

Pricing and Market Access Outlook

2017 Edition



We are pleased to introduce the 2017 Pricing and Market Access Outlook. As we move forward with a new identity as QuintilesIMS, so too does our Outlook. Rather than waiting once a year to bring you our thoughts about evolutions in the industry, we will be having an ongoing dialogue about trends throughout the year. As part of this approach, you will notice a more streamlined Outlook focused specifically on our annual launch pricing and time to market access trends. Many of you have shared with us that this is a section you value and regularly reference in your day-to-day work. We look forward to continuing our conversation over the coming year.

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The facts versus fiction of 2015 product launches: Analysis of price premiums and time to market

Policymakers and payers across global markets continue to debate pharmaceutical drug pricing following recent public cases relating to high-cost drug launches and price increases for marketed therapies. In Europe, action has already been taken to restrict the pricing for new drugs and we expect this to continue in the near future. However, in the United States (US), the fragmented nature of the market and recent political events are expected to limit possibilities for government intervention.

The European Commission has already voiced its concern about the unsustainable cost of new drugs across European Union (EU) member countries and the potential impact on patient access to life-saving medicines. Indeed, the Commission has signaled its intention to champion price controls and has started to explore potential solutions, including price regulation, price transparency, strengthened market exclusivity rules, and enhanced cross-market collaboration. We expect details on the path towards realizing some of these proposals to be revealed in 2017.

At the individual EU market levels, policy changes have been enacted to reduce the impact of novel high-cost drugs. Germany implemented a sales cap of €250 million for the reimbursement of newly launched drugs in their first year on the market before completing price negotiations.

Meanwhile in the US, public attention has been captured by headlines of significant price increases for a number of marketed drugs and the increasing patient out-of-pocket burden across a host of therapeutic areas. The resulting scrutiny is putting pressure on pharmacy-benefit managers (PBMs) and managed care organizations (MCOs) to be more restrictive and on manufacturers to offer concessions. However, a path beyond private market forces is less clear given the recent election results.

In order to better understand payer concern, QuintilesIMS analyzed new molecular entities (NMEs) approved by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) in 2015. The analysis focused on NME public pricing strategies that pharmaceutical companies adopted at launch versus the nearest comparator or standard of care (SoC) and the time NMEs took from regulatory approval to first sales.

It is important, however, to recognize that the price premium analysis is only a partial view of payers' perspective on drug prices. It does not reflect the complete picture of NME prices that impact healthcare budgets, partly owing to the following reasons:

- The analysis only looks at public prices without considering confidential discounts or rebates applied during price negotiations
- The analysis did not account for the incremental clinical or economic value that NMEs may bring relative to the nearest comparator or SoC
- Some NMEs may target different or more niche patient populations compared with the SoC or the nearest comparator

THE EVOLUTION OF LAUNCH PRICES AND PAYER CONCERNS

One of the drivers of payer concerns is that the number of products approved by the EMA and FDA has increased to more than 40 NMEs per year in 2015 compared with just over 12 NMEs in 2012 (see Figure 1). Indeed, initial analysis of 2016 approvals suggests that NMEs have continued to increase at similar rates, putting an unrelenting squeeze on already constrained healthcare budgets.

This is further impacted by the shift from primary care to specialty products. Not only have specialty medicines been the greatest drivers of drug expenditure over the past few years – tending, as they do, to come attached with a hefty price tag – they also represent the largest category of new approvals in 2015, accounting for up to 78% of all NMEs in Europe and 51% of NMEs in the US.

Payer concerns about the increasing number of orphan drugs also appear to be partly justified as the number of orphan medicines approved by the EMA has jumped more than 18% since 2010, with 12 EMA approved and 17 FDA approved orphan NMEs in 2015 – undoubtedly a consequence of the research incentives put in place to increase focus on patient and treatment need in the field of rare and ultra-rare diseases. As a result of this research and commercial shift, we forecast that – in the EU – approximately 120 new orphan drugs will receive market authorization by 2025, with an estimated budget impact of ~€22 billion.

Although payers recognize the benefit these new developments will bring to patients who are currently underserved, there are clear and substantial concerns about how already stretched budgets will be able to afford the expected growth.

