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Injectable Oncology Therapies: Benchmarking Gross and Net Price Differentials in Europe vs US

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Objective

To compare gross ex-factory and net prices of injectable oncology therapies in Europe (EU4/UK) vs US

Methods

- Reviewed all injectable oncology therapies approved by the EMA between 2020 to 2022 and approved/available in the US as of May 2024.
  - Only therapies with visible ex-factory prices available in at least three European countries were included in the final analysis for price benchmarking
- Gross ex-factory prices/wholesale acquisition cost (WAC) were gathered in all 6 countries in May 2024 using various national and local sources (Table 1).
- A further deep dive was conducted to examine relative net price differences between.
  - **US:** Average sales price (ASP) and Federal Supply Schedule (FSS)
  - **Germany:** Net price post AMNOG and including statutory discount/rebate
  - **Italy:** Net post completion of P&R negotiations at the national and local level (based on a review of tenders)
- Price comparisons were conducted on a per mg basis to ensure any differences in authorized presentations were addressed.
- Prices were converted to USD using the exchange rates from the International Monetary Fund- IMF (April 2024).
  - €1=$1.073; 1£=$1.252

Table 1: Sources for pricing data

Country	Sources
US	• MediSpan
France	• Légifrance, Theriaque
Germany	• Lauer Taxe
Italy	• Gazetta Ufficiale, Local tenders
Spain	• Vademecum, Botplus
UK	• NHS DMD

Results

- Ten injectable oncology therapies were approved across jurisdictions and available in at least 3 of the 5 European countries (EU4/UK) (Table 2).
- While ex-factory prices for all ten therapies were available in Germany, Italy, and the UK, only 2 therapies had a published price that could be used for analysis in France because of the lengthy time to completion of pricing negotiations. Prices available as part of early access (AAP/ATU) in France were not included in our review. Ex-factory prices were available for 9 of the 10 therapies in Spain.
- In vast majority of cases (80%), the US WAC at launch was higher than the EU4/UK ex-factory (defined as >10% difference); for ~20% it was similar (within +/−10%) (Figure 1).
- Tight ex-factory price corridor in Europe was the norm (Figure 2). Italy was at the higher end and UK at the lower end for most therapies.

Table 2: Injectable oncology therapies included in the analysis

Medicine	Active substance	Therapeutic area
Lunsumio	mosunetuzumab	Follicular lymphoma
Kimmtrak	tebentafusp	Uveal neoplasms
Padcev	enfortumab vedotin	Urothelial carcinoma
Enhertu	trastuzumab deruxtecan	Breast neoplasms
Minjuvi	tafasitamab	Diffuse large B-cell lymphoma
Trodelvy	sacituzumab govitecan	Breast neoplasms
Jemperli	dostarlimab	Endometrial neoplasms
Tecartus	brexucabtagene autoleucel	Mantle-Cell lymphoma
Sarclisa	isatuximab	Multiple Myeloma
Polivy	polatuzumab vedotin	B cell lymphoma

