2014 CMR INTERNATIONAL PHARMACEUTICAL R&D EXECUTIVE SUMMARY

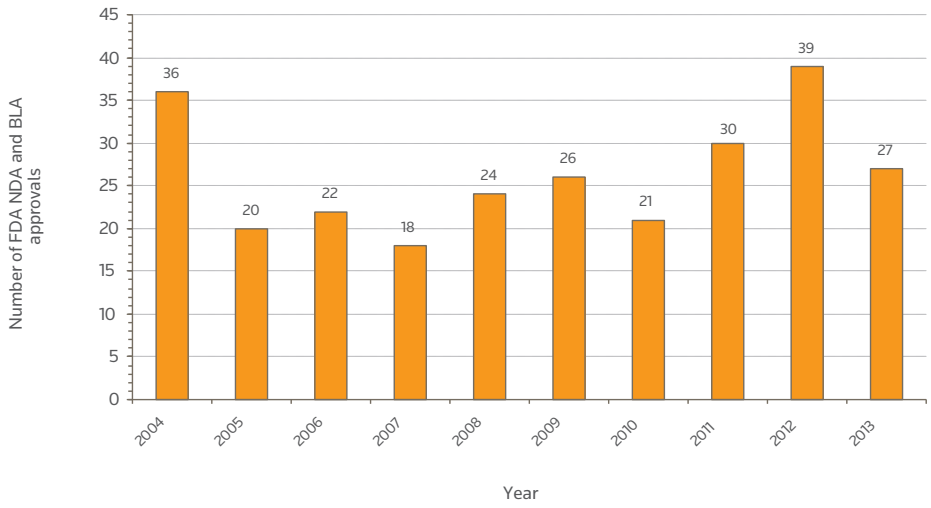
AUGUST 2014

THOMSON REUTERS™

INTRODUCTION

The decline of R&D productivity across the global biopharmaceutical industry is a well documented topic. With the end of each year the recurring question of whether the R&D productivity of the biopharmaceutical industry has increased or declined has been routinely discussed. Looking at the New Molecular Entity (NME) approvals paints a gloomy picture at first sight. The number of NME approvals by the FDA has dropped significantly by over 30 percent between 2012 and 2013. Some industry observers see this drop as a clear decline in productivity while others have a more optimistic view citing 2013 as a typical year not very different to the ten year average. In fact, reacting to these concerns the FDA has stated that the success rates are on par with the long-term averages and last year's approval numbers fell between the five and ten year averages suggesting "a regression to the mean following an outlier.[1]

FIGURE 1 – NUMBER OF FDA NME AND BLA APPROVALS, 2004 TO 2013



Source: fda.gov

Key metrics identified in the 2014 CMR International Pharmaceutical Factbook indicate a number of more positive trends emerging across the pharmaceutical industry including:

- The third highest number of New Molecular Entity first world launches in the last decade registered in 2013
- A decline in early phase pipeline volumes and success rates coupled with relatively stable late phase success rates suggestive of the industry's ability to 'fail fast, fail cheaply'

NEW MOLECULAR ENTITIES FIRST-WORLD LAUNCHES

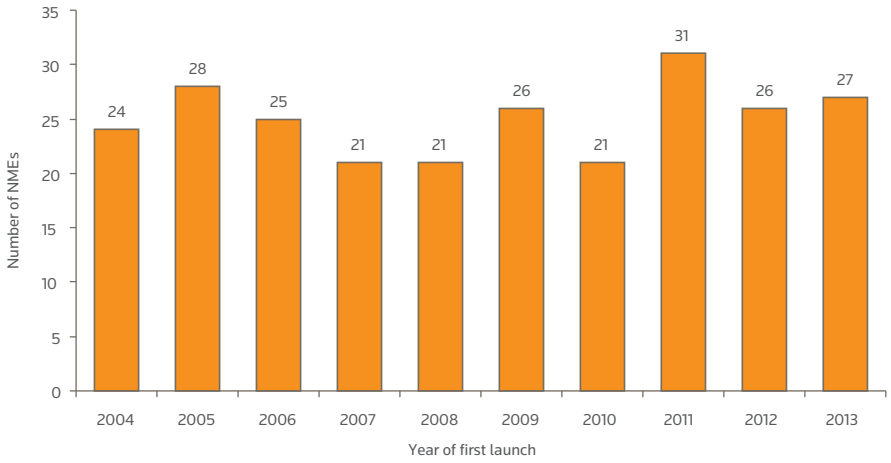
Expanding beyond the US, Figure 2 illustrates biopharmaceutical R&D output through a different metric; by counting the number of New Molecular Entities (NME) first world launches in the global market over time. The first world launches list also consists of 27 first launches but the composition is somewhat different to the FDA approvals. There are a number of reasons to rationalize the differences including:

- A number of FDA approvals were only approved and not launched by the end of 2013 and therefore not included in the launches list. For example, Sovaldi (Sofosbuvir) was approved by the FDA on 6th December 2013 but not launched
- Differences in NME definitions. CMR definition does not classify prodrugs and metabolites of previously launched products as NMEs and therefore these are excluded from the launches list. For example Kadcyla (Trastuzumab emtansine) is included in the FDA 2013 NME approvals but excluded from the CMR NME first launches as it is the active compound Trastuzaumab was launched in 1999.[2]

Data from Figure 2 indicates 2013 still achieved the second highest number of NME first launches over the last five years and the third highest number of NME first launches over the last ten years

