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FORECASTING PHARMACEUTICAL EXPENDITURE IN EUROPE: ADJUSTING FOR THE IMPACT OF REBATES AND DISCOUNTS

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BACKGROUND AND OBJECTIVES

- European healthcare systems are under pressure to contain healthcare expenditure. Understanding future drug expenditure is an important consideration for payers when formulating policies.
- QuintilesIMS (QI) publishes European drug expenditure forecasts based on its audited volume data and, in most cases, publicly available list prices.
- However, it is well known that net prices, and therefore expenditure, can vary significantly from list prices. With increasing price pressures, list to net price divergence is believed to be growing, although some of this information is commercially sensitive and thus not publicly available.
- The objective of this study was to adjust an established forecast to account for this list to net divergence and explore its impact.

METHODS

- QI publishes historical estimates of drug expenditure for EU5 countries based on its comprehensive capture of medicines volume from the pharmaceutical distribution chain. QI regularly forecasts future drug sales values at a country level using a combination of extrapolations from historical trends combined with market expertise and event-based prognostics (see previously described methodologies) [1]. The forecasts aim to reflect the total pharmaceutical market in a country, including brand and generic, and prescription and non-prescription drugs.
- Historical estimates of drug expenditure were adjusted, where possible, for each EU5 country to account for rebates and discounts that are not reflected within QI data, including industry-level rebates and product-level discounts to national, regional and hospital payers (Table 1). QI forecasts were re-calibrated using the adjusted net historical drug expenditure data.
- Adjustments were made based upon publicly available aggregate net expenditure data reported by national health system organisations and validated through interviews with country experts. Details of country specific adjustments and sources are summarised in Table 2.
- Given imperfect information on full list to net differences, the emphasis of the analysis was on investigating the impact of adjustments on expenditure growth rates (historical and forecast) rather than on absolute differences in expenditure between list and net estimates at any particular time point.

RESULTS

EU5 Aggregate Data (Figure 1)

CAGRs EU5	Unadjusted ('list')*	Adjusted ('net')*
Historical (2010–2016)	3.4%	2.0% (range 1.5%–2.5%)
Forecast (2017–2021)	2.9%	1.5% (range 1.0%–2.0%)

*'List' expenditure refers to original QI model estimates, whereas 'net' expenditure refers to adjusted estimates using official public data and authors' views.

France (Figure 2)

CAGR	Unadjusted ('list')	Adjusted ('net')
Historical (2010–2016)	0.5%	-0.4%
Forecast (2017–2021)	1.8%	0.6%

- Expenditure in retail sector is falling due to implementation of cost control methods, loss of exclusivity of major products, and some shift towards hospital spend.
- Hospital expenditure is also largely controlled at list price level, with growth remaining relatively slow despite launch of high budget impact HCV products in recent years.
- Health authorities in France actively manage aggregate drug expenditure against annual targets and utilise payback agreements and price cuts to control growth. For example, paybacks by industry doubled from €520M in 2014 to€1,020M in 2015.
- Given that CEPS has publicly stated a target of €1bn reduction in aggregate drug expenditure in 2018, growth could be lower than the forecast 0.6% CAGR.

Germany (Figure 3)

CAGR	Unadjusted ('list')	Adjusted ('net')
Historical (2010–2016)	3.9%	2.5%
Forecast (2017–2021)	3.2%	2.0%

- The retail segment is dominant in Germany (86% of market) with many 'hospital-type' treatments delivered through office-based physicians. Total market and retail expenditure have both been growing historically at ~4% CAGR before confidential discounts/rebates are considered.
- AMNOG rebates are already captured in QI forecast, but as more products become subject to them over time, the impact becomes greater (partly accounting for lower unadjusted forecast growth rate of 3.2% compared with historical growth rate).
- Two mechanisms substantially reduce net expenditure estimates: mandatory discounts that are applied to retail products and sick fund clawbacks (rebates paid due to negotiated contractual agreements).
- Mandatory rebates have fluctuated between 6% and 16% since 2010.
- Clawback payments increased threefold over 7 years from €1,310M in 2010 to €3,890M in 2016.