Data collection cut off May 2024

Figure 1: Ex-factory launch price ratio- US vs. individual European countries

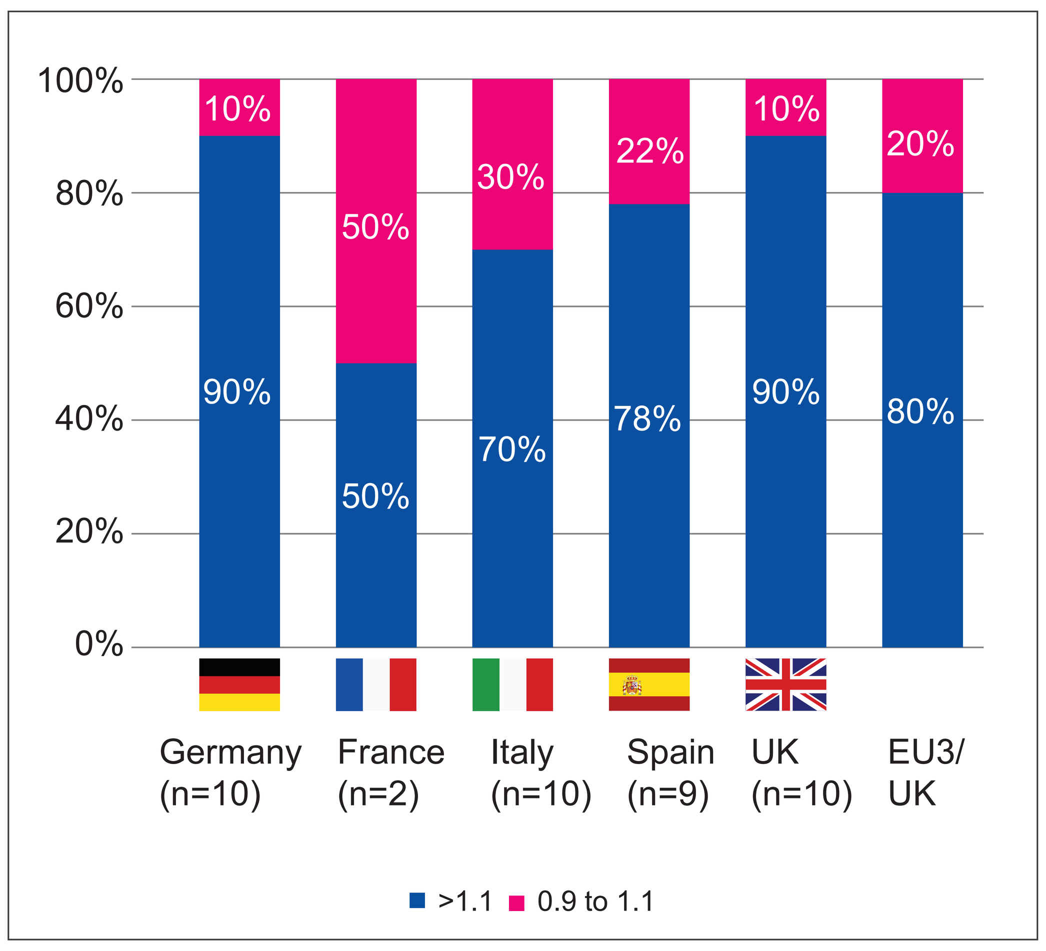
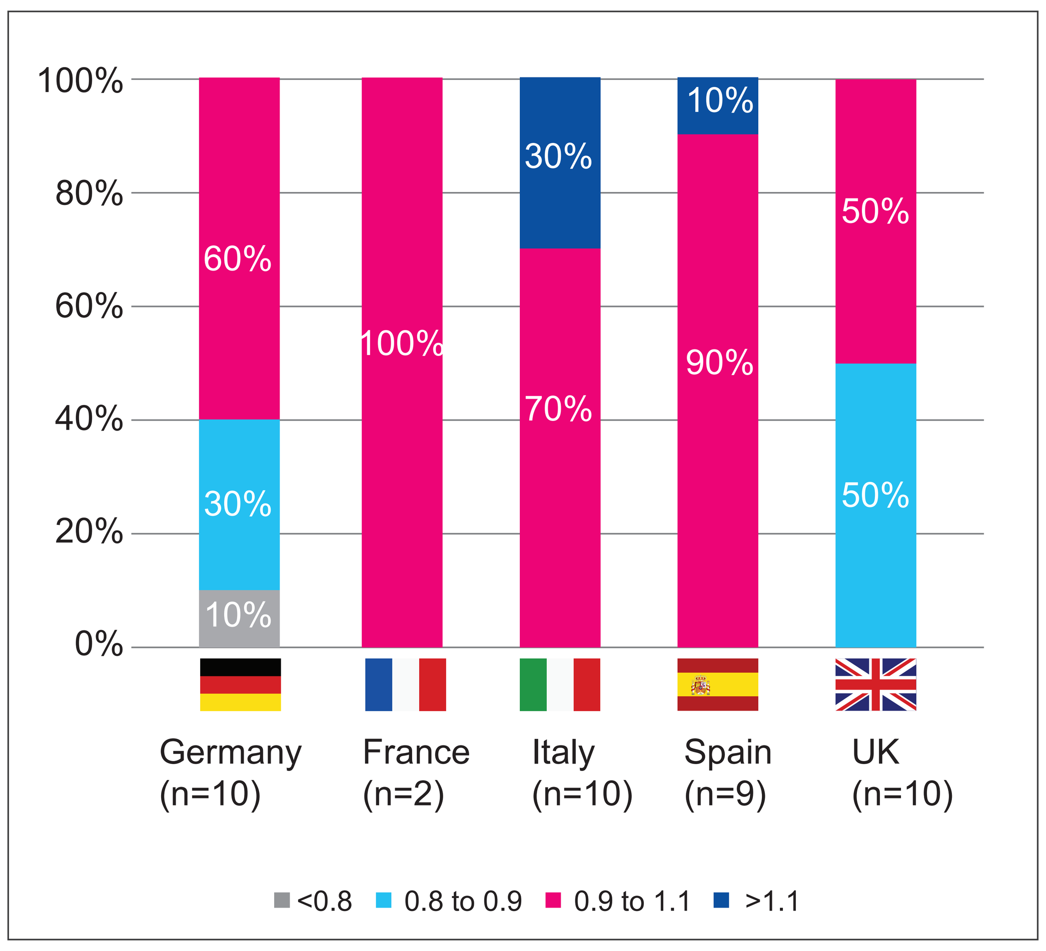


