

2011 CMR INTERNATIONAL PHARMACEUTICAL R&D FACTBOOK

JUNE 2011



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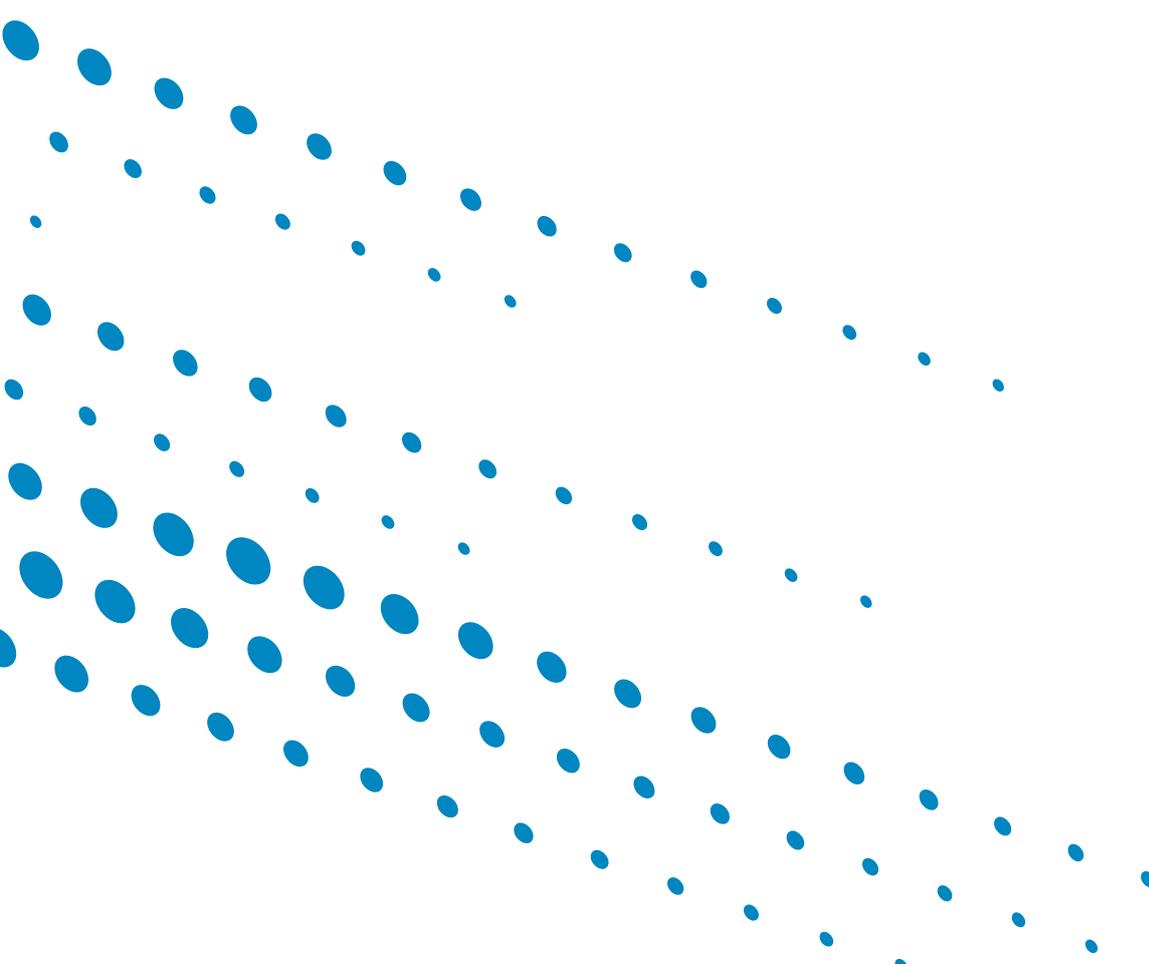
CMR OVERVIEW

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

INTRODUCTION

Key metrics identified from the 2011 CMR International Pharmaceutical R&D Factbook indicate that prescription medicine sales continue to increase while there has been a slight dip in R&D expenditure. However, development time continues to increase, with a decrease in the number of compounds entering each stage of development with high late stage attrition rates.