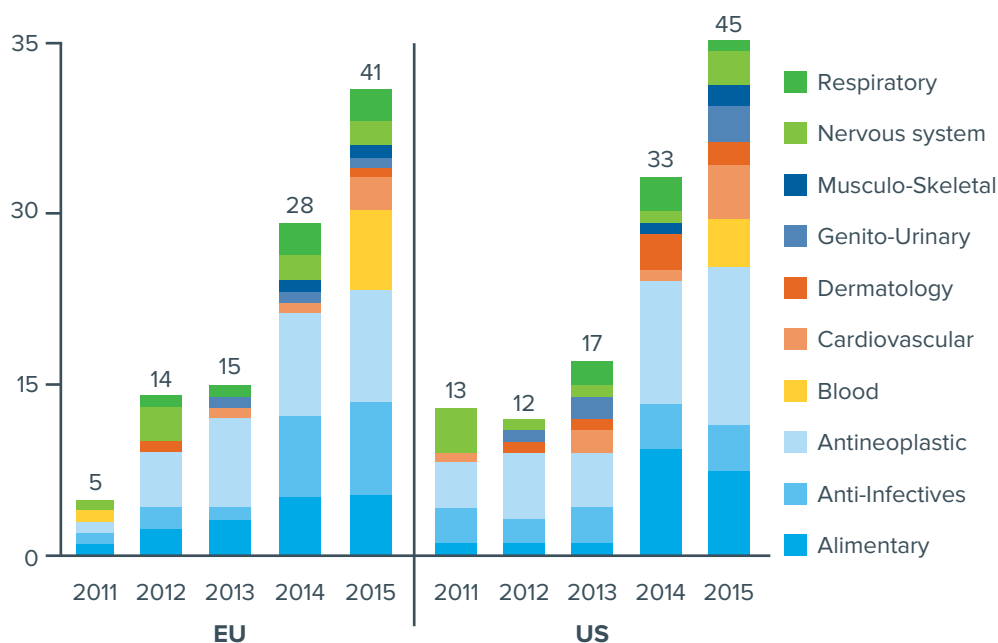


The number of products approved by the EMA and FDA has increased to more than **40 NMEs** per year in 2015



In the EU, approximately **120** new orphan drugs will receive market authorization by 2025, with an estimated budget impact of **~€22 billion**

Figure 1. Number of NME approvals in the EU and US (2011–2015)



Source: QuintilesIMS Consulting Services analysis

2015 LAUNCH PRICE PREMIUMS IN THE EU: “PREMIUM” IS IN THE EYE OF THE COMPARATOR

Although publicity around prices of specific NMEs has helped fuel the perception of high premiums for pharmaceuticals across EU markets, when we compared 2015 publicly available NME prices to their nearest clinical comparators, some 60% of the medicines analyzed were indeed priced at a premium – with the majority adopting a premium of more than 36% (see Figure 2).

- Perhaps surprisingly, premiums for orphan drugs were generally in line with other innovative therapies – except for a few outliers – and the average cost of orphan drug therapies has not increased over the past few years
- However, closer analysis does suggest that NMEs with very high premiums tend to be highly innovative medicines in therapy areas where low-priced generics represent either the current SoC or clinical comparator, as in the case of heart failure drugs and anticoagulants
- In contrast, where an NME’s closest clinical comparator is also a newly launched innovator medicine, as has been seen in the fields of hepatitis C and cystic fibrosis, the product followed a discount pricing strategy at the public price level (see Table 1)
- With budget holders and payers across the EU evaluating the cost of an NME against the publicly available price of existing therapies for that condition, it becomes clear why NMEs launching in therapy areas where generic therapies are the SoC or clinical comparator are of major concern to payers

