CMR OVERVIEW

_CMR International_, a Thomson Reuters business, is the world leader in global pharmaceutical R&D performance measurement. For close to 15 years, _CMR International_ has worked with the leading global pharmaceutical and biotech companies to assess R&D productivity and provide insights that are used to strengthen the planning and effectiveness of R&D.

We provide our clients with the most accurate, trustworthy performance benchmarks and industry information. 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 shorter benchmarking surveys

Our experience, independence and integrity in combination with our dedication to providing the highest quality information, insights and opinions, makes us the first port of call for the world’s leading pharmaceutical innovators.
EXECUTIVE SUMMARY

In 2009, twenty six New Molecular Entities (NME) were launched which is an increase of five from 2008. Half of these NME launches were by ‘Major’ companies.*

R&D expenditure dropped by 0.3% in 2009 which is in stark contrast to the growth rate of previous years. Pharmaceutical companies are re-investing ~15% of global sales back into ethical Research and Development (R&D).

The proportion of total sales derived from products first launched within the last 5 years has dropped to below 7%, indicating a high reliance on more established products in a company’s portfolio.

These more mature products are increasingly threatened by generic competition. With the average time from ‘First NDA approval’ for a molecule to ‘First FDA notification of a paragraph IV challenge’ between 8-10 years, the capacity to bring new and innovative products to market is paramount to the continued success of pharmaceutical companies in the future.

Success rates throughout drug development continue to show the declining trends of the past decade. Of particular concern to the industry should be the number of phase III terminations in 2007-2009 which has now doubled compared with that in 2004-2006.

* Major companies are defined as those spending >US$ 2Bn in 2009 on ethical pharmaceutical R&D.

FIGURE 1. NUMBER OF NMES FIRST LAUNCHED ONTO THE WORLD MARKET BY COMPANY SIZE.

FIGURE 2. PROPORTION OF GLOBAL SALES GENERATED FROM PRODUCTS LAUNCHED IN PREVIOUS 5 YEARS.
Based on historical data and cross industry performance, our data shows that for every 12 active substances that are entered into Preclinical research (First toxicity dose), only one can expect to reach submission. The challenge for the industry remains finding ways to improve this attrition profile in the future.

**Figure 3.** Number of projects terminated in Phase III between 2004-2009.

**Figure 4.** The number of active substances required at each stage of development to achieve one submission.
Various characteristics affect a product’s probability of success (PoS) including molecule origin, size and indication. Upon entering phase II, New Biological Entities (NBE) are more than twice as likely to be launched as New Chemical Entities (NCE) with a PoS to market of 43%.

Anti-Cancer remains the therapeutic area with both the largest proportion of R&D expenditure and first launches in 2009.

Despite a growing proportion of investment in NBE research (17.5% of total R&D expenditure) only 10.8% of sales are attributable to NBEs.

With the obvious challenges faced in developing an NME and the need to protect revenue streams, effective life cycle management strategies are critical to maintain. ‘Parallel’ and ‘Line extension’ projects now represent more than 50% of projects reaching key development milestones beyond phase II.

Competition from the generics sector is increasing in particular due to contributions from companies based in India and emerging markets. A number of generics companies, the majority of which are based in India, now have new molecule R&D pipelines further increasing the competition for existing pharmaceutical companies.