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Busting a myth: Is achieving US drug prices in Europe impossible?

Few myths within the global drug pricing community seem as factual as the inability to achieve a US-like price for an innovative New Molecular Entity (NME) in Europe. Willingness and ability to pay are just too different in the different systems. Or are they?

Methodology

Our starting point was the combined experience of over 30 pharma pricing strategy consultants to identify potential candidates – having worked on hundreds of pricing strategies, they should know. In addition to anecdotal experience, we searched for evidence in the individual countries. Germany and the UK, for example, are the two European countries where manufacturers can still set their list price for NMEs and – after EMA marketing authorization – the price is automatically reimbursed. While free pricing is the theory, in practice it is not that straightforward. In the UK, NICE acts as a gatekeeper to access to NMEs via heath technology assessment (HTA), with price the main driver for cost-effectiveness and patient access. In Germany, a reimbursement price negotiation process was introduced in 2011 (AMNOG), which results in a publicly disclosed rebate a year after launch that reduces the reimbursed price for the public health system.

Our methodology looked at publicly available prices and wholesaler acquisition cost (WAC) from the IBM Micromedex RED BOOK in the US and public, ex-manufacturer (ex-Man), reimbursed list prices in Europe, as found in MIMS (UK), Lauer Taxe (Germany), BOT Plus web (Spain), Gazzetta Ufficiale (Italy) and Ameli BdM IT (France). We excluded undisclosed discounts – on both sides of the Atlantic – due to lack of transparency and confidentiality. We then compared prices of NMEs of similar pack sizes from the date of first publication and used the exchange rate USD to EUR/GBP on that date. To account for time gaps and exchange rate changes between US strategy decision / launch (which must pre-date Europe to set the base price) and EU approval / implementation time, we defined ‘similar’ prices as EU prices above US prices or up to 20% lower.

We reviewed WAC and ex-Man prices for all EMA approved NMEs that underwent the AMNOG process in Germany looking for similar US/EU list prices before AMNOG rebate negotiation between 2011-2018. For the same EMA approved NMEs, we looked through MIMS to identify relevant products in the UK (after deducting distribution margins). We then looked at the NMEs identified in Germany and the UK in France, Italy and Spain on the basis that it would be more challenging to achieve negotiated, reimbursed US prices in these countries – or for other NMEs than those with freely set list prices in Germany and/or the UK.

Result: The myth is busted!

Based on this approach, we identified 16 different NMEs that in at least 1 of the 5 big EU markets had a similar price to the US (12 were EMA approved between 2011 and 2018, and 4 before 2007). 13 of these products had at least one big EU market price that was within 10% of the US WAC. Several of these products had a higher ex-Man price in Europe than WAC in US (see Table 1).

Table 1: NMEs with US / EU price parity

Product	Launch TA area	EMA approval	OD designation	List/price ratio at launch						EMA MA to reimbursement in months		
				US/GER	US/GER current	US/UK	US/SP	US/IT	US/FR	Spain	Italy	France
NME 1	Oncology	Q2 2004	No	**0.82**	n/a	1.25	**1.02**	**1**	n/a	**126**	**9**	
NME 2	Immunology	Q1 2006	No	**0.65**	**0.75**	1.38	**0.69**	n/a	**1**	**71**		**11**
NME 3	Immunology	Q3 2006	No	**0.65**	**0.66**	**1.09**	n/a	**1.1**	n/a		**50**	
NME 4	Immunology	Q2 2007	Yes	**0.86**	**0.85**	1.3	**1.02**	**1**	n/a	**76**	**91**	
NME 5	Oncology	Q3 2011	No	1.6	1.62	**1.03**	1.24	**1.09**	n/a	16	**19**	
NME 6	Ophthalmology	Q1 2012	No	**0.85**	**0.9**	**0.94**	**1**	**1.03**	1.36	**77**	**59**	86
NME 7	Oncology	Q1 2012	No	**0.82**	1.76	**0.81**	**1**	**0.85**	**0.81**	**22**	**15**	**12**
NME 8	Ophthalmology	Q1 2013	No	**0.73**	**1.07**	**0.88**	**0.86**	**0.91**	n/a	**45**	**24**	
NME 9	Oncology	Q3 2013	No	1.22	1.94	**0.9**	1.48	**0.99**	1.22	9	**14**	1
NME 10	Oncology	Q3 2013	Yes	**0.93**	1.48	**0.84**	1.23	**1.16**	n/a	11	**24**	
NME 11	Oncology	Q4 2013	No	**0.94**	1.32	**1.03**	**1**	**1**	**1.2**	**20**	**10**	**9**
NME 12	Oncology	Q3 2014	Yes	**1.2**	1.9	**0.97**	1.5	1.55	n/a	16	31	
NME 13	Oncology	Q3 2015	No	**1**	1.26	**0.93**	**0.91**	**0.92**	n/a	**18**	**9**	
NME 14	Oncology	Q3 2015	Yes	1.34	1.93	**0.92**	n/a	1.73	1.93		25	3
NME 15	Genetic disease	Q1 2018	Yes	**0.82**	**1.08**	**0.92**	n/a	**0.88**	**ATU 0.83**		**11**	
NME 16	Oncology	Q3 2018	Yes	**1**	**1.2**	n/a	**1.04**	n/a	**ATU 0.97**	**10**		