	INCREASING	DECLINING	
	Sales	R&D expenditure	
	Development time	Phase starts	
	Phase III terminations	Success rates	
		Launches	

PIPELINE ACTIVITY AND SALES

In 2010 the total number of New Molecular Entities (NME) launched onto the global market returned to the previous level of 21, a decrease from the 26 launched in 2009. Only one third of these NME launches were by 'Major' companies (Figure 1.)*

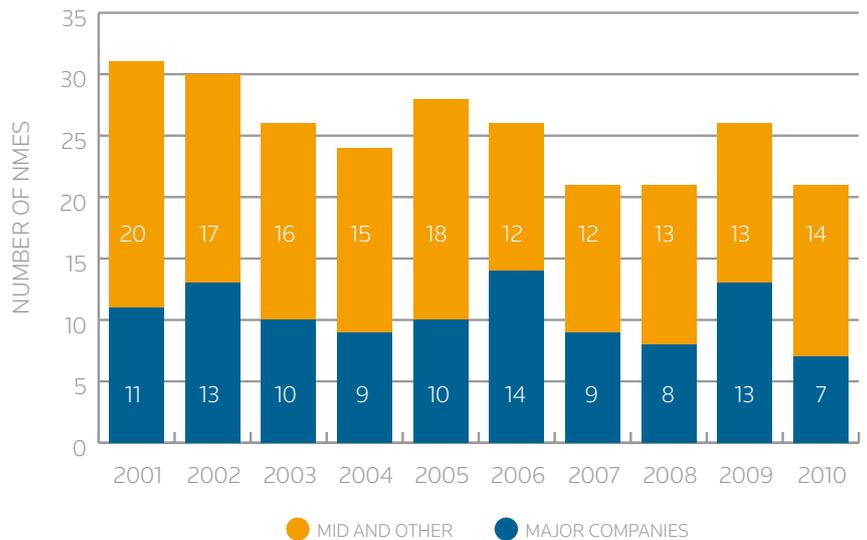


FIGURE 1. NUMBER OF NMEs FIRST LAUNCHED ONTO THE WORLD MARKET BY COMPANY SIZE

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

R&D expenditure continued to drop in 2010 to an estimated three year low of \$68 billion, in stark contrast to the growth rate up to 2008. Sales continue to rise, reaching an all time high of \$856 billion and pharmaceutical companies are re-investing up to 22% of global sales back into ethical Research and Development (R&D).

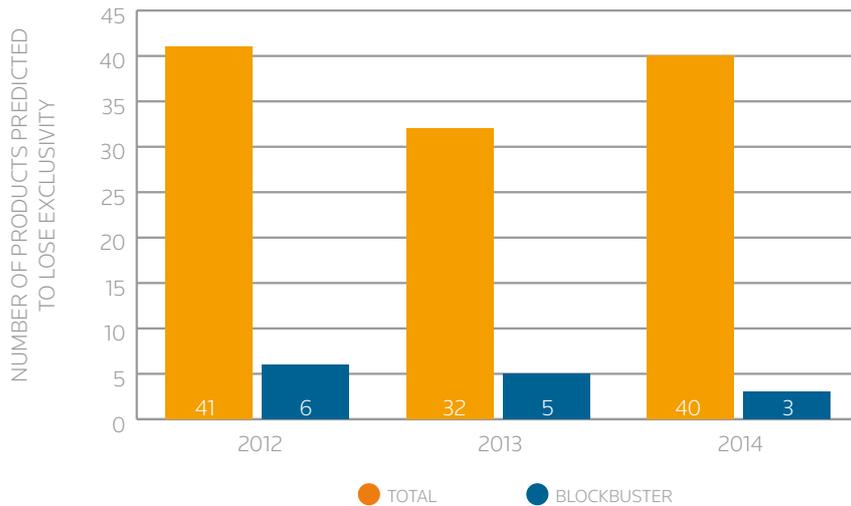
Of these sales, only 5% are driven by products first launched within the last 5 years – indicating the industry, especially Major pharmaceutical companies, still has a high reliance on more established products (Figure 2.)

