CMR OVERVIEW

CMR International, a Thomson Reuters business, is the world leader in global pharmaceutical Research and Development performance measurements. For over 16 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 the most accurate, trustworthy performance metrics and industry benchmarks. Our clients use this information to make critical decisions on how to:

• Stay competitive in the marketplace 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 shorter performance metrics surveys

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.
EXECUTIVE SUMMARY

INTRODUCTION
Key metrics identified from the 2012 CMR International Pharmaceutical R&D Factbook indicate a number of encouraging trends across the pharmaceutical industry:

• Global ethical pharmaceutical sales continue to increase year on year
• 2011 saw a ten year high in the number of New Molecular Entities (NMEs) launching onto the market
• The number of late stage R&D project terminations is declining, coupled with a five year high in terms of the number of R&D projects entering the regulatory submission phase

Examining the data in more detail, there are a number of other emerging trends across the industry. For example, although the USA continues to be the largest individual contributor to patient recruitment globally, its total share continues to decrease, providing 34% of recruited patients in 2010. With respect to alliances and collaborations across the industry there appears to have been a change in industry strategy, moving away from collaborative deals and towards full licensing activity.

PIPELINE ACTIVITY AND SALES
In 2011 the total number of New Molecular Entities launched onto the global market reached a 10 year high increasing to 31 NMEs; mainly driven by an increase in output from Major* pharmaceutical companies (Figure 1).

Sales continue to rise, reaching an all time high of approximately $880 billion with pharmaceutical companies re-investing anything between 2% and 25% of global sales back into ethical R&D. Of these sales, only 7% are driven by products first launched within the last 5 years, indicating the industry’s continued reliance on more established products (Figure 2.)

ATTRITION
Early stage success rates continue to show the declining trends of the past decade. However, the trend in late stage success in Phase III and Submission seems to be reversing, with success rates for the most recent year range comparing favorably with previous years. While late stage terminations are still a concern to the industry, peaking at 53 between 2008 and 2010, the most recent year range indicates that the volume of compounds terminated in the latter, more expensive phase of development has declined. (Figure 3.)

This picture combined with the previously mentioned decline in number of compounds entering early stages of development would suggest that the change in industry strategy towards quality over a ‘shots on goal approach’ is having a positive impact; with an increase in the number of compounds being submitted and launched onto the market.

Data derived from the CMR international Global R&D Programme, illustrate that various compound or R&D project characteristics impact probability of success (PoS) including compound origin and therapeutic area. For example, New Biopharmaceutical Entities have 11% greater chance of reaching the market from Phase III as compared to New Chemical Entities.
THERAPEUTIC AREA HIGHLIGHTS

Anti-cancer development continues to attract the highest amount of investment across all therapeutic areas; with approximately 20% of total R&D expenditure (Figure 4). In terms of therapeutic area spend by phase, the two therapeutic areas which appear to have the most atypical distribution of expenditure are Alimentary & metabolism (39% in Phase III) and Cardiovascular (45% in Research) (Figure 5).

FIGURE 4. TOTAL R&D EXPENDITURE BY THERAPEUTIC AREA, 2011

PATIENT RECRUITMENT

There is substantial shift in patient recruitment from the USA and core European countries (for example France and Germany) and towards South East Asia and West Pacific and non-core European countries (for example Poland and Hungary). Many factors are driving this change in patient recruitment not least numerous cost containment initiatives implemented over the past few years across many pharmaceutical companies. Additional factors such as access to large heterogeneous populations in countries such as India and evolving regulatory environments in countries such as China and also driving clinical study activity in these countries.

Further data from the CMR International Global Clinical programme demonstrate that this change in patient recruitment is to a large extent being driven by changes in Phase II studies rather than across the whole of the clinical development process.

FIGURE 5. DISTRIBUTION OF R&D EXPENDITURE BY THERAPEUTIC AREA

METhODOLOGY

The 2012 CMR International Pharmaceutical R&D Factbook is based on data from a group of pharmaceutical companies representing circa 65% of the global R&D pharmaceutical spend in addition to analyses derived from content across other Thomson Reuters products and databases.

CONCLUSIONS

Taken together, the wide range of data aggregated in this year’s edition of the CMR International Pharmaceutical R&D Factbook depict a pharmaceutical industry in the midst of a significant strategic transformation. It is clear that the industry has systematically been moving away from the gambles on blockbusters that marked much of the 1990s and early 2000s and toward a “quality over quantity” approach that emphasizes marketing of existing products, drug repurposing, and more rigorous, cost-effective clinical trials. Despite this largely positive set of emerging trends, however, the data in this year’s report also underscore some issues that should raise concern among industry executives. Paramount among these is the fact that all-time high global pharmaceutical sales records are being driven by established drugs that are getting ever-closer to reaching the end of their patent protection. Just seven percent of the $880 billion in global sales in 2011 came from drugs that were established in the last five years. As its new strategic approach to drug development evolves, the industry will need to pair its laser focus on efficiency with the ability to produce breakthrough new NMEs.
CMR CONTACTS

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

Ben Mussell
Clinical Practice Consultant
+44 (0) 207 433 4289

The Johnson Building
77 Hatton Garden
London
EC1N 8JS

T +44 (0) 20 7433 4000
F +44 (0) 20 7433 4310

info@cmr.thomsonreuters.com

---

IP & SCIENCE REGIONAL OFFICES

North America
Philadelphia  +1 800 336 4474
              +1 215 386 0100

Latin America
Brazil       +55 11 8370 9845
Other countries  +1 215 823 5674

Europe, Middle East and Africa
London       +44 20 7433 4000

Asia Pacific
Singapore    +65 6775 5088
Tokyo        +81 3 5218 6500

For a complete office list visit:
science.thomsonreuters.com/contact

Copyright © 2012 Thomson Reuters