Price ratio <1 = EU price is higher than US price; price ratio >1 = US price is higher than EU price (based on 2019 prices with AMNOG rebate deducted 2011-2018); OD = orphan designation; bold = similar prices US/EU. *Source: CRA analysis*

During the period 2011-2015, the EMA approved just over 100 NMEs, of which 11 in at least two of the big five EU countries achieved a price similar to the US at launch. Furthermore, of the ~40 oncologic NMEs approved over the same time period by the EMA, 9 were similarly priced in the US and in at least 2 of the 5 big EU markets. These numbers provide sufficient evidence to conclude the myth is busted.

We can also identify some characteristics of NMEs that have a higher chance of achieving US-like prices in Europe:

- 10 NMEs are for oncologic indications
- 6 have an orphan designation
- All 16 are limited to specialist and / or hospital prescribing in EU markets
- There is significant unmet need in all indications

Looking in closer detail, the free pricing (at launch) markets of Germany and the UK are the countries most likely to achieve US-like prices (13 of 16 and 12 of 16, respectively). Of the approximately 100 NMEs that went through the German AMNOG process from 2011 to August 2018, 9 went into the process with similar (reimbursed) list prices. Interestingly, 4 of these managed to keep a US-like reimbursed price even after the negotiated rebate (see Table 1, US/GER current).

Of the 16 NMEs from our Germany/UK list in Table 1, 12 also achieved a US-like price in Italy and 9 in Spain. This was surprising as list prices in these countries are the result of reimbursement negotiations with public institutions. All US priced NMEs are reimbursed for hospital-only use in Italy and Spain, with an expectation of significant discounts at the purchaser level. This does not contradict our myth-busting conclusion, as it is not different from the US where there are also significant discounts at the purchaser level.

The downside of achieving US-like prices is that they come at the cost of increasing negotiation timelines. Only looking at products launched in 2011-2018, data presented by the European Federation of Pharmaceutical Industries and Associations (EFPIA) show that Spain had an average time gap from approval to launch for all NMEs of approximately 17 months and for oncology NMEs approximately 13 months. For all 6 NMEs with US-like prices launched 2011-2018 it was 32 months, and 18 months for all 4 US-like priced oncology NMEs. In Italy, the time gap was smaller in the period 2011-2018, at around 13 months for all NMEs compared to 23 months for the 9 NMEs with US-like prices. For oncology NMEs, the difference was much smaller at 12 months for all oncology drugs launched in Italy compared to 15 months for the 6 NMEs that achieved US-like prices.

The toughest myth to bust was France, as prices for 8 of the 16 NMEs were not publicly available. However, of the 8 NMEs with publicly available prices, 5 had US-like prices. Of these, 2 had US-like prices within the context of an early access scheme (ATU). Further investigation revealed that the other 3 NMEs were earlier part of an ATU program and sold at US prices during the ATU period. They also had very positive HTA evaluation ratings by the French health authority (Haute Autorité de Santé), which seems to be a key driver of achieving a US-like price in France, although this conclusion is drawn from a small sample size.

What does it mean?

Considering the limitations of our research design and the restricted pool of evidence, definitive conclusions cannot be drawn. In addition, there are many influential factors that we did not take into account, such as HTA outcomes and access constraints beyond label. Our anecdotal findings, however, seem to suggest that a US-like pricing strategy could be considered as a viable strategic option in Europe, at least for the (reimbursed) list price when the following success factors can be ticked off:

- ✓ NME in oncology or a rare / orphan disease for specialist / hospital use
- ✓ Convincing clinical profile with benefit confirmed by the medical community
- ✓ Possibility for somewhat credible economic justification of the price tag
- ✓ High unmet need that allows for early access scheme (e.g. ATU in France)
- ✓ ATU price in France and German/UK list price at launch set at parity to US by the company
- ✓ No concerns about longer negotiation time in countries like Spain, Italy

Provided these factors are in place, achieving a US-like price in Europe also requires a different approach to pricing strategies and/or product development. Rather than asking 'What price can we achieve?' manufacturers should answer the following questions:

- **Do we want to achieve a US-like price with this NME?**
- **Under what conditions can we achieve it for this NME?**

These questions might help get you there – if you dare.

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