PRODUCTS LAUNCHED IN PREVIOUS 5 YEARS	
	% OF GLOBAL SALES
ALL COMPANIES	5.3
MAJOR	4.1
MID AND OTHER	9.1

FIGURE 2. PROPORTION OF GLOBAL SALES GENERATED FROM PRODUCTS LAUNCHED IN PREVIOUS 5 YEARS

The combination of this reliance and the fact that over the next three years (2012-2014) more than 110 products will lose patent exclusivity in the US, including 14 "Blockbusters", will introduce considerable risk to the revenue streams of innovative R&D companies. (Figure 3)

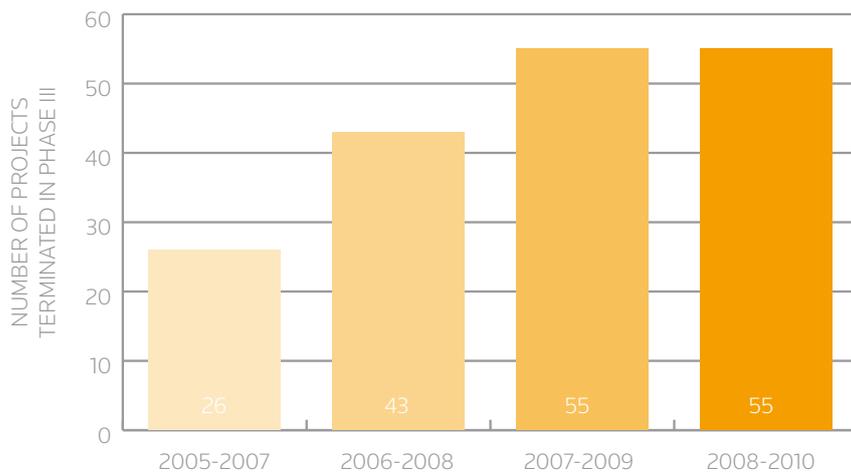
FIGURE 3. NUMBER OF PRODUCTS PREDICTED TO LOSE PATENT EXCLUSIVITY 2012-2014



ATTRITION

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 and 2008-2010 which appears to be stabilizing at more than double the number of terminations witnessed in 2005-2007 (Figure 4.)

FIGURE 4. NUMBER OF PROJECTS TERMINATED IN PHASE III 2005-2010



This picture is particularly alarming given the fact that over the past three years there has also been a steep decline in the number of active substances entering Phase III – 2010 saw a 55% decline in the number of compounds entering pivotal trials compared to 2007. This issue is not confined to Phase III however, as CMR International reports a 47% and 53% decline in phase I and phase II starts respectively.

According to the CMR international Global R&D Programme various characteristics affect a product's probability of success (PoS) including molecule origin, size and indication. For example, self originated molecules have 20% greater chance of reaching the market from both Phase III and Submission when compared to licensed in/ acquired compounds.

ONCOLOGY

Despite the overall decrease in the number of new compounds entering each stage of development, Anti-Cancer is one of only two therapeutic areas to see positive growth in the number of projects being developed for launch compared to 2008 pipeline volumes. Anti-cancer development continues to attract the highest proportion of investment across the industry, with in excess of 25% of total R&D expenditure (Figure 5) and also contributed to over one third of all NME launches in 2010. Since 2008, 19% of all new drug targets identified have been within Anti-Cancer (Figure 6).