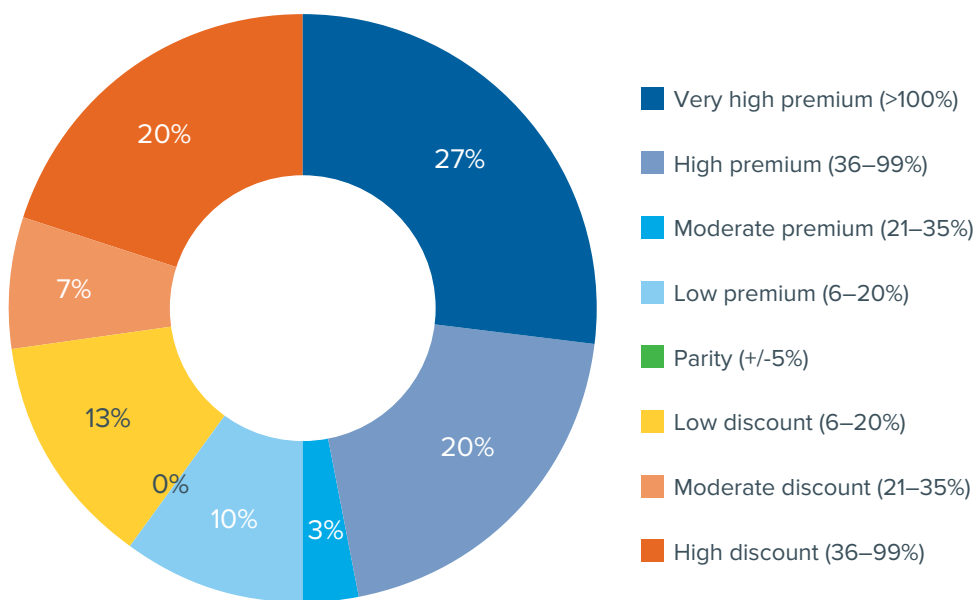


60% of the medicines analyzed adopted a premium of more than **36%**

- What is not clear – and what is not taken into account – is the real impact or significance of these premiums for the healthcare system given the lack of transparency of, or access to, negotiated confidential discounts between industry and payers. In many cases, these agreements can reduce public prices by up to 50% in some EU markets

However, given payers’ and budget holders’ clear need for predictability of funding requirements, it comes as little surprise that this is likely to raise a flag of concern over affordability. In this respect, greater transparency of the discounts applied as a consequence of the confidential negotiations between industry and payers would deliver a more accurate picture of the value of innovative medicines and actual cost to individual healthcare systems.

Figure 2. Comparative launch prices of EMA approved NMEs (2015)*



Source: QuintilesIMS Consulting Services analysis

*Only products with list prices published by November 2016 were considered for this analysis

TABLE 1: NME LAUNCHES IN THE EU, 2015

Brand Name (Molecule Name) Manufacturer	Indication	Orphan	Nearest Comparator	Percentage Premium or Discount								
				FR	DE	DK	ES	IT	NL	SE	UK	
AKYNZEO (netupitant/ palonosetron) Helsinn Birex Pharmaceuticals Ltd	Prevention of acute and delayed nausea and vomiting	N	ALOXI (palonosetron)		98%	50%		39%				23%
CERDELGA (eliglustat) Genzyme Europe BV	Gaucher disease type 1	Y	CEREZYME (imiglucerase)		619%	430%						
COSENTYX (secukinumab) Novartis Pharmaceuticals Corporation	Psoriasis	N	STELARA (ustekinumab)	21%	13%	-12%	18%	N/A	2%	2%		70%
COTELLIC (cobimetinib) Genentech, Inc	Advanced melanoma	N	TAFINLAR (dabrafenib)		-12%	-16%						-41%
CRESEMBA (isavuconazonium sulfate) Astellas Pharma Inc	Invasive aspergillosis Invasive mucormycosis	Y	NOXAFIL (posaconazole)		99%			97%				110%
ELOCTA (efmoroctocog alfa) Biogen Idec Ltd	Treatment of Haemophilia A	N	NUVIQ (human coagulation factor VIII)		-88%	-43%				-24%	-17%	
ENTRESTO (sacubitril; valsartan) Novartis Pharmaceuticals Corporation	Heart failure	N	VALSARTAN (valsartan)		754%	1792%		2169%	1079%	1324%		474%
EXVIERA (dasabuvir) AbbVie Ltd	Hepatitis C virus (HCV)	N	DAKLINZA (daclatasvir)	-87%	-82%	-88%	-89%	-89%	-88%	-89%		-89%
FARYDAK (panobinostat) Novartis Pharmaceuticals Corporation	Multiple myeloma	Y	REVLIMID (lenalidomide)		-8%	-34%				-18%		7%
GENVOYA (elvitegravir, cobicistat, emtricitabine, and tenofovir) Gilead Sciences, Inc	HIV-1 infection	N	SUSTIVA (efavirenz)	662%	261%	576%				720%		339%
KANUMA (sebelipase alfa) Alexion Pharmaceuticals, Inc	Lysosomal acid lipase (LAL) deficiency	Y	CRESTOR (rosuvastatin)		172995%	177314%						192637%
KENGREXAL (cangrelor) The Medicines Company	Blood clots in the coronary arteries	N	BRILINTA (ticagrelor)			-60%				-60%		-65%
KEYTRUDA (pembrolizumab) Merck Sharp & Dohme Limited	Advanced melanoma	N	OPDIVO (nivolumab)		25%	61%	25%			28%		20%
KYPROLIS (carfilzomib) Amgen Europe B.V.	Multiple myeloma	Y	REVLIMID (lenalidomide)		25%	30%				46%		45%
LENVIMA (lenvatinib) Eisai Inc	Progressive, differentiated thyroid cancer (DTC)	Y	NEXAVAR (sorafenib)		53%	55%					40%	35%

*Only products with list price published by November 2016 were considered for this analysis

