around 10% of new active substances (NAS) that enter man making it to its 1st market.

An increasing number of NAS are 1st launched by small to medium companies and the questions is, are these products only available to patients in the country of first market or do these NASs benefit a wider patient population. Comparison of drug approvals in six mature markets based on a cohort of medicines first launched 2005-2010 allows the investigation of internationalization of NAS's and the underlining factors that impact the potential availability of new medicines to patients.

Objective

To review new active substances (NASs) first launched globally between 2005-2010 and their regulatory status by 2012 in the US, Europe, Japan, Australia, Canada, and Switzerland to identify how the regulatory review and companies' submission strategies relate to the time to approval in each jurisdiction

Methods

146 1st launched NASs were identified from the CMR International First launched database. This provided information on, the date of 1st marketing and country. These NAS were then identified in the CIRS Regulatory Review times database which tracks, submission and approval dates, approval route, company and therapeutic area. The data were collected to evaluate and characterise the factors impacting international drug roll out across the six jurisdictions (Figure 1). Companies with an R&D spend of over 3bn USD in 2010 were classified as a top company*

Figure 1: Schematic outline of timeline analysis

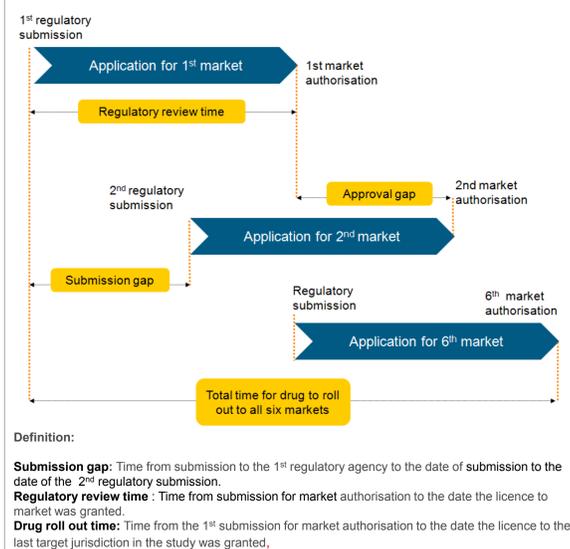


Figure 2: For new medicines first launched between 2005-2010, the majority of the NASs were first launched in US

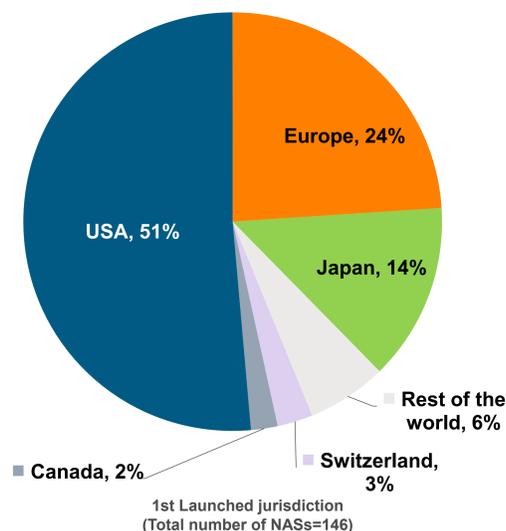


Figure 3: Only 34 % of 1st Launches 2005-2010 were approved in all six jurisdictions by 2012
Main therapeutic area Breakdown

Number of jurisdiction available (Number of NASs approval)	1	2	3	4	5	6	Total 1st launched NASs (146)
Anti-cancer	11%	23%	15%	15%	19%	38%	22%
Anti-infective	18%	0%	8%	15%	15%	15%	14%
Alimentary & Metabolism	11%	8%	15%	8%	4%	19%	12%
Blood & Blood-forming organs	14%	8%	0%	0%	4%	8%	7%
Cardiovascular	4%	23%	23%	0%	19%	4%	10%
Nervous system	7%	15%	8%	8%	15%	4%	8%
Other	36%	23%	31%	54%	23%	13%	27%

Percentage of NASs by therapeutic area

Figure 4: Greater proportion of NAS launched by top companies are availability in more jurisdictions than non top companies

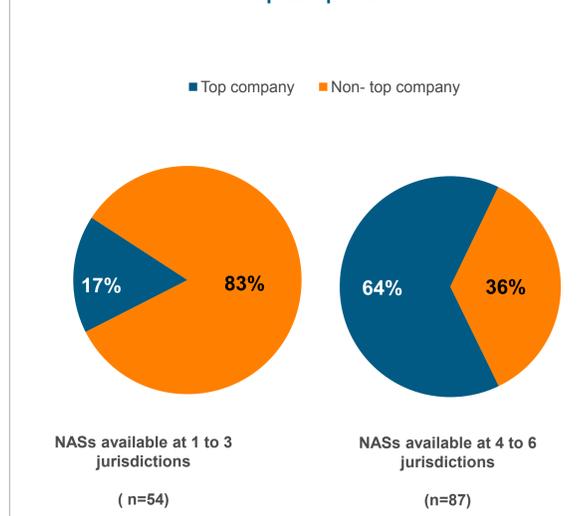


Figure 5: Median Submission gap and Regulatory review time of the 47 products approved in all six jurisdictions