TOTAL R&D EXPENDITURE IN 2010 BY THERAPEUTIC AREA

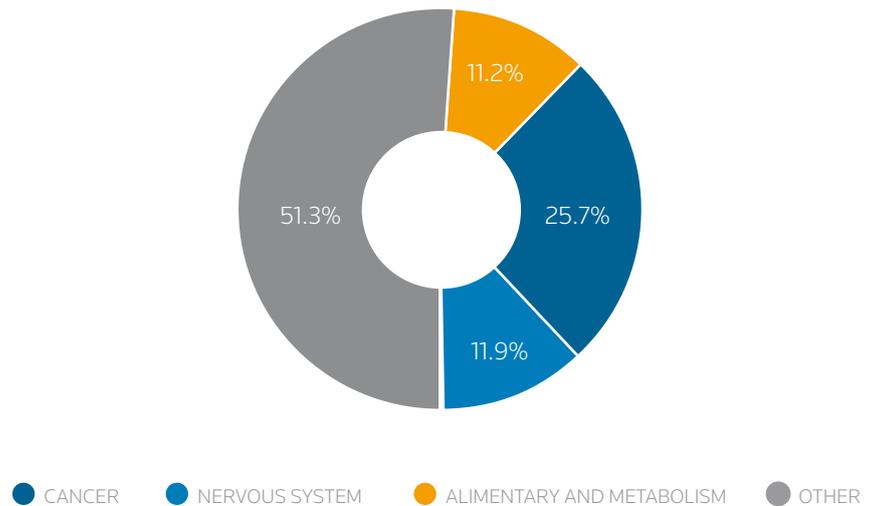


FIGURE 5. TOTAL R&D EXPENDITURE BY THERAPY AREA

The proportion of total R&D expenditure by therapeutic area presented in this figure is based on data from 14 companies (6 Major, 8 Mid and Other)

Total R&D expenditure represented = US\$31.70bn

THERAPY AREA FOCUS OF THE MOST POPULAR EMERGING TARGETS SINCE 2008

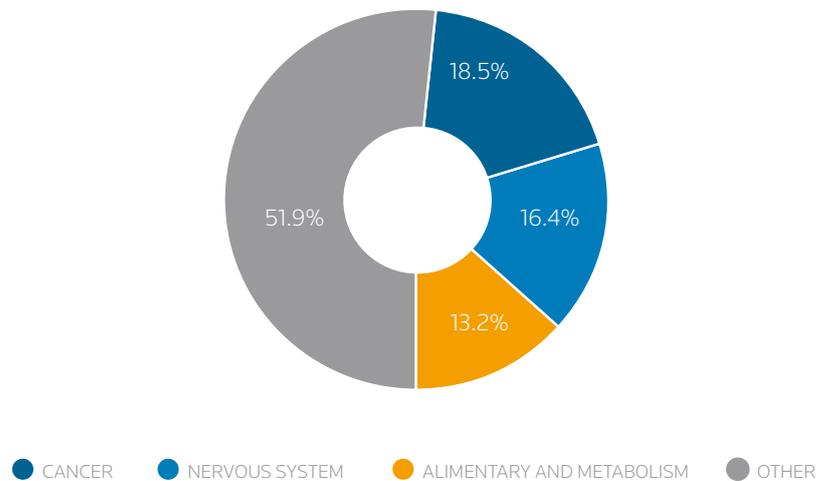


FIGURE 6. THERAPY AREA FOCUS OF EMERGING TARGETS

Other = Dermatological, Blood disorder, Anti-infective and Sensory organs

PATIENT RECRUITMENT

Each phase of development has seen an increase in the time taken to complete patient recruitment when compared to 2005. However, phases II and III have experienced the most dramatic increases of 29% and 20%, respectively. Such changes are likely to be a contributing factor in the shift of patient recruitment away from North America towards SE Asia and West Pacific (Figure 7).