TABLE 1: NME LAUNCHES IN THE EU, 2015 continued

Brand Name (Molecule Name) Manufacturer	Indication	Orphan	Nearest Comparator	Percentage Premium or Discount							
				FR	DE	DK	ES	IT	NL	SE	UK
LIXIANA (edoxaban) Daiichi Sankyo	Stroke	N	XARELTO (rivaroxaban)		30%	38%			38%	45%	43%
OBIZUR (susoctocog alfa) Shire plc	Haemophilia caused by antibodies to Factor VIII	N	NOVOSEVEN (coagulation Factor VIIa, [recombinant])								-55%
OFEV (nintedanib) Boehringer Ingelheim International GmbH	Idiopathic pulmonary fibrosis (IPF)	Y	ESBRIET (pirfenidone)	0%	12%	-8%	-38%	0%	0%	-10%	0%
OPDIVO (nivolumab) Bristol-Myers Squibb Company	Unresectable or metastatic melanoma	N	YERVOY (ipilimumab)		16%	-32%		-14%	-15%		-24%
ORKAMBI (lumacaftor; ivacaftor) Vertex	Cystic fibrosis	N	KALYDECO (ivacaftor)		-64%	-69%			-64%		-64%
OTEZLA (apremilast) Celgene Europe Limited	Psoriatic arthritis (PsA)	N	STELARA (ustekinumab)		-19%	-34%	-15%		-24%	-27%	-23%
PRALUENT (alirocumab) Sanofi Aventis	High cholesterol	N	EZETROL (ezetimibe)		1251%	1278%			1077%		1174%
PRAXBIND (idarucizumab) Boehringer Ingelheim Pharmaceuticals, Inc	Reverse blood- thinning effects	N	FEIBA (anti-inhibitor coagulant complex)						235%		-12%
REPATHA (evolocumab) Amgen Inc	High cholesterol	N	PRALUENT (alirocumab)		38%	39%			56%		40%
SIVEXTRO (tedizolid phosphate) Cubist Pharmaceuticals (UK) LTD	Acute bacterial skin and skin structure infections (ABSSSI)	N	ZYVOX (linezolid)			-33%			-2%	-8%	-3%
VIKIRAX (ombitasvir/ paritaprevir/ritonavir) AbbVie Ltd	Hepatitis C	N	HARVONI (ledipasvir/ sofosbuvir)	-57%	-58%	-70%	-59%	-61%	-61%	-60%	-59%
XADAGO (safinamide) Zambon SpA	Parkinson's disease	N	AZILECT (rasagiline)		44%	-6%		-10%	37%	-13%	
ZERBAXA (ceftolozane/ tazobactam) Merck Sharp & Dohme Limited	Intra-abdominal infections	N	TYGACIL (tigecycline)			-12%			55%		98%
ZYKADIA (ceritinib) Novartis Europharm Ltd	(ALK)-positive metastatic non- small cell lung cancer (NSCLC)	N	XALKORI (crizotinib)		49%	-19%			8%	15%	5%

*Only products with list price published by November 2016 were considered for this analysis

2015 LAUNCH PRICE PREMIUMS IN THE US: NOT THE MAIN EVENT

In stark contrast to Europe, the public debate in the US has been dominated by perceived price hikes for existing drugs rather than launch premiums for NMEs. Despite this, however, a familiar pattern has emerged in our analysis of FDA-approved NMEs, with 56% of NMEs priced at a premium relative to their nearest comparator and almost 31% adopting a premium of 100% or greater (see Figure 3).

Interestingly – and in contrast to Europe – this premium pricing strategy was adopted for both specialty and primary care products, primarily where the NME brought innovation to therapy areas traditionally dominated by generics, e.g., heart failure.

However, in a similar trend to that observed in Europe, NMEs where the closest clinical comparator is a recently launched innovative product were more likely to be priced at parity or discount, e.g., targeted oncologic therapies (see Table 2).

Outside of high price increases that have made the headlines in recent months, the average price growth for protected marketed brands was 12.4% in 2015 across all therapy areas. Therefore, with some clear exceptions, the price increases for existing medicines falls in line with the average witnessed over the past 5 years.

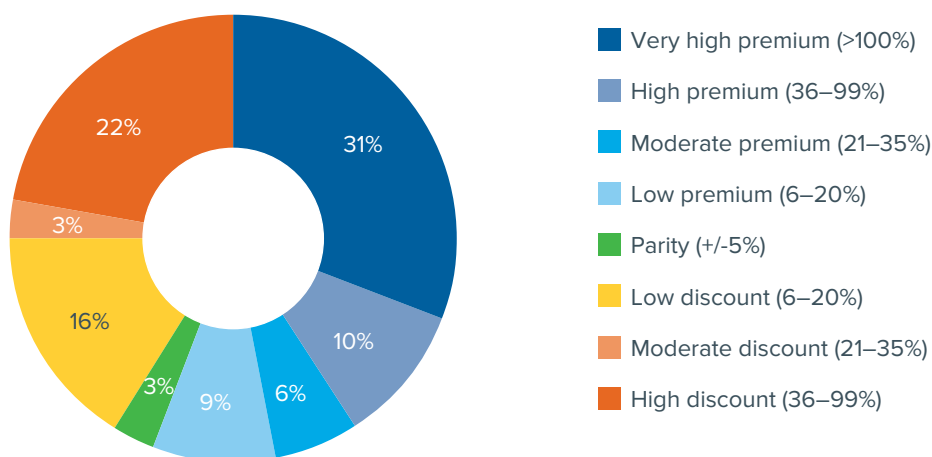
On the other hand, the growth in average net prices slowed to 2.8% in 2015 from 9.5% over the past 5 years, which can be attributed to greater price concessions offered by manufacturers.

