



Launch control

Realistic values are needed to predict product success

Leaders in the pharma sector are well aware that tough investment decisions have to be made, but also recognise the foundations for these decisions must be solid. Investments are usually supported by sophisticated sales forecast models using well defined and rigorously challenged assumptions about the potential market.

The impact of the probability of launch (PoL) on achieving the sales forecast is crucial because it is the single most important factor in the calculation of the risk-adjusted net present value (rNPV). The rNPV is a critical component when comparing products to make strategic portfolio decisions, yet companies commonly use template 'default' values for PoL based on overall industry experience.

Our investigation defined the top 10 pharma

companies by market capitalisation as at April 10, 2009 and used the MedTrack biomedical corporate intelligence database (www.MedTrack.com) to identify all drugs in phase III industry-sponsored studies that were initiated or already ongoing between January 1, 1999 and April 10, 2009.

Fixed-drug combinations, such as Avandia and Avandamet, were treated as separate products. We noted products launched in the US or the EU top five markets and products not approved, pending approval, or still in phase III development.

Life cycle management is vital for maximising the value of a brand, so we also tracked outcomes of phase III trials for new additional indications in the same way over the same time period. In this second analysis, drugs can appear in more than one category,

Table 1. Product phase III success rates

Company	NUMBER OF PRODUCTS				Success rate*
	Launched	Failed	Pending approval	Still in phase III	
Roche	11	2	1	6	85%
Pfizer	8	11	2	8	42%
Novartis	14	13	6	18	52%
GlaxoSmithKline	19	12	6	17	61%
Sanofi-aventis	6	9	2	30	40%
Wyeth	9	1	1	6	90%
Merck	11	5	3	6	69%
Amgen	5	3	1	2	63%
AstraZeneca	3	7	3	15	30%
Bristol-Myers Squibb	9	4	1	9	69%
AVERAGE	10	7	3	12	59%

*success rate = launched/launched + failed

Table 2. New indication phase III success rates

Company	NUMBER OF PRODUCTS				Success rate*
	Launched	Failed	Pending approval	Still in phase III	
Roche	20	3	3	25	87%
Pfizer	7	15	6	21	32%
Novartis	22	22	6	32	50%
GlaxoSmithKline	27	22	8	31	55%
Sanofi-aventis	12	17	2	41	41%
Wyeth	10	3	3	16	77%
Merck	14	6	4	15	70%
Amgen	7	3	2	11	70%
AstraZeneca	13	13	6	21	50%
Bristol-Myers Squibb	12	9	1	18	57%
AVERAGE	14	11	4	23	56%

*Success rate = launched/launched + failed

perhaps where they were launched for one indication but failed to get approval for another.

This analysis showed an average phase III product launch success rate of 59 per cent, consistent with previous studies, but also highlighted a very large range (30-90 per cent) in success rates across companies (Table 1).

Once a product is approved for a first indication, the common view is that there is a higher probability of success in additional indications. However, as shown in Table 2, the success rates of trials to obtain additional new indications for products also ranged from 32-87 per cent, with an average of 56 per cent (Table 2).

A further analysis of phase III outcomes revealed an overall PoL of 74 per cent for biologics compared with only 54 per cent for small-molecule drugs. This confirms the widely held belief that biologics, with their highly targeted modes of action, have a higher chance of success than small molecules. Comparison of the product and indication success rates with the percentage mix of biologics and novel modes of action (MOA) at each company does not suggest, however, a simple and direct relationship with PoL (Table 3).

Other factors that may impact on PoL include:

- Company experience in a disease area
- A proven regulatory pathway with established end points or surrogates
- First-in-class versus follow-on candidate
- First versus supplementary indications.

Other tools, such as sensitivity analysis, could be applied to test the impact of different ideas and increase confidence around rNPVs. Senior managers with cross-portfolio responsibility should challenge the product team to ensure

that relative values for PoL between different brands are reasonable. This should lead to more realistic values being used to calculate rNPVs.

Defining consistent criteria for PoL assumptions and applying these across brands, could improve the ability to compare business options accurately and support better business investment decisions.

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Table 3. Top 10 pharma: phase III portfolio mix

Company	PHASE III PRODUCTS (%)	
	Biologic	Novel MOA
Roche	54	38
Pfizer	9	54
Novartis	20	22
GlaxoSmithKline	28	20
Sanofi-aventis	40	23
Wyeth	25	25
Merck	21	17
Amgen	75	67
AstraZeneca	11	40
Bristol-Myers Squibb	23	50