Examining the nature of the first launches also provides a more encouraging picture in terms of the industry's ability to explore new scientific opportunities especially in the areas of unmet need. Approximately, half of all launches were specialty drugs indicated for the treatment of diseases such as cancer, pulmonary arterial hypertension and HIV. Additionally, all oncology NME First World launches in 2013 received orphan drug status from the relevant regulatory authority[3]

FIGURE 2 – NUMBER OF NME FIRST WORLD LAUNCHES 2004 TO 2013



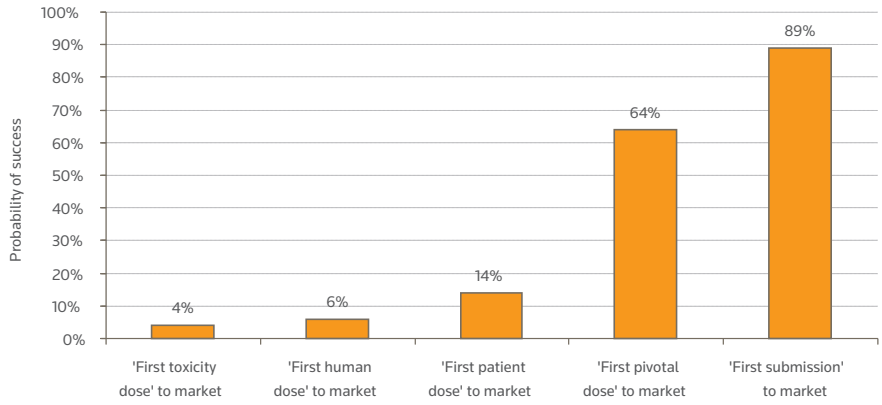
Source: 2014 CMR International Pharmaceutical R&D Factbook

ATTRITION AND SUCCESS RATE

Across the industry there has been a decline in pipeline volumes and success rates in the early phases.[4] Yet despite this the number of terminated projects in Phase III are declining as well as a stable success rate is observed for the submission phase.[4] Combining these observations together actually paints a more positive picture for the industry as some encouraging conclusions may be drawn:

- The decline in early development pipeline volume coupled with a declining number of terminated projects in Phase III means the industry is improving its ability to 'fail fast, fail cheaply' thereby progressing compounds which are more likely to succeed in later phases
- The increasing focus into areas of unmet medical need and speciality care coupled with improving late phase success rates data means these types of strategies may be proving to be successful across development

FIGURE 3 – PROBABILITY OF SUCCESS TO MARKET FOR ACTIVE SUBSTANCES



Source: 2014 CMR International Pharmaceutical R&D Factbook

Probabilities of success to market were calculated using success rates between phase for active substances entering phase between 2007 and 2009 and year of assessment 2012.

CONCLUSION

The data presented in this executive summary highlights an industry that demonstrates an ability to respond successfully to various challenges to improve R&D productivity overall.

The 2014 CMR International Pharmaceutical R&D Factbook contains metrics and analyses on R&D productivity and many other key topics relevant to the biopharmaceutical industry, such as R&D resources and pipelines, patents and generic drugs. For a full list of figures or additional information, please visit our website **cmr.thomsonreuters.com** or contact us using the information below.

CMR OVERVIEW

CMR International, a Thomson Reuters business, is a world leader in global pharmaceutical research and development (R&D) performance measurements. For over 17 years, CMR International has worked with the leading global pharmaceutical and biotechnology companies to assess R&D productivity and provide insights, which are used to strengthen planning and execution across R&D functions.

We provide our clients with accurate, trustworthy performance metrics and industry benchmarks. Our clients use this information to make critical decisions on how to:

- Stay competitive and compare their overall R&D performance to their peers
- Optimize their R&D portfolio and strategy based on our therapeutic-area specific project durations and success rates information
- Create realistic targets for R&D projects that will motivate and challenge their organization
- Refine clinical trials and patient enrollment strategies based on unique country and site intelligence provided by participants in CMR International's annual programs and focused performance metrics modules

Our experience, independence and integrity—in combination with our dedication to providing the highest quality information, insights and opinions—makes us an essential service for the world's leading pharmaceutical innovators.

References

1. Mullard, Asher. "2013 FDA Drug approvals". Nature Reviews Drug Discovery Vol 13, 85-89 (February 2014)
2. Thomson Reuters Cortellis Regulatory Intelligence
3. CMR International New Medicine Launches 2013
4. 2014 CMR International Pharmaceutical R&D Factbook

ABOUT THOMSON REUTERS

Thomson Reuters is the world's leading source of intelligent information for businesses and professionals. We combine industry expertise with innovative technology to deliver critical information to leading decision makers in the financial and risk, legal, tax and accounting, intellectual property and science and media markets, powered by the world's most trusted news organization. With headquarters in New York and major operations in London and Eagan, Minnesota, Thomson Reuters employs approximately 60,000 people and operates in over 100 countries. For more information, go to thomsonreuters.com.

To find out more, go to ip-science.thomsonreuters.com.

CMR CONTACTS

Phil Miller
Clinical Practice Director
+44 (0) 207 433 4163

Jasmin Mehta
Manager, Insight Solutions
+44 (0) 207 433 4294

Thomson Reuters
77 Hatton Garden
London
EC1N 8JS
T +44 (0) 207433 4000
F +44 (0) 207433 4310
info@cmr.thomsonreuters.com

102013

THOMSON REUTERS™