



IMAGE COPYRIGHT: DREAMSTIME

THE CMR INTERNATIONAL 2009 PHARMACEUTICAL R&D FACTBOOK



THE *CMR INTERNATIONAL 2009 PHARMACEUTICAL R&D FACTBOOK* IS AVAILABLE IN A PAPER OR AN ELECTRONIC FORMAT.

TO ORDER YOUR COPY OF THE *CMR INTERNATIONAL 2009 PHARMACEUTICAL R&D FACTBOOK*, PLEASE VISIT cmr.thomsonreuters.com/shop

The *CMR International 2009 Pharmaceutical R&D Factbook* is the definitive up-to-date business-planning tool for decision-makers in R&D, corporate finance, business strategy, marketing planning and corporate communications.

This essential reference work can help you to:

- gain an in-depth understanding of industry dynamics and trends
- determine how your organization performs against the market as a whole
- gauge your productivity relative to your competitors
- recognize the key differences between individual therapeutic areas
- appreciate the consequences of adopting different R&D strategies
- set internal performance targets that will motivate and challenge your businesses

Each finding is presented in a clear, easily-understood chart, accompanied by a succinct commentary highlighting the key message, and an explanation of the methodology used and the definitions applied.

The following pages outline the complete **LIST OF FIGURES**.

cmr.thomsonreuters.com



LIST OF FIGURES

CHAPTER 1. OVERVIEW

- 1.1 Summary of R&D Statistics for 2008
- 1.2 Global R&D expenditure, development times, global pharmaceutical sales and new molecular entity output 1998-2008
- 1.3 Global pharmaceutical R&D expenditure 1998-2012
- 1.4 Global pharmaceutical sales 1998-2012
- 1.5 Total R&D expenditure : sales ratio in 2008 by company size (max/median/min)
- 1.6 Number of new molecular entities and new active substances first launched onto the world market 1998- 2008
- 1.7 Number of new molecular entities first launched onto the world market 2004-2008 by company size
- 1.8 Breakdown of total sales in 2008 by top 3 products and products launched in the previous 5 years

CHAPTER 2. R&D RESOURCES

- 2.1 Proportion of total R&D expenditure in 2008 by function
- 2.2 Proportion of total R&D FTEs in 2008 by function
- 2.3 Proportion of total R&D expenditure on alliances or joint ventures by stage of R&D in 2008
- 2.4 Number of drug commercialisation / licensing deals between 2004-2008
- 2.5 Total R&D expenditure in 2008 by each stage of R&D
- 2.6 Proportion of total FTEs in 2008 allocated to each stage of R&D
- 2.7 Allocation of R&D expenditure between new development and line extension projects in 2007 and 2008

CHAPTER 3. R&D PIPELINE VOLUME

- 3.1 Summary of R&D pipeline volume statistics for 2008
- 3.2 Trend in mean number of active substances developed for first launch between 2004-2008
- 3.3 Indexed trend in number of active substances entering each phase of development 2004-2008

- 3.4 Number of projects achieving key milestones between 2004-2008 by project type
- 3.5 Number of lead, parallel and line extension projects entering each phase of development between 2004-2008
- 3.6 Change in the number of lead projects in each development phase between 2004 and 2008 by active substance origin
- 3.7 Number of projects terminated in phase III between 2003-2008

CHAPTER 4. SUCCESS RATES

- 4.1 Probability of success to market for active substances
- 4.2 Probability of success to market from key milestones: Changes over time
- 4.3 Probability of success to market for origin
- 4.4 Predicted number of active substances required at each stage to achieve one marketed active substance

CHAPTER 5. CYCLE TIMES

- 5.1 R&D key milestones
- 5.2 Development time for new molecular entities first launched onto the world market 1998-2008
- 5.3 Trend in actual clinical development time for lead projects submitted 1999-2007
- 5.4 Composite median interval duration for lead projects 2003-2007
- 5.5 Indexed trend in median interval durations for lead projects between 1999-2007

CHAPTER 6. REGIONAL COMPARISONS

- 6.1 Regional distribution of total R&D expenditure in 2008
- 6.2 Region of first launch for new molecular entities 2004-2008
- 6.3 Proportional change of enrolled patients in each geographical region between 2001 and 2007
- 6.4 Median approval times for new active substances approved for six major regulatory agencies between 1998-2008
- 6.5 Regulatory approval times from date of submission to approval for new active substances approved between 2004-2006