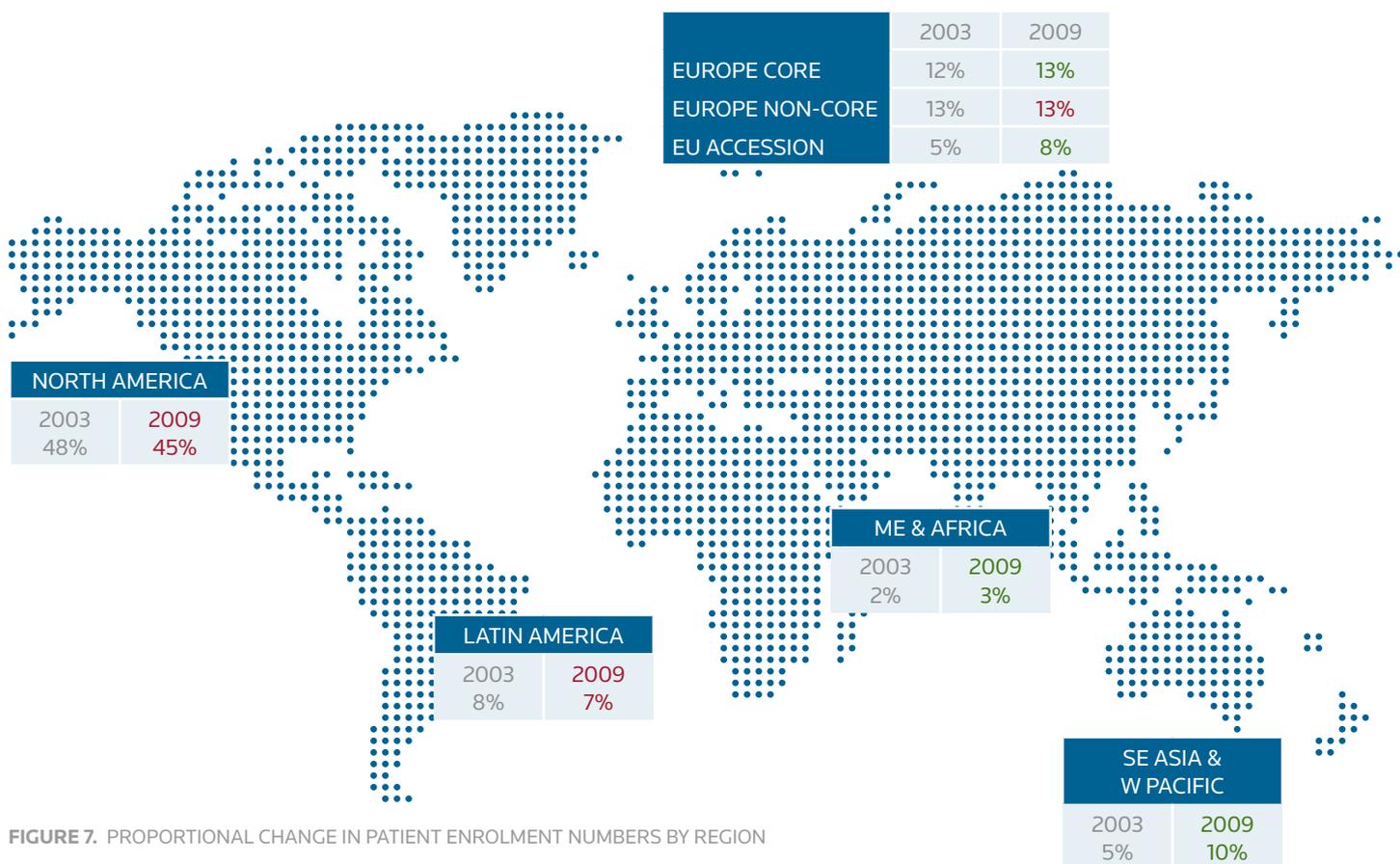


FIGURE 7. PROPORTIONAL CHANGE IN PATIENT ENROLMENT NUMBERS BY REGION

The 2011 CMR International Pharmaceutical R&D Factbook is based on data provided directly from pharmaceutical companies and Thomson Reuters supporting data sets. For further information or to order your copy please e-mail info@cmr.thomsonreuters.com.

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