Italy (Figure 4)

CAGR	Unadjusted ('list')	Adjusted ('net')
Historical (2010–2016)	4.5%	2.8%
Forecast (2017–2021)	3.2%	1.1%

- Italian retail sector sales have been falling since 2010 with growth attributed to hospital sector due to the increasing role taken by hospitals in procuring 'retail' drugs. These drugs are distributed either directly by hospitals or by community pharmacies on behalf of hospitals.
- The most important discounts and rebates in the Italian system that are not already captured in the QI model are:
  – Industry level payback based on level of hospital and outpatient expenditure as proportion of total health expenditure, estimated at 1.6% of total drug expenditure between 2013 and 2016.
  – Discounts negotiated with AIFA and at hospital level which have accounted for a list-to-net difference of 8% of total drug expenditure in 2010 increasing to 22% in 2016.
  – Rebates from managed entry agreements (MEAs) for HCV drugs that averaged 4.3% of total drug expenditure between 2015 and 2016, and MEAs for other drugs that averaged 0.3% (2014 – 2016).

Spain (Figure 5)

CAGR	Unadjusted ('list')	Adjusted ('net')
Historical (2010–2016)	2.2%	NC
Historical (2014–2016)	9.4%	4.8%
Forecast (2017–2021)	2.5%	1.1%

NC = Could not be calculated

- Publicly available historical net expenditure data for hospital sales was only available from 2014 – 2016 (during this period HCV drugs were launched in Spain).
- In Spain, retail sector sales have been falling since 2010, with most growth attributed to hospital sector due to oncology costs and short term spending on HCV drugs (Spain has particularly high HCV prevalence).
- The difference between net expenditure on hospital drugs, as reported in Spanish Ministry of Health, versus aggregate expenditure at list prices was 22%, 28% and 34% for 2014, 2015 and 2016 respectively.
- Industry level rebates have not been relevant since their introduction in 2015 due to drug expenditure growth falling below GDP growth over this period, however this legislation could act as an upper limit on future growth.
- Payments from the compulsory payback mechanism are not captured in the QI model, however they have remained flat (1.5 – 2%) since their introduction in 2006.
- Mandatory discounts applied to invoices for all hospital drugs (7%; 4% for orphans) have been in place since 2010. Increasing usage of hospital products means these savings are forecasted to increase.

UK (Figure 6)

CAGR	Unadjusted ('list')	Adjusted ('net')
Historical (2010–2016)	6.8%	NC
Historical (2013–2016)	7.9%	4.3%
Forecast (2017–2021)	3.8%	2.3%

NC = Could not be calculated

- Publicly available historical net expenditure data was only available from 2013 – 2017 (Q2) and was only for the proportion (51% in 2013) of the UK drug market covered by the Pharmaceutical Price Regulation Scheme (PPRS).
- No adjustments were made to account for confidential discounts and rebates in the non-PPRS market, which includes generics and also HCV expenditure on products marketed by Gilead (not members of PPRS). Given that these products are likely to be subject to discounts of a similar magnitude to PPRS products, the adjustment in the UK is likely to be under-representative of the true list-to-net difference and to overestimate growth rates.

