Office of Health Economics Consulting

Consulting Report

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August 2018

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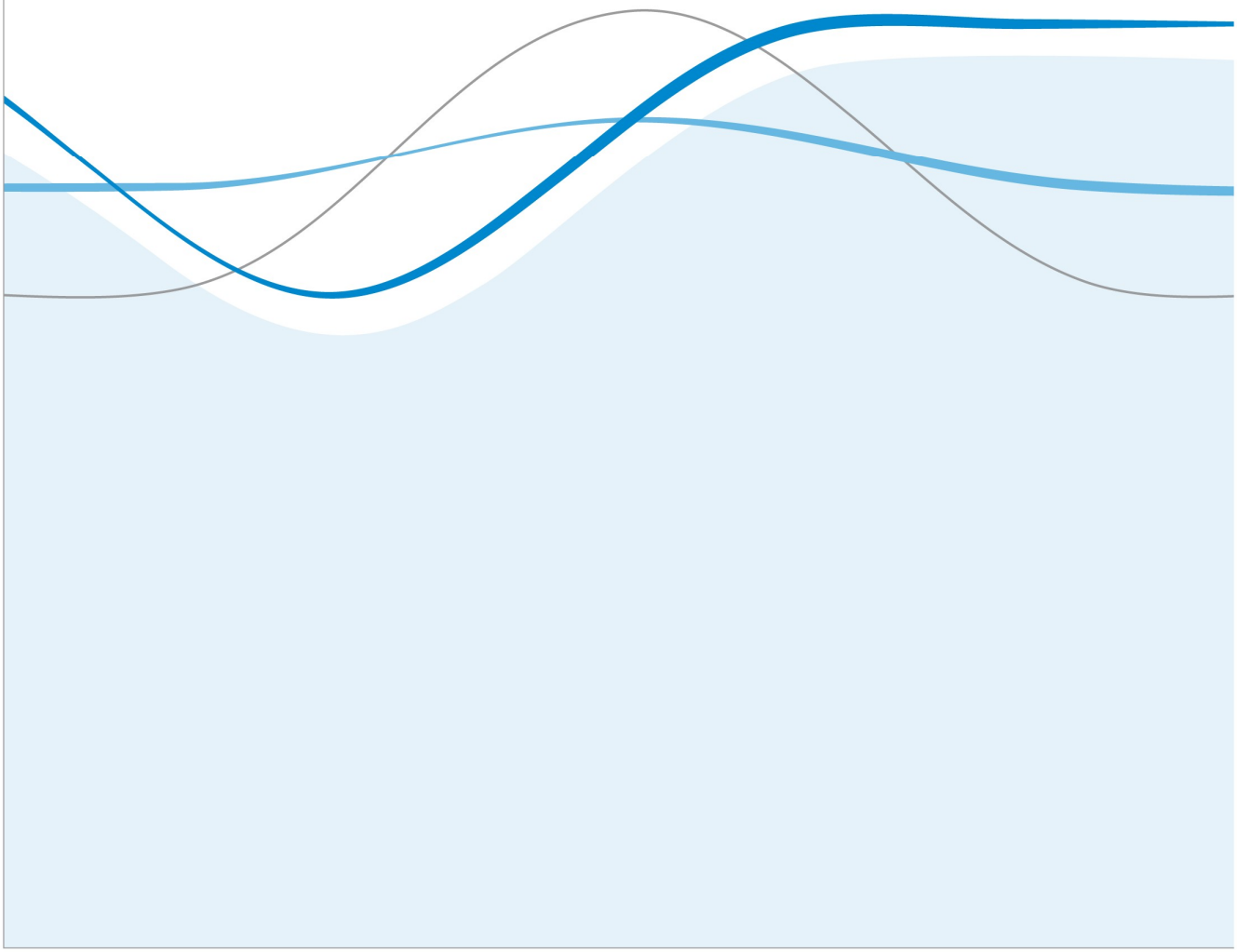

# Measurement of Medicines Expenditure in the Context of the 2014-18 PPRS

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August 2018

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## EXECUTIVE SUMMARY

For the year 2015/16, the Treasury reported growth in Government funded healthcare expenditure in the UK of 4.0% whilst NHS Digital reported medicines expenditure growth for the English National Health Service (NHS) for the same period at 8.0%. However, NHS Digital reported much reduced medicines expenditure growth for England of 3.5% for 2016/17, suggesting a complex underlying picture. NHS Digital growth rates are at list price as NHS Digital is not able to take account of rates of discount obtained by the NHS, which our analysis suggests are increasing, or of the rebate payments for branded drugs under the 2014-18 Pharmaceutical Price Regulation Scheme (PPRS). NHS Digital list price growth rates therefore overestimate underlying growth in net expenditure.