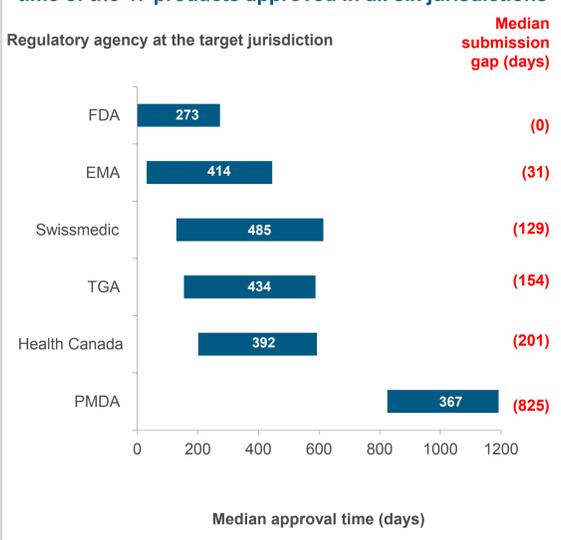
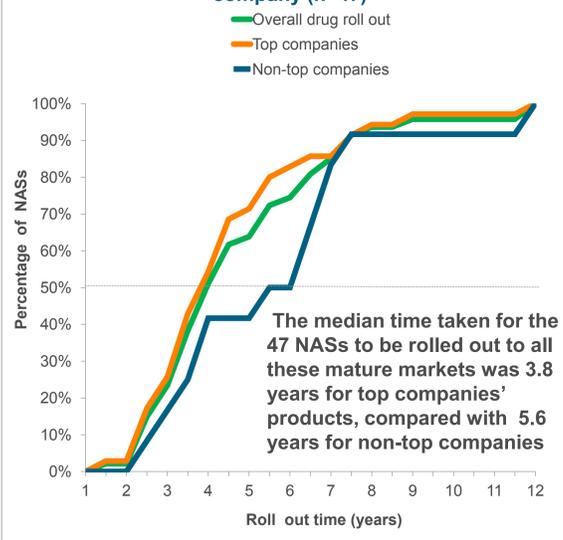


Figure 6: Drug roll out time to all markets by the size of company (n=47)



Result not graphed:

- Fifty-four NASs were designated by FDA for a priority review, of which 42 (78%) were approved in five or more jurisdictions, compared with 61% of those NASs designated by FDA for a standard review.
- Three therapeutic areas made up 48% of 1st launches (anti-cancer, anti-infective, alimentary and metabolism), and 72% of the cohort of 47 NASs approved in all six jurisdictions.
- Forty-six percent of the overall NASs were from top companies (2010 R&D spend greater than 3billion USD) but made up 74% of the 47 NASs approved in all six jurisdictions.

Conclusion

- Only 47 new medicines first launched between 2005-2010 were licensed across all six jurisdictions by the end of 2012 and the median time for a product to be approved in all countries was around 4 years for top companies and 6 years for non top companies
- A number of factors can influence both the number of products licensed and the time it takes to achieve licensing across these jurisdictions. These include the therapy area, with anti-cancer making up only 22% of the total numbers first launched but 38% of the cohort of medicines found in all six jurisdictions.
- Timing can be influenced by not only the company strategy in terms of submission timing, which in turn can be driven by market size, need for new data to be generated and reimbursement policies of the jurisdiction, but also by the time it takes the agencies to review a new medicine.
- This study reflects these factors in that the US has both the greatest number of first launches and also the most rapid approval times; medicines were licensed in 172 days (median) before being licensed in Europe.
- In terms of roll out time to the last market, Japan was the market with the longest time to submission by about 600 days, suggesting the need for a different development strategy for this market. (However in recent years approval times in Japan have reduced which may change company strategies to this market)
- However results from this study indicate that the key influencer for the availability of a new medicine across these six markets relates to the size of the company, as companies with large R&D budgets are more likely to have the resources to undertake the submission of dossiers and to support their review in multiple jurisdictions.
- These findings suggest that smaller companies should investigate mechanisms to supplement their ability to offer their products for assessment in multiple jurisdictions, thereby finding opportunities for their novel products to quickly reach patients.

Data Source

CIRS Regulatory Review Time database
CMR International 1st Launch database

Reference

- Hirako M, McAuslane N, Salek S, Anderson C, Walker S. A Comparison of the Drug Review Process at Five International Regulatory Agencies. *Drug Info J.*2007; 41:291–308.
- McAuslane N, Anderson C, Walker S. The Changing Regulatory Environment: Reality and Perception. Epsom, UK: CMR International; 2004. *R&D Briefing 42*. Available at <http://213.120.141.158/node/73>. Accessed February 2014.

Center For Innovation in Regulatory Science

Mission
To maintain a leadership role in identifying and applying scientific principles for the purpose of advancing regulatory and HTA policies and processes in developing and facilitating access to medicinal products

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