Table 1. Rebates/discounts in EU5 countries included or excluded in QI drug expenditure forecast

FRANCE	QI	ADJ	GERMANY	QI	ADJ	ITALY	QI	ADJ	SPAIN	QI	ADJ	UK	QI	ADJ
Industry rebates	✗	✓	Mandatory discounts in SHI	✗	✓	Industry rebates	✗	✓	Industry rebates	✗	✓	PPRS industry rebates	✗	✓
Clawback payments	✗	✓				Mandatory discounts	✓	✓	Compulsory paybacks	✗	✓	Patient access schemes (NICE)	✗	—
MEAs (e.g. pay for performance, etc)	✗	✓	AMNOG price reduction	✓	✓	Product level discounts	✗	✓	Product level discounts	✗	✓	National tenders / contractual agreements	✗	—
			Sick fund clawbacks	✗	✓	MEAs + PVAs	✗	✓	Negotiated discounts	✗	✓			
Tenders / discounts	✗	✓	Tenders / discounts	✓	✓	Tenders / discounts	✗	✓	Tenders / discounts	✗	✓	Tenders / discounts	✗	—
Rebates	✗	✗	Rebates	✗	✗	Rebates	✗	✓	Rebates	✗	✗	Rebates	✗	—

✓ / ✗ Included / excluded in forecast — In the UK, those factors were adjusted only for the PPRS part of the market

QI: QI forecast ADJ: Adjusted forecast MEA: Managed entry agreement PVA: Price-volume agreements SHI: Statutory health insurance

National level — Regional/Hospital level

Table 2. Country level adjustments and publicly available data used for country adjustments

COUNTRY	HISTORICAL QI EXPENDITURE ESTIMATES ADJUSTED TO REFLECT:	SOURCES
France	• Aggregate net expenditure data on reimbursed drugs reported by CEPS (2010 – 2015) • Manufacturer payback data reported by CEPS (2010 – 2015)	CEPS Activity reports (2010–2015) [2]
Germany	• Mandatory discounts for SHI drugs in retail setting (2008 – 2016) • Aggregate net expenditure data on SHI drugs (2005 – 2016) • SHI clawbacks (savings due to discount agreements) (2008 – 2016)	Arzneiverordnungs-report (2008 – 2016) [3] WHO [4]
Italy	• Aggregate net expenditure data for NHS reimbursed medicines, including discounts applied at national and local levels (2009 – 2016) • Industry level payback where total drug expenditure caps are exceeded (2013 – 2016) • Rebates from managed entry agreements, including HCV medicines (2013 – 2016)	L'uso dei Farmaci in Italia. AIFA reports (2010 – 2016) [5] Monitoraggio della spesa farmaceutica regionale (2013-2016) [6]
Spain	• Aggregate net expenditure data reimbursed drugs (split by hospital/retail) (2014 – 2016) • Industry level rebates (not applied since introduction) (2014 – 2016) • Compulsory payback levels (2006 – 2016)	MoH [7] Spanish legislation [8]
UK	• Aggregate net expenditure for PPRS-covered medicines ('measured spend') (2013 – 2017) • Industry PPRS rebate payments (2013 – 2017)	Aggregate Net Sales and Payment Information May 2017 and Annual reports DoH [9,10]