This OHE Consulting report provides an estimate of the actual NHS net spend on medicines by reconciling different sources of information. Overall it finds that:

- Primary care expenditure on branded and generic drugs at list prices grew at less than 5% per annum for the period 2012/13 to 2015/16, whilst hospital expenditure at list prices grew at more than 10% per annum.
- The main growth areas for branded medicines in primary care are the Novel Oral Anti-Coagulants and new treatments for diabetes. In the hospital sector, branded growth is coming from new infectious disease medicines, notably for Hep C and HIV, and from new oncology drugs, including immunomodulation treatments.
- Most of the branded medicines that have a significant impact on growth are, however, not sold at list prices. Of the top 250 medicines, 27% are associated with one or more of a Patient Access Scheme, Cancer Drugs Fund or NHS England (NHSE) tendering process. These products account for 50% of the absolute growth of the top 250 products at list price.
- Data from the 2014 PPRS Scheme, which gives the Department for Health and Social Care (DHSC) an accurate view of net spend on branded medicines from companies within the scheme suggests that:
    - IQVIA list price data reported 2016/17 growth for brands at list price of 5.9%, yet DHSC reported 2016/17 net growth for brands of 3.6%;
    - The discount "residual" grew by 15.9% in 2016/17 indicating an increasing difference between list and net prices, supporting our analysis that the NHS is getting better at extracting discounts from list prices from companies.
- The 2014 PPRS Scheme introduced a cap on growth of the branded medicines bill for 2014-18. The allowed growth rates average out over the 5 years at a compound average growth rate of 1.1% per annum, which is a significant real terms reduction in net branded spend by PPRS member companies.
- As the PPRS scheme progresses, a rebate payment percentage for each year is calculated if growth exceeds the allowed rate. Between 2014 and 2016 total payments made under the scheme were £1,779m.
- Medicines expenditure as a share of NHS spend in 2015 was estimated by NHS Digital at 14.3% for England. Reproducing for the four nations this approach produces an estimate of 15.4%. However, adjusting for estimated discounts and PPRS payments, the share of medicines spend is closer to 13.5%.

It is important to stress that we are analysing data to understand trends since 2014. This work does not allow us to make any predictions about future trends.

# 1 DEFINING MEDICINES EXPENDITURE

Expenditure on medicines appears to be a readily identifiable element of UK National Health Service (NHS) costs. It is the focus of much attention by national and local NHS Commissioners, and by the Department of Health and Social Care (DHSC). It receives close scrutiny when reported growth rates are perceived as "high" in comparison with NHS expenditure generally. For the year 2015/16, the Treasury reported growth in Government funded healthcare expenditure in the UK of 4.0%[1] whilst NHS Digital reported medicines expenditure growth for England for the same period of 8.0%[2]. The most recent NHS Digital report[3] however showed a decline in the growth rate for medicines expenditure for England in 2016/17 to 3.5% as compared to Treasury reported growth for the UK NHS of 3.4%[1]. The picture is complicated by a substantial increase in price discounting, such that these headline growth rates do not reflect the underlying trend in transaction prices paid by the NHS. Transaction prices are the actual prices paid, after taking account of discounts, rebates or any other payment. We also refer to these as net prices.

In spite of its importance, it has therefore become difficult to answer the question of what the true cost of medicines is in the UK. We aim to provide an estimate of the actual NHS net spend on medicines by reconciling different sources of information. Net expenditure on branded medicines can be obtained from the DHSC. Accurate information on net sales is provided by PPRS members who report "measured spend" which is sales net of discounts. This covered almost 80% of branded spend in 2016. However, data on expenditure on (i) unbranded generic medicines, and (ii) brand equalisation deals, are excluded from PPRS reported "measured spend"[4]. IQVIA Health data[5] can provide information on gross expenditure at list prices on medicines, including generic products and brand equalisation. Medicines spend at list prices is not, however, the actual medicines expenditure of the NHS. Hence the need to reconcile data from different sources to build up a picture of what is actually happening to NHS spend on medicines.