- 6.6 Time between first world approval and submission in emerging market countries for new active substances approved between 2004-2006
- 6.7 Number of expedited and standard new active substance approvals, 1997-2002 compared with 2003-2008
- 6.8 Median time in roll out to emerging market countries for new active substances approved between 2004-2006

CHAPTER 7. THERAPEUTIC AREA FOCUS

- 7.1 Total R&D expenditure in 2008 by therapeutic area
- 7.2 Proportion of first new molecular entity launches in 2008 by therapeutic area
- 7.3 Change in number of lead projects in development for first launch between 2006 - 2008 by therapeutic area
- 7.4 Therapeutic area diversification between 2006-2008 by company size
- 7.5 Probability of success to market by therapeutic area (1) CMR success rates methodology
- 7.6 Probability of success to market by therapeutic area (2) CMR success rates methodology
- 7.7 Composite median interval durations for lead and parallel projects between 2003-2007 by therapeutic area
- 7.8 Median approval times for new active substances between 2003-2008 by therapeutic area

CHAPTER 8. BIOPHARMACEUTICAL FOCUS

- 8.1 Proportion of R&D expenditure in 2007 and 2008 by active substance type
- 8.2 Proportion of ethical pharmaceutical sales in 2008 by active substance type
- 8.3 Number of first NME launches between 1997-2008 by active substance type
- 8.4 Proportion of NBE active substances in development between 2004-2008 by company size
- 8.5 Proportion of licensed-in or acquired active substances in development in 2004 and 2008 by active substance type
- 8.6 Probability of success to market by active substance type

- 8.7 Composite median interval durations for lead projects between 2003-2007 by active substance type

CHAPTER 9. CLINICAL FUNCTION

- 9.1 Median total study duration in 2007
- 9.2 Clinical study median interval durations by study phase in 2007
- 9.3 Comparisons of the change in clinical study median interval durations between 2003 and 2007 by study phase

CHAPTER 10. PATENTS

- 10.1 Number of pharmaceutical patent applications and granted patents for 5 major patent issuing authorities 1998-2008
- 10.2 Total and new compound WO, EP or US patent document filings 2000-2008
- 10.3 Most popular targets by number of 'new entrants' since 2006 for the industry
- 10.4 Most popular targets by number of 'new entrants' since 2006 for the 30 most innovative companies
- 10.5 Therapy area focus of the most popular emerging targets since 2006

CHAPTER 11. GLOBAL GENERICS MARKET

- 11.1 Number of ANDA final approvals in each year between 2006-2008 by county of origin
- 11.2 Number of ANDA approvals for Indian generic companies between 1999-2008
- 11.3 Exposure of products to paragraph IV challenges in USA between 2005-2008
- 11.4 Total paragraph IV challenges by country (count of single filing per group)
- 11.5 Number of products predicted to lose exclusivity in USA between 2009-2013
- 11.6 Current experience of generic API manufacturers with regard to supplying the regulated markets
- 11.7 Number of European certificates of suitability (COS) granted between 1999-2008 by location of company headquarters
- 11.8 Number of US DMF granted each year between 1999-2008 by location of company headquarters

- 11.9 Number of Japanese DMF Filings in each year between 2005-2008 by location of company headquarters
- 11.1 API Plants inspected by FDA in each year between 2001-2008 by location of company headquarters
- 11.11 Average time from first NDA approval to first FDA notification of paragraph IV challenge 2002-2008
- 11.12 Number and value of mergers and acquisitions by generic companies between 2004-2008
- 11.13 Number of new molecules in development by companies with a primary focus in generic products between 2004-2008
- 11.14 Number and value of pipeline deals by generic companies to support R&D capabilities for new molecules between 2004-2008
- 11.11 Average time from first NDA approval to first FDA notification of Paragraph IV challenge 1985-2007

Scientific Regional Head Offices

Americas

Philadelphia +1 800 336 4474
+1 215 386 0100

Europe, Middle East and Africa

London +44 20 7433 4000

Asia Pacific

Singapore +65 6411 6888
Tokyo +81 3 5218 6500

For a complete listing of Scientific offices, visit:
scientific.thomsonreuters.com/contact