It is this slowing net price growth combined with increasing price transparency and higher patient out-of-pocket burden in the US that is likely to result in greater manufacturer price concessions at the public price level.

Indeed, two companies – Novo Nordisk and Allergan – have already unveiled their commitment to limiting annual price increases to single digits. In an unfolding environment that will bear witness to greater private market pressures and increased restrictions, there is growing interest in value framework assessments that will continue to shift discussions around value of drugs for both payers and providers, especially in specialty therapy areas.

However, we expect that US companies will continue to find creative ways to address net pricing pressure – through both payer and provider negotiations and innovative direct to consumer models.

Figure 3. Comparative launch price of FDA approved NMEs (2015)



Source: QuintilesIMS Consulting Services analysis

TABLE 2: NME LAUNCHES IN THE US, 2015

Brand Name (Molecule Name) Manufacturer	Indication	Orphan	Comparator	US Percentage Premium or Discount
ARISTADA (aripiprazole) Alkermes, Inc	Schizophrenia	N	ABILIFY (aripiprazole)	-12%
AVYCAZ (avibactam; ceftazidime) Allergan, Inc	cIAI and cUTI	N	ZERBAXA (ceftolozane/ tazobactam)	392%
BRIDION (sugammadex) Merck & Co., Inc	Reversal of neuromuscular blockade	N	BLOXIVERZ (neostigmine)	-71%
CORLANOR (ivabradine) Amgen Inc	Bile acid synthesis due to single enzyme defects and adjunctive treatment of peroxisomal disorders	N	VASOTEC (enalapril)	585%
COSENTYX (secukinumab) Novartis Pharmaceuticals Corporation	Plaque psoriasis, psoriatic arthritis, ankylosing spondylitis	N	STELARA (ustekinumab)	26%
COTELLIC (cobimetinib) Genentech, Inc	Unresectable or metastatic melanoma with BRAF V600E or V600K+	N	TAFINLAR (dabrafenib)	-36%
CRESEMBA (isavuconazonium) Astellas Pharma Inc	Zygomycosis and invasive aspergillosis	Y	NOXAFIL (posaconazole)	-39%
DARZALEX (daratumumab) Janssen Biotech, Inc	Multiple myeloma	Y	KYPROLIS (carfilzomib)	-12%
EMPLICITI (elotuzumab) Bristol-Myers Squibb Company	Multiple myeloma	N	KYPROLIS (carfilzomib)	-35%
ENTRESTO (sacubitril; valsartan) Novartis Pharmaceuticals Corporation	Heart failure	N	VALSARTAN (valsartan)	1295%
FARYDAK (panobinostat) Novartis Pharmaceuticals Corporation	Multiple myeloma	Y	REVLIMID (lenalidomide)	-75%
IBRANCE (palbociclib) Pfizer Inc	Metastatic breast cancer	N	AFINITOR (everolimus)	72%
KENGREAL (cangrelor) The Medicines Company	Periprocedural thrombotic events	N	BRILIQUE (ticagrelor)	-80%
LENVIMA (lenvatinib) Eisai Inc.	Follicular, medullary, anaplastic and metastatic or locally advanced papillary thyroid cancer	Y	NEXAVAR (sorafenib)	-56%
LONSURF (trifluridine and tipiracil) Taiho Pharmaceutical Co. Ltd	Metastatic colon or rectal cancer	N	STIRVAGA (regorafenib)	101%

*Only products with list price published by November 2016 were considered for this analysis