This Briefing will:

- outline the components of medicines spend;
- explain how medicines expenditure and usage is measured;
- look at growth in the medicines bill over the period of the current PPRS;
- put medicines expenditure in the context of total NHS expenditure.

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[1] House of Commons Briefing Paper Number SN0724, NHS Funding and Expenditure, 14 June 2017 using HM Treasury Country and regional analysis 2016, Tables A11. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/569815/Country_and_Regional_Analysis_November_2016.pdf Accessed on 18 December 2017).

[2] "Prescribing Costs in Hospitals and the Community, England 2015/16". NHS Digital. November 2016. Available at: http://www.content.digital.nhs.uk/catalogue/PUB22302 (Accessed on 1 June 2017).

[3] Prescribing Costs in Hospitals and the Community, England 2016/17" NHS Digital November 2017. Available at: https://digital.nhs.uk/catalogue/PUB30152 (Accessed on 18 December 2017).

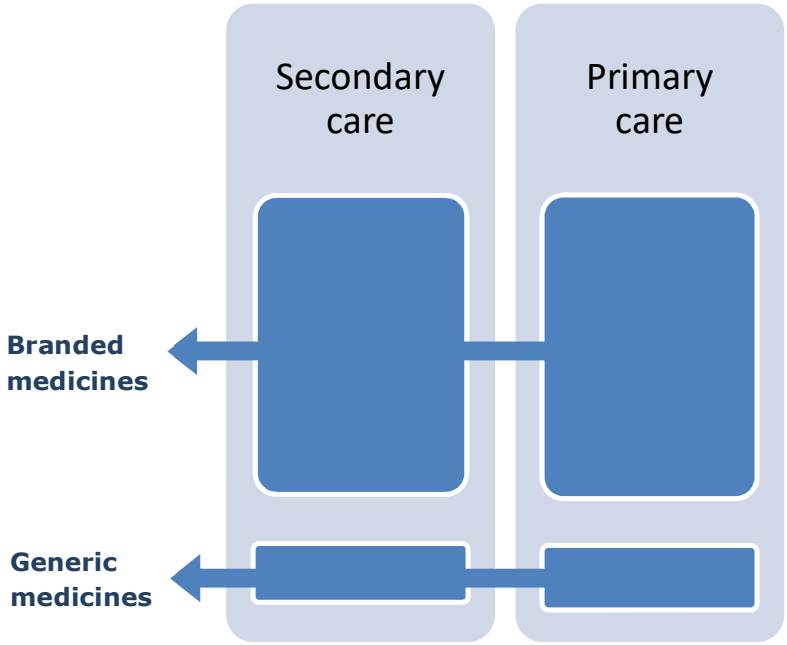
[4] The measured spend is expenditure on branded medicines supplied by companies included in the voluntary scheme, the PPRS, at net prices. For more details, including exclusions, see Section 4.1.

[5] IQVIA Health (formerly known as IMS and then QuintilesIMS) is a private company that provides information, services and technology for the healthcare industry.

# 2 THE COMPONENTS OF MEDICINES SPEND AND HOW TO MEASURE THEM

NHS medicines spend can be classified in two quite different ways. Each has two components: branded and generic medicines spend; primary and secondary care spend[6]. This is illustrated in Figure 1.

**Figure 1: The components of the medicines spend**




Source: Own elaboration.

An assessment of the accuracy of any measure of the total medicines bill can be made using the components in Figure 1. The volume of medicines used and the price paid will determine total expenditure for each component. There are two aspects of accuracy:

i) how well does the measure capture volumes of medicines used? and,
ii) which "prices" are applied? Specifically are list or net prices used?

We consider each component in turn, outlining the various data sources used to generate a value for medicines expenditure.

## *2.1 Primary care branded medicines expenditure*

There are two data sources for primary care medicines: i) Prescription Cost Analysis (PCA), and ii) IQVIA Analysis Manager.