Figure 1: Historical and forecast drug expenditure: Aggregate EU5

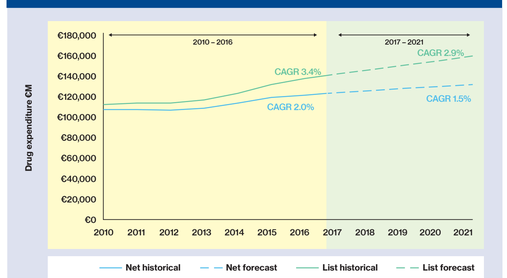


Figure 2: Historical and forecast drug expenditure: France

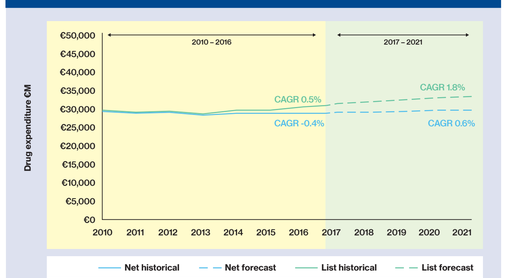


Figure 3: Historical and forecast drug expenditure: Germany

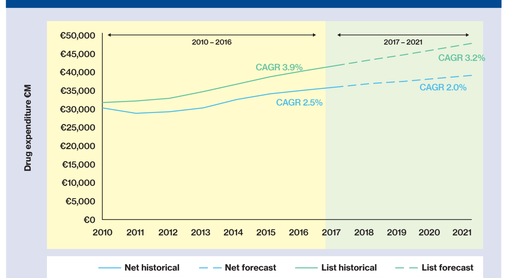


Figure 4: Historical and forecast drug expenditure: Italy

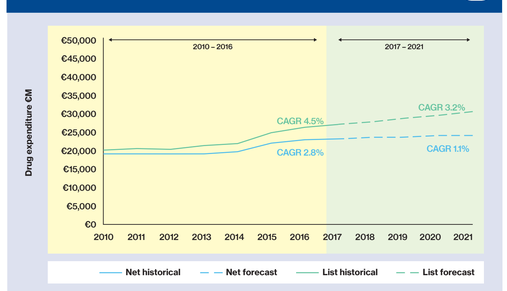


Figure 5: Historical and forecast drug expenditure: Spain

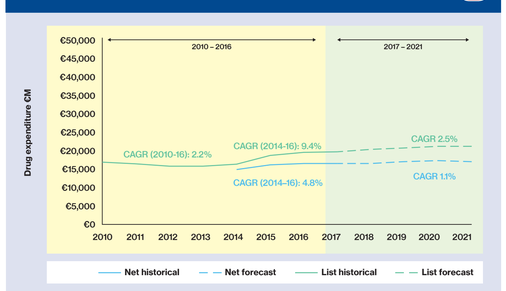
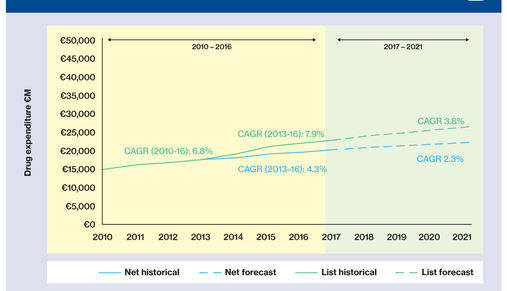


Figure 6: Historical and forecast drug expenditure: UK



UNCERTAINTY IN ANALYSIS

- While this analysis has sought to characterise as much as possible, the list to net difference in aggregate drug expenditure, not all confidential discounts or rebates are captured. For example, net data was only available for approximately half of the UK market by value (drugs covered by PPRS).
- This analysis was reliant upon published net expenditure data reported at the national level. Rebates that are paid to hospitals and regional health authorities are not fully captured in many countries.
- Given the number and size of biologics that are losing patent protection in coming years, the evolution of the market for biosimilars will be an important variable impacting future expenditure growth rates.
  – Typical historic biosimilar assessments, as applied in the QI forecast could be an underestimate of future biologic value erosion after biosimilar launch.
  – There are €30-40bn of cumulative sales that can be exposed to biosimilar competition through to 2021.
  – If biosimilars lead to value erosion that is closer to that seen for small molecules, overall future net growth rates in the EU5 based on this analysis would be nearer to 0.5% – 1% over the next 5 years.

CONCLUSIONS

- The increasing frequency and magnitude of patient access schemes, rebates and discounts have led to a growing divergence between list and net prices for medicines in Europe.
- This is driven by policies such as external reference pricing, growth in risk sharing arrangements, direct rebate/discount requirements and a shift in pharmaceutical innovation from retail to hospital settings in many countries.
- After adjusting for discounts and rebates, net expenditure growth in EU5 is predicted to be 1% - 2% over the next 5 years.
- This is below predicted healthcare expenditure growth in Europe and in line with long-term economic growth rates [11,12].
- As biosimilar market evolves with more new entrants, drug expenditure growth could be around up to 1% point lower than base case.

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