2016 CMR INTERNATIONAL PHARMACEUTICAL R&D FACTBOOK EXECUTIVE SUMMARY

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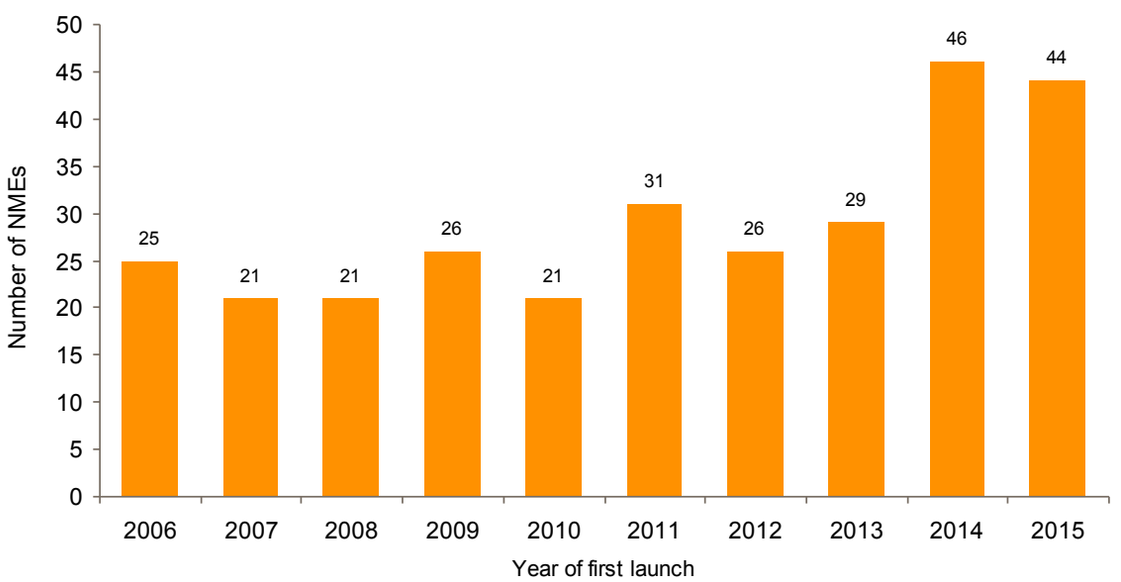
The rise and fall of R&D productivity across the global biopharmaceutical industry is a well-documented and much-discussed topic, with industry commentators quantifying productivity in many different ways. However, in recent times, there have been a number of indicators that paint a more positive story for the pharmaceutical industry. For example, in 2015, the biopharmaceutical industry achieved the highest number of approvals in over a decade with 45 New Molecular Entities (NME) approvals.[1]

Expanding beyond the United States and looking at launches, **Figure 1** counts the number of NME first-world launches in the global market over time. This analysis illustrates an equally positive message with 44 first-world launches in 2015. Although the number of first launches is less than the peak in 2014, last year still achieved the second-highest number of launches in the past two decades.[2]

FIGURE 1 – NUMBER OF NME FIRST-WORLD LAUNCHES: 2006 TO 2015



Source: 2016 CMR International Pharmaceutical R&D Factbook

Examining the nature of these first-world launches also provides an encouraging picture for the industry:

- 16% (7 out of 44) of the first-world launches received orphan designations
- Thirteen NMEs were indicated within oncology, four of which received orphan drug status
- 75% (33 out of 44) of the first-world launches were specialty drugs indicated for the treatment of such diseases as cancer, hepatitis C virus (HCV), and eye disorders

It is important to note here that there are some differences in NME definitions between the CMR first-world launches and the FDA NME approvals. Among other aspects, the FDA includes certain acids in its NME definition, whereas the CMR definition does not classify these types of drugs as NMEs. In 2015, one such approval of cholic acid (Cholbam®) was included in the FDA NME approvals but excluded from the CMR NME first-world launches because it is a form of bile acid.

Examining the pipeline in development, it is likely that this trend in the growing number of approvals and launches will continue in the future. The *2016 CMR International Pharmaceutical R&D Factbook* shows that late-stage pipeline volumes have increased between 2011 and 2015 coupled with a decline in the number of Phase III terminations in the same year range.[2] Moreover, the *Factbook* demonstrates that the overall drug development times have reduced by more than 15% in the same year range.[2] Given these findings, it seems that the industry is improving its ability to launch innovative drugs onto the market faster with fewer late-stage terminations.

Moving on to biopharmaceutical sales, the *2016 CMR International Pharmaceutical R&D Factbook* estimates that in 2015, global pharmaceutical sales surpassed the $1.1 trillion mark, and this growth is likely to continue by many fold up until 2019.[2]

Despite these positive messages, further observations in **Table 1** suggest a cautionary note as the growth in global sales cannot readily be correlated to recent NME launches nor can it be correlated – with any confidence – to potential recent improvements to R&D productivity.

TABLE 1 - KEY METRICS FROM THE *2016 CMR INTERNATIONAL PHARMACEUTICAL R&D FACTBOOK*

METRIC	VALUE
Total Pharmaceutical sales in 2015	$1.1 trillion
Total R&D expenditure-to-sales ratio in 2015	~20%
Median percentage of sales from top three products per company in 2015	~50%
Median percentage of sales from products launched in last five years per company in 2015	<10%

Source: 2016 CMR International Pharmaceutical R&D Factbook

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 in terms of volume; however, the question on commercial value perhaps remains unanswered.

The *2016 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 cmr.thomsonreuters.com or contact us using the information presented on the next page.

REFERENCES

1. **www.fda.gov** "2015 Novel Drug Summary"
2. *2016 CMR International Pharmaceutical R&D Factbook*

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