[6]In addition the NHS supplies homecare medicines. In England these are contracted for by the NHSE Commercial Medicines Unit (CMU). We treat these as part of hospital expenditure. NHS Digital data includes IQVIA national level data. OHE have previously undertaken an audit of homecare data using company returns and found that underreporting of expenditure due to lack of IQVIA coverage is not significant. See https://www.ohe.org/publications/projecting-expenditure-medicines-nhs
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*Prescription Cost Analysis (PCA)* data is a by-product of the reimbursement system for medicines dispensed through pharmacies. Each of the four UK nations generates their own PCA data. How the data is made available varies slightly, for example, the labelling for individual medicines will not equate. This creates challenges combining UK nations' data to create a UK figure and so generally this data is reported for individual UK nations. Because the data is linked to reimbursement, by definition, reported volumes will completely capture the actual volumes reimbursed by the NHS in each UK nation. The prices used in reported PCA data are reimbursement values, known as Net Ingredient Cost (NIC). Using NIC means that the total reported values for the cost of medicines are overstated. This is because the various UK Department(s) of Health adjust the final payments for pharmacy reimbursement to reflect an estimate of the actual prices paid by pharmacists for medicines, a mechanism known colloquially as "clawback".

Clawback recognises that for some categories of medicines there are multiple sources of supply, and hence price competition. This is usually the case for generic medicines, most of which are multi-source. In the case of branded medicines, there are cases where imported parallel traded alternatives for on-patent medicines are available at a price lower than the UK price offered by the original (innovator) manufacturer. In these situations, wholesalers can offer discounts to retail pharmacists relative to reimbursement or NIC prices in order to attract orders for parallel imports.

UK reimbursement bodies assume that the level of discounting a pharmacist is able to get will depend on volumes dispensed. The average clawback is approximately 10% of the value of all medicines primary care dispensed, both branded and generics. It is, however, not possible to disaggregate this block discount to the individual prices of medicines.

*IQVIA Analysis Manager* is a commercial database primarily using volume data captured by pharmacy IT systems to manage the supply of databases. IQVIA Health validate this data using information captured through the supply chain, including manufacturers ex-factory returns and wholesaler data. Coverage for the UK, measured as a share of pharmacists supplying data, is high at greater than 90%. For UK reported volume figures, IQVIA Health will extrapolate from the sample. To create an estimate of total value of primary care branded medicines expenditure, IQVIA Health will apply list prices to the volume data captured. Again this will over-estimate the "value" of NHS expenditure on primary care medicines as it does not adjust for "clawback". There are at least two further features of the database that mean that the value of NHS expenditure will be overstated. Firstly, where a branded medicine is dispensed against a generically written prescription and the pharmacist is reimbursed for the generic price of the medicine. In these instances the price applied is the originator brand and not the generic. The former price is usually greater than the latter and hence overstates the price paid by the NHS. This feature of the medicines market is known as "brand equalisation". Secondly, the IQVIA Health database is unable to separate medicines dispensed against private prescriptions, which are not reimbursed by the NHS.

## *2.2 Primary care generic medicines*

The two sources of information on primary care generic medicines are the same as for primary care branded medicines; the UK four nations' PCA data and IQVIA Analysis Manager. PCA data is essentially panel data and IQVIA Analysis Manager captures a reasonable sample. For most generic medicines there will be more than one potential supplier and price competition means than pharmacists usually do not pay the

reimbursement price for these[7]. As pointed out earlier, however, it is not possible track the clawback adjustment to individual medicine prices and hence list prices are used.

As discussed, IQVIA Analysis Manager does not separately identify branded medicines dispensed through brand equalisation arrangements, for which the pharmacist is reimbursed at the generic price and will therefore understate the value of the primary care generic market. For PCA data, all branded medicines dispensed and reimbursed as a generic will be included in the data for generic medicines with generic NIC prices applied.