TABLE 2: NME LAUNCHES IN THE US, 2015 continued

Brand Name (Molecule Name) Manufacturer	Indication	Orphan	Comparator	US Percentage Premium or Discount
NINLARO (ixazomib) Takeda Pharmaceutical Company Ltd	Multiple myeloma	Y	KYPROLIS (carfilzomib)	81%
ODOMZO (sonidegib) Novartis Pharmaceuticals Corporation	Advanced basal cell carcinoma	N	ERIVEDGE (vismodegib)	5%
ORKAMBI (lumacaftor; ivacaftor) Vertex Pharmaceuticals Inc	Cystic fibrosis	Y	KALYDECO (ivacaftor)	-53%
PORTRAZZA (necitumumab) Eli Lilly and Company	Metastatic squamous lung cancer	N	IRESSA (gefitinib)	23%
PRALUENT (alirocumab) Sanofi	High cholesterol	N	EZETROL (ezetimibe)	1287%
PRAXBIND (idarucizumab) Boehringer Ingelheim Pharmaceuticals, Inc	Reversal agent for NOAC Pradaxa	N	FEIBA (anti-inhibitor coagulant complex)	17%
REPATHA (evolocumab) Amgen Inc	Homozygous familial hypercholesterolemia	Y	PRALUENT (alirocumab)	6%
REXULTI (brexpiprazole) Otsuka America Pharmaceutical, Inc	Major depression or schizophrenia	N	ABILIFY (aripiprazole)	5%
SAVAYSA (edoxaban) Daiichi Sankyo, Inc	Stroke or systemic embolism	N	ELIQUIS (apixaban)	-19%
TAGRISSO (osimertinib) AstraZeneca	Epidermal growth factor receptor mutation- positive NSCLC	Y	IRESSA (gefitinib)	314%
TRESIBA (insulin degludec) Novo Nordisk	Diabetes	N	LANTUS (insulin glargine)	170%
VARUBI (rolapitant) Tesaro, Inc	Chemotherapy-induced nausea and vomiting	N	EMEND (aprepitant)	-9%
VELTASSA (patiromer) Relypsa, Inc	Hyperkalemia	N	KAYEXALATE (sodium polystyrene sulfonate)	122%
VIBERZI (eluxadoline) Allergan, Inc	Irritable bowel syndrome	N	LOTRONEX (alosetron)	-19%
VRAYLAR (cariprazine) Allergan, Inc	Bipolar I disorder or schizophrenia	N	REXULTI (brexpiprazole)	116%
YONDELIS (trabectedin) Janssen Products, LP	Ovarian cancer and soft tissue sarcoma	Y	HALAVEN (eribulin)	65%

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TIME TO MARKET

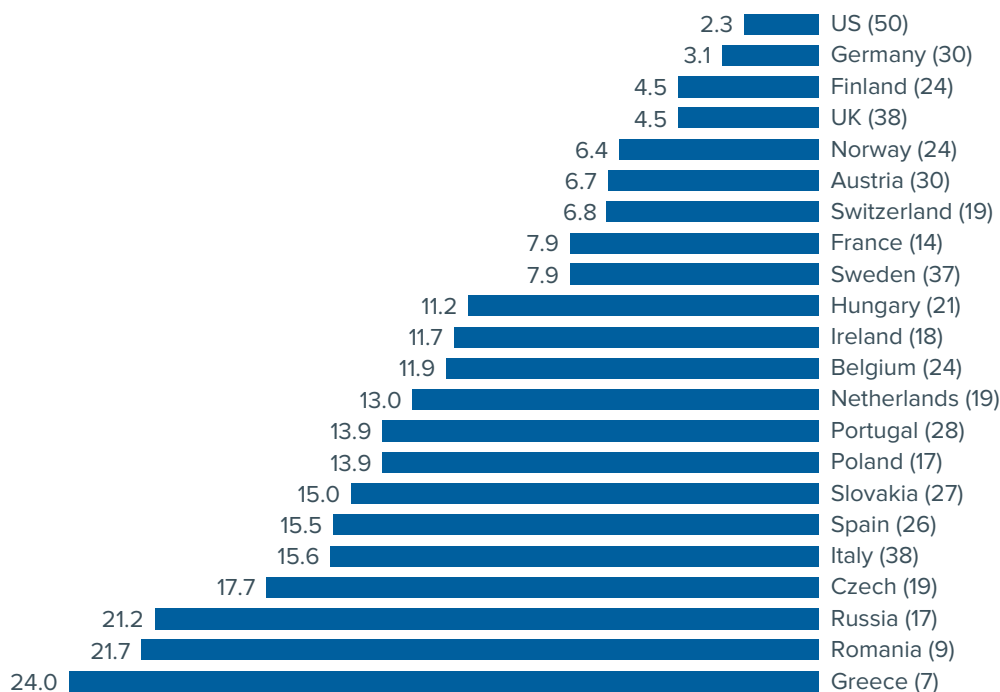
Analysis of time to market and time to reimbursement continues to play a critical role in the success of new pharmaceutical products, with QuintilesIMS tracking all products launched in key markets.