Figure 2: Ex-factory price ratio- EU4/UK average vs. individual European countries



- On average, the visible ex-factory price at launch in the EU4/UK was 0.69 relative to the US WAC at launch
  - Because of price increases in the US, the current ratio was 0.60
- Although Italy was at the higher end of the visible ex-factory price (0.76) even relative to Germany (0.64), further net price analysis showed a different picture
- Indexing WAC of $100 in the US at launch translated into a visible ex-factory price of $76 in Italy and $64 in Germany (Figure 3)
- Average discounts for injectable oncology therapies were 1.4% (ASP) and 12% (FSS) in the US, the average in Germany was 32% and in Italy was 55%
  - Post negotiations, however the net in the US is $88 (FSS) to $98 (ASP), whereas it is $34 in Italy and $44 in Germany post AMNOG negotiations (Figure 4)

Figure 3: Ex-factory launch price comparison- US/DE/IT

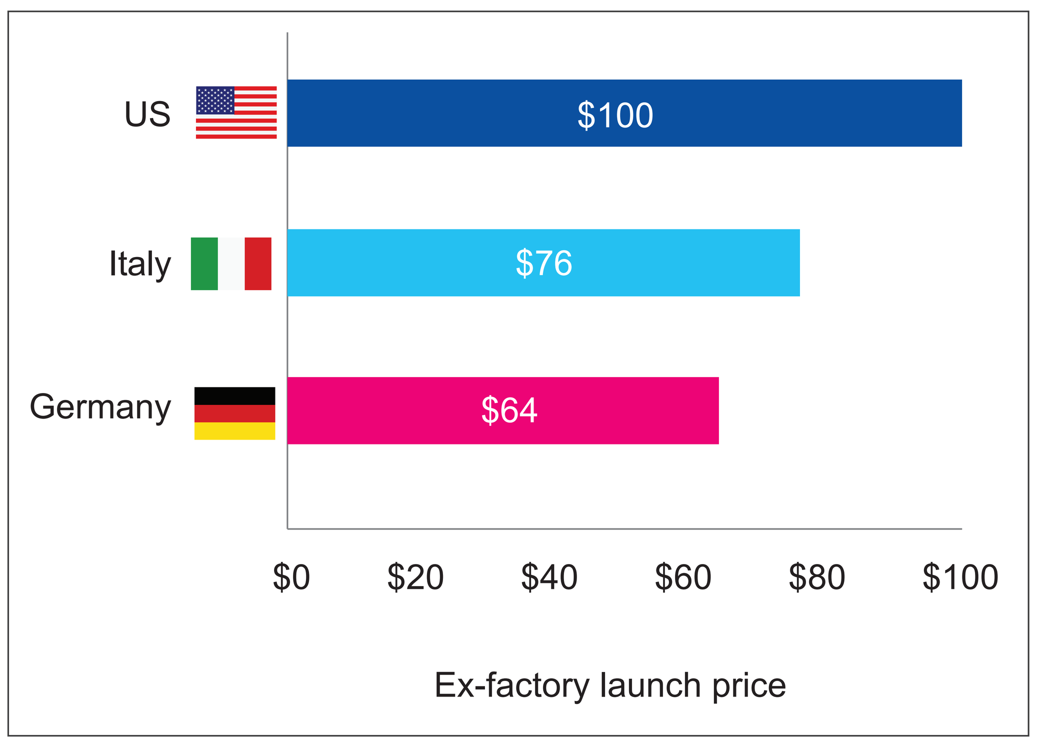
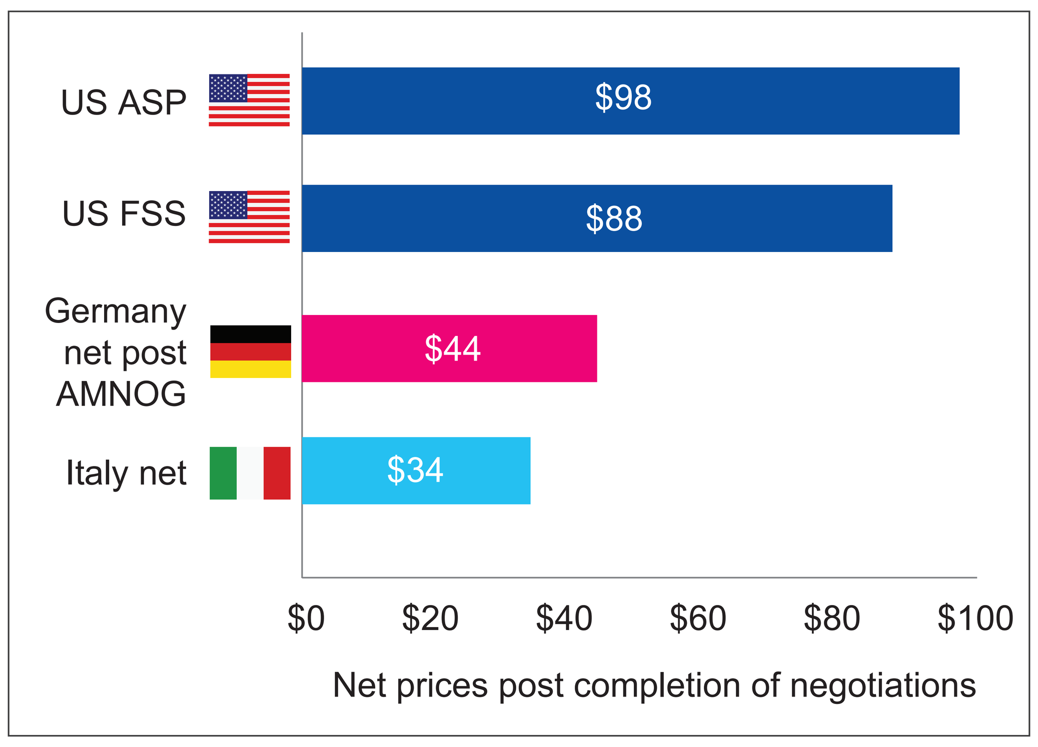


Figure 4: Net price comparison post completion of negotiations- US/DE/IT



Conclusion

- The gap in injectable oncology drug prices between the US and key European countries is an example of the present market realities.
- With the ongoing speculation that IRA will shift R&D focus to biologic therapies, understanding these dynamics and how they impact the commercialization of bio/pharmaceuticals across countries and therapy areas both currently, and in the future, is critical.
- Further research needs to be conducted to understand the net price differentials in other therapeutic areas which constitute a major share of biopharma's development pipeline also in light of the push towards implementing external referencing in the US.

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