## *2.3 Secondary care branded medicines*

The most frequently cited source for secondary care medicines expenditure is IQVIA Analysis Manager. For secondary care, there is no equivalent to the PCA data generated by the NHS in each of the UK nations. This is because most hospital medicines are not reimbursed separately by NHS Commissioners. Their costs are included in hospital activity[8]. The measurement of NHS coverage used by IQVIA Health is the share of total NHS inpatient beds represented by the hospitals included its sample. For UK nations this ranges from around 90% in England to 85% in Scotland. IQVIA Health uses extrapolation to report UK volume figures. This general metric may not accurately capture coverage for medicines used in specialist indications or those not routinely used throughout the NHS. As in primary care, IQVIA Health estimate the value of medicines sold in secondary care by applying list prices to the volume data it collects. Use of list prices means that the reported value of this part of the medicines bill will be overstated. Discounting against list prices is common practice for medicines sold in secondary care as mechanisms such as Patient Access Schemes (PAS) and therapeutic tendering are increasingly applied. In almost all cases the details of such arrangements are reached under confidentiality arrangements, and therefore it is not possible to adjust for list prices and recalculate the value paid.

## *2.4 Secondary care generic medicines*

Again, the main source for secondary care generic medicines data is IQVIA Analysis Manager. The coverage issues discussed for branded medicines equally apply for generic medicines. List prices are used to estimate the total value of expenditure. In secondary care, the purchasing of generic medicines is subject to rigorous tendering processes and list prices will not reflect actual prices paid. Actual prices paid are tracked by the DHSC Commercial Medicines Unit but this information is not available in a public domain format that would enable list prices to be adjusted.

In summary, therefore there are a number of factors that mean that reported values for medicines expenditure, notably those reported by NHS Digital, for each of the components of the medicines bill do not equate to the actual cost to the NHS. The most

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[7] The DHSC seek to ensure that reimbursement prices for generic medicines track prices paid by the pharmacist (a mechanism known as Category M prices) but there will be a lag relative to market transaction prices.

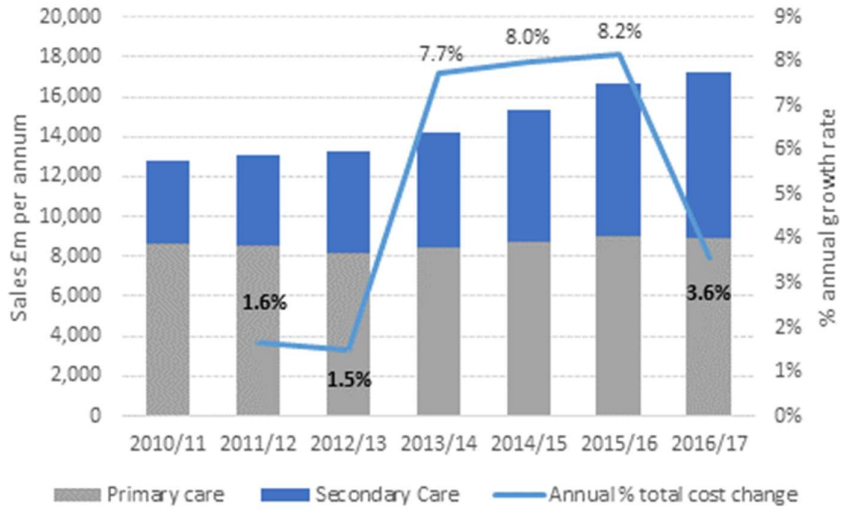
[8] In principle, analysis of NHS Provider accounts in England, collected by NHS Improvement, give an additional perspective, see for example https://improvement.nhs.uk/documents/1264/M12_201617_provider_sector_performance_report_-_Fin_Accts_-_FINAL.pdf However, our understanding is that the quality of the data is still improving.

important factor is the use of list prices in a number of markets to estimate the value of medicines expenditure, where competition or the role of NICE means that these are not prices "paid" by the NHS.

# 3 EVOLUTION OF MEDICINES EXPENDITURE 2014-2017

NHS Digital reported that the prescribing cost, at list price, across the NHS in England had been increasing since 2013/2014, driven by growth in hospital medicines. In 2016/17 there was a fall in the rate of growth contributed to by a decline in primary care expenditure and a slowdown in the growth rate in secondary care (see Figure 2 below and Figure 3 overleaf).[9]

**Figure 2: Estimated prescribing cost to the NHS in England, in £m**




Source: NHS Digital[10].
Note: Primary care also includes FP10HP[11].