However, while the centralized EU regulatory approval process ensures coordinated approval for NMEs, there is substantial variation in the average time from EMA regulatory approval to first sales for all products in the EU20 and Russia (see Figure 4). As a consequence, patient access to new treatments varies widely as, despite unified EU approval, NMEs are still subject to local post-marketing authorization (PMA) processes:

- Only markets with free pricing at launch have been able to keep the average time to access close to the four month mandatory period set in 2012 by the European Commission Transparency Directive (see Figure 5)
- Trends over the past 3 years suggest that time to sales has not changed drastically for the EU5 markets; Spain and Italy continue to be heavily delayed compared with the other EU3 countries (see Figure 6)
- Time to reimbursement is closely tied to the length of the health technology assessment (HTA) and price negotiation process except where there are early access programs in place or private market sales

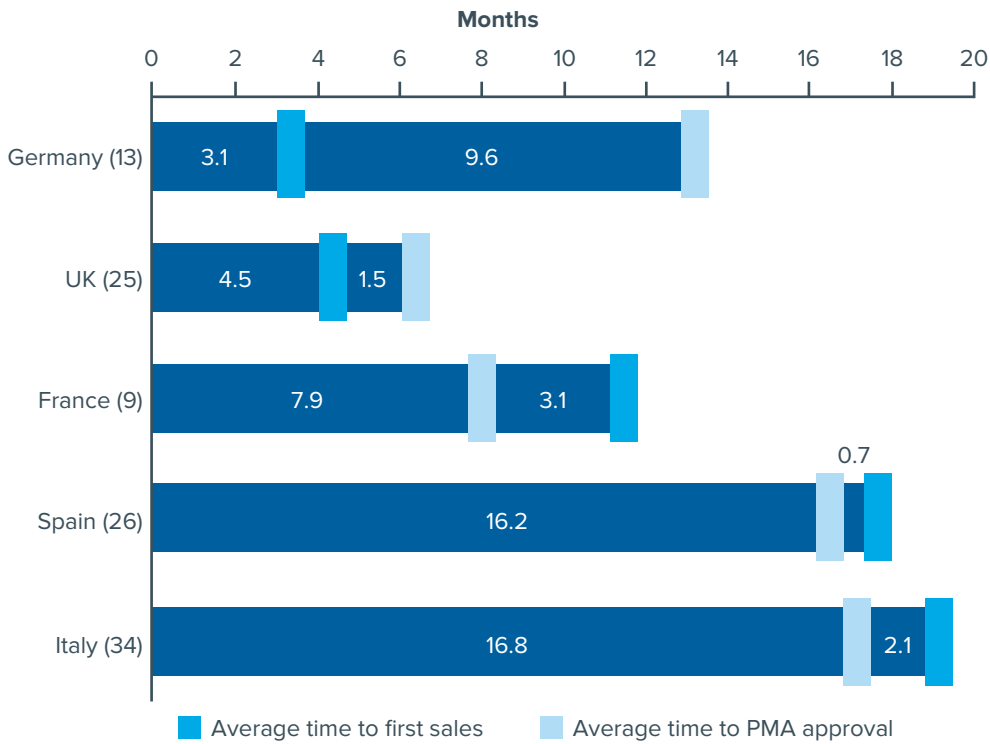
Overall, there is no evidence to suggest that these trends can be linked to the pricing strategies that pharmaceutical companies have adopted in these markets; instead it appears to be related to respective appraisal processes in each market.

Figure 4. Average time (months) from regulatory approval to first sales 2015



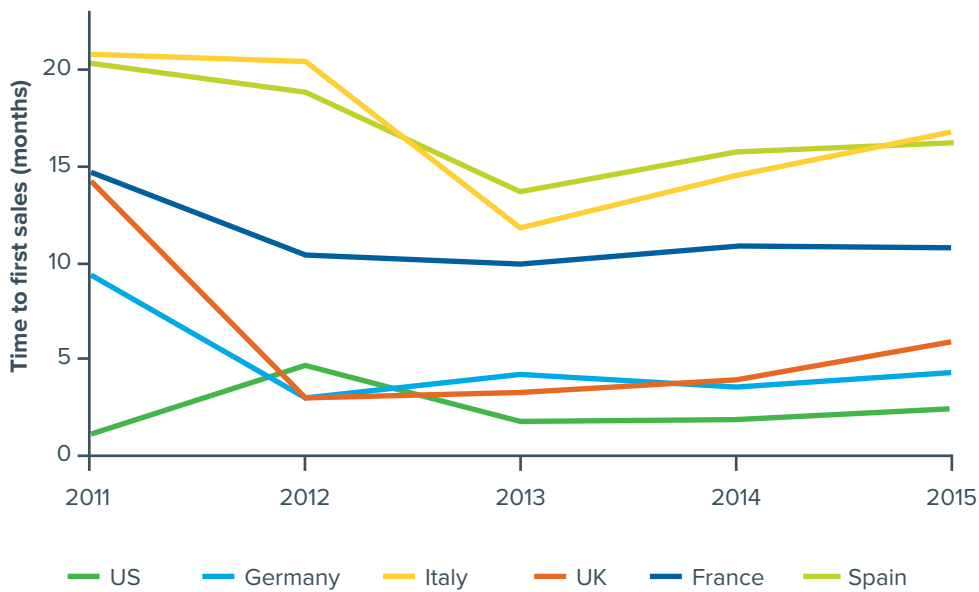
Source: QuintilesIMS Consulting Services analysis