We can see from Figure 3 that primary care expenditure at list prices has been growing at less than 5% per annum in the period 2012/13 to 2015/16 whilst hospital expenditure at list prices has been growing at more than 10% per annum over the same period. There has been a slowdown in growth in both primary care and secondary care expenditure during 2016/17.

NHS Digital reported recent growth in medicines expenditure as being at a rate faster than NHS expenditure generally. Figure 4 shows that since 2012/13, NHS Digital estimates that medicines expenditure at list prices as a share of total NHS expenditure has increased from 12.7% to 14.5%.

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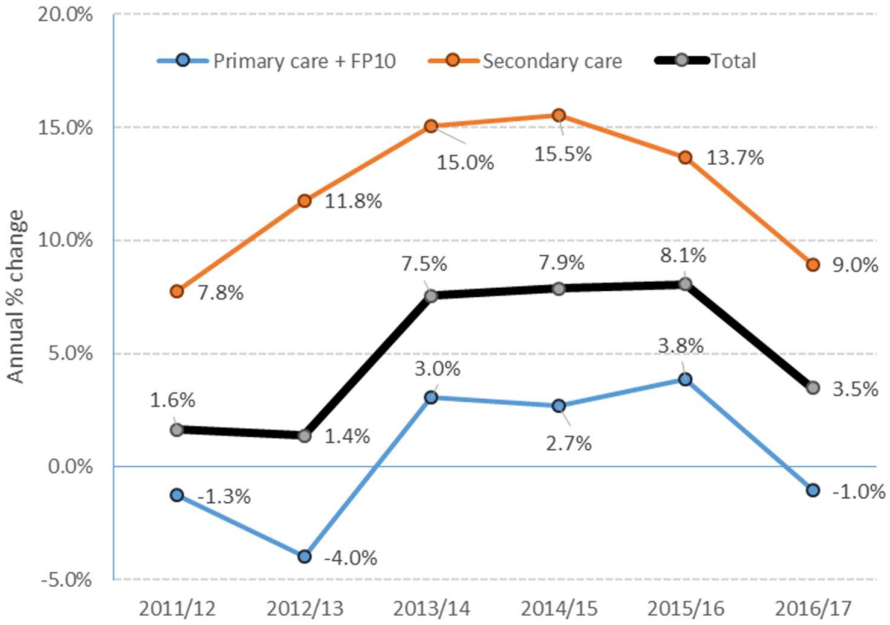
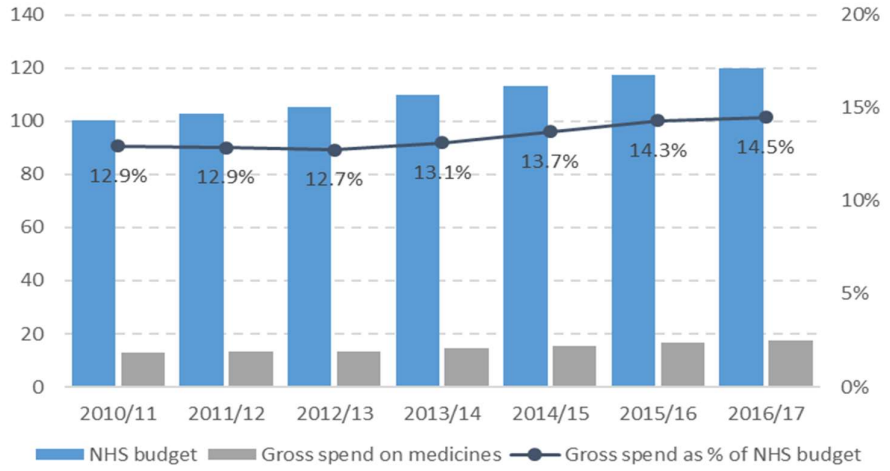
[9] NHS Digital uses the Hospital Prescribing Audit Index (HPAI) database provided by IQVIA for hospital use of medicines and the databases maintained by the Prescription Services Division, part of the NHS Business Services Authority, for the data for medicine use in the other two sectors, primary care and hospital prescribed medicines dispensed in the community.
[10] "Prescribing Costs in Hospitals and the Community, England 2016/17". NHS Digital. November 2017. Available at: https://digital.nhs.uk/catalogue/PUB30152 (Accessed on 30 November 2017).
[11] FP10HP prescriptions are medicines prescribed in a secondary care setting, such as an outpatient clinic, and dispensed for use by the patient at home.

**Figure 3: Annual estimated prescribing cost growth in England, 2011/12 to 2016/17**




Source: NHS Digital.[7]

**Figure 4: NHS budget and estimated prescribing cost in England, 2010/2011 to 2016/2017**

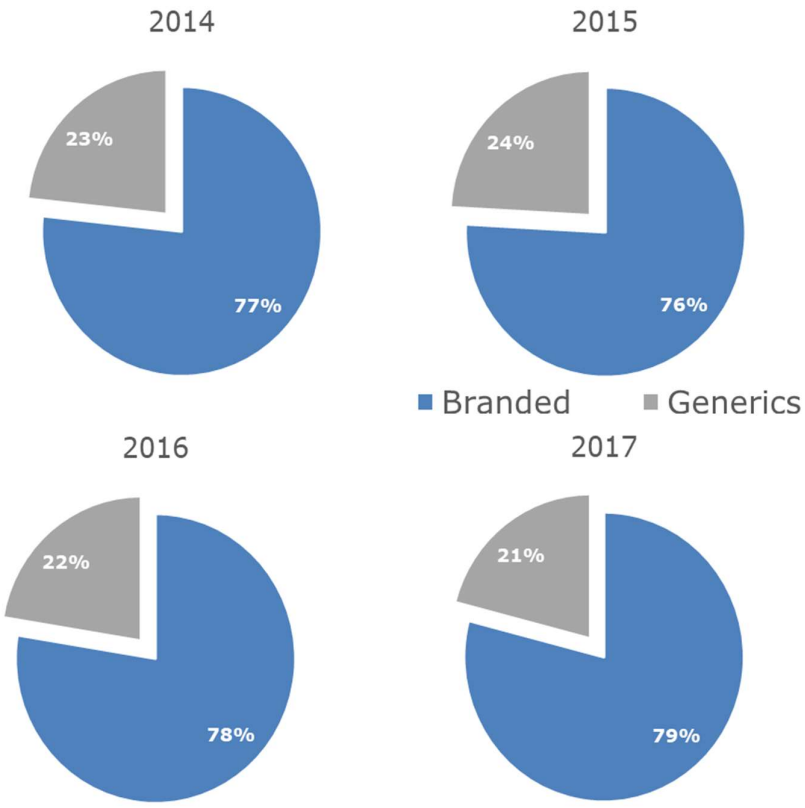



Source: NHS Digital[1] and HM Treasury[12].
Notes: The NHS budget is the Departmental Expenditure Limits (DEL) for the NHS. It is the government budget that is allocated to and spent by the NHS and it covers spending that the government argues can be controlled rather than being driven by demand.

[12] "Public Expenditure Statistical Analyses 2017". National Statistics, HM Treasury. July 2017. Available at: https://www.gov.uk/government/statistics/public-expenditure-statistical-analyses-2017 (Accessed on 16 January 2018)

We next explore the contribution of various segments of the medicines bill. For the UK, using IQVIA Health data, we can identify, at list prices, how much of the medicines spend corresponds to generics and branded medicines.