Figure 5. Average time (months) from EMA regulatory approval to first sales and from first sales to PMA approval in 2015



Source: QuintilesIMS Consulting Services analysis

Figure 6. Trend of time (months) from regulatory approval to first sales (2011–2015)



Source: QuintilesIMS Consulting Services analysis

SUMMARY AND CONCLUSIONS

2015 was a landmark year for the pharmaceutical industry when innovation and pricing butted heads and the ensuing – and often frenzied – debates became headline news across the world, no more so than when new therapies launched in areas traditionally dominated by low-cost generics.

Yet the QuintilesIMS analysis suggests that European payers may be justified in their concern over the high cost of new medicines as manufacturers rampantly pursue premium list price strategies for the majority of NMEs. That said, the payer view of the magnitude of these premiums is sometimes exaggerated by the prevalence of generic products that are considered to represent current standard of care across a range of therapeutic areas and also ignores the impact of confidential discounts/rebates applied to these prices.

Despite this, the revised pricing strategies being explored and implemented in the EU do not appear to be making a dent on time to first sales. Although the overall trend of time to market suggests that it has not worsened over the past few years, patient access to innovative medicines continues to fall below the four month mandatory period in several EU markets. Meanwhile, our US analysis suggests the average net price growth of marketed drugs has not increased in the past few years, despite the very public examples of high list price increases.

The multifactorial and sustained pressure on prices across global markets is resulting in the increasing willingness of manufacturers to accommodate healthcare budget constraints by adopting parity or discount list prices and pursuing contracts to reduce the price paid by healthcare systems. With major US companies already demonstrating their commitment to limit annual price rises, the conversations around the value of drugs for both payers and providers look set to continue, particularly for specialty medicines.

Ultimately, the often conflicting pressures and challenges facing both pharmaceutical industry and healthcare systems are not going to go away. In this respect, greater cooperation between payers and manufacturers to find mutually beneficial contracts will continue to be a critical success factor in bringing innovative products to patients at reasonable costs and with minimal administrative delays.

Methodology

Price premium analysis

- QuintilesIMS analyzed products that were approved between 1 January 2015 and 31 December 2015, excluding branded generics, indication expansions, reformulations, and biosimilars
- Public list prices of an NME's highest selling pack (as per QuintilesIMS data) were obtained from QuintilesIMS Pricing Insights (collected November 2016)
- Nearest comparators were based on available HTA assessments and published clinical trials
- For chronic therapies, post-titration dosage per year calculated; non-chronic treatment pricing calculated on median duration of exposure reported in clinical trials
- 70 kg male adult patient; 65 kg female adult patient; 35 kg child patient; 1.7 m² average body surface area (BSA)

Time to market

- 2015 product launches (defined as having first non-zero sales in 2015) identified
- Primary data source QuintilesIMS MIDAS monthly data (2009–2015)
- Product cohort included branded, innovative products, exclusions as per above
- Products with sales or regulatory approval before 2009 were removed from the cohort
- For EU5 markets, PMA approval dates for all products were defined based on the specific HTA process in that market
- Regulatory approval date for each product collected directly from either the EMA or FDA websites

About QuintilesIMS Consulting Services

QuintilesIMS Consulting Services enables clients to accelerate innovation and transform healthcare with an unparalleled mix of practical expertise, therapeutic depth and execution capabilities. And with presence in local markets across five continents and privileged access to QuintilesIMS data, our highly-specialized team of consultants are uniquely positioned to help clients drive healthcare forward.

QuintilesIMS (NYSE:Q) is a leading integrated information and technology-enabled healthcare service provider worldwide, dedicated to helping its clients improve their clinical, scientific and commercial results. Formed through the merger of Quintiles and IMS Health, QuintilesIMS' approximately 50,000 employees conduct operations in more than 100 countries. QuintilesIMS provides solutions that span clinical to commercial bringing clients a unique opportunity to realize the full potential of innovations and advance healthcare outcomes.



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