**Figure 5: Medicines spend at list prices, branded and generics spend in the UK**



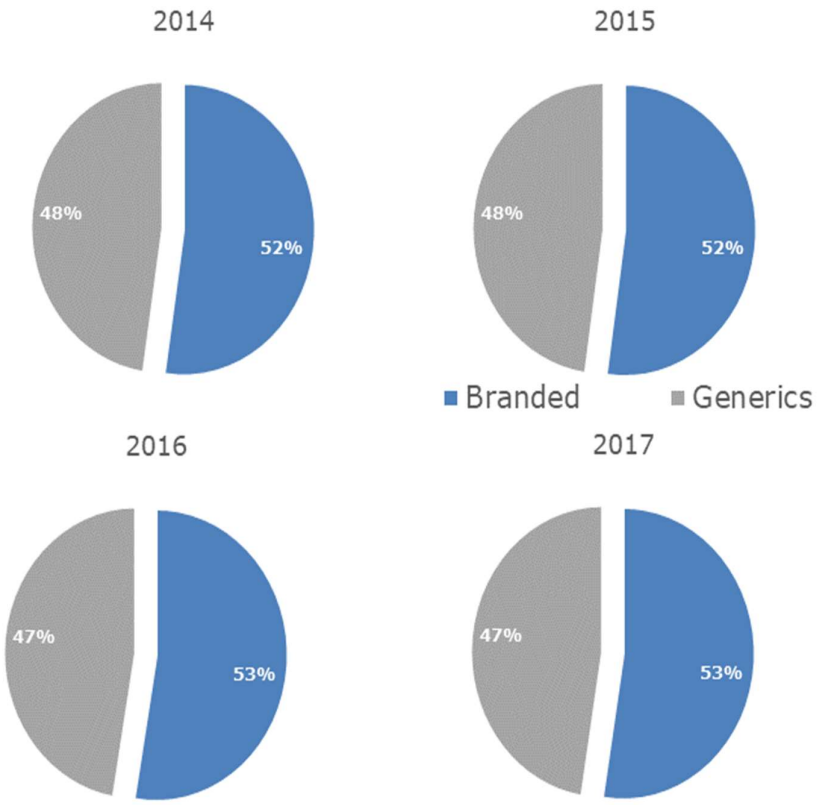

Source: Source IQVIA Analysis Manager accessed on 7 February 2018

Figure 5 shows that the IQVIA reported share of branded and generic spend on the total medicines spend at list prices has remained relatively stable during the last years, at around 25% and 75% respectively for the share by value of generic and branded spend. Note branded medicines in IQVIA data include those that are dispensed and reimbursed as generics.

Although a greater share of medicines expenditure is accounted for by branded medicines, assessing the market using volume shares provides a different view. Figure 6 below shows, for the primary care market only, the share of branded and generic medicines using counting units as the measure[13]. Figure 6 below plots the market share for branded and generic medicines and show the split between the two, using this measure, is more equal.

[13] Counting Units seek to approximately equate different dose forms to a standard measure of a single dose e.g. one tablet or vial. Secondary care medicines have been excluded from the analysis as summary statistics are skewed by changes in the definition of counting units over time.

**Figure 6: Volume market share, branded and generics primary care sales, in the UK**

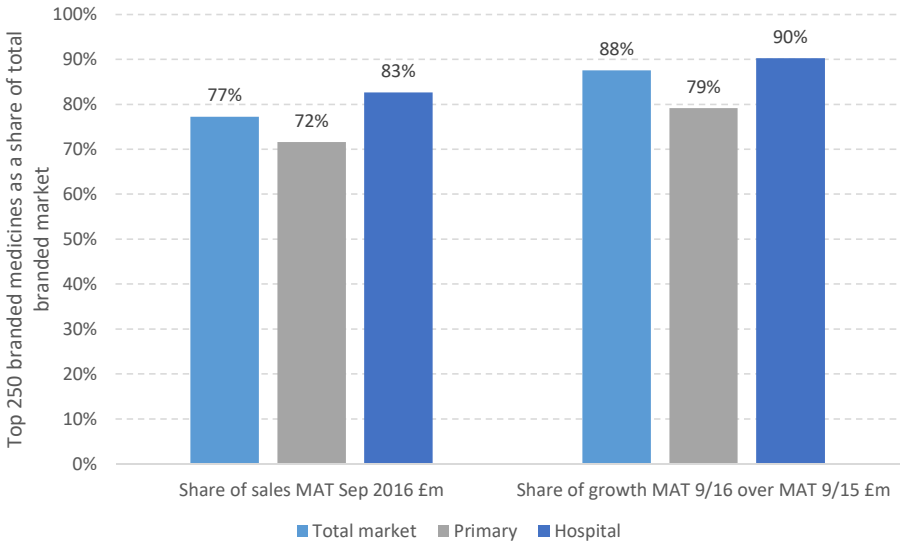



Source: Source IQVIA Analysis Manager accessed on 7 February 2018

## *3.1 The branded medicines market in 2016*

For most commodities, growth in the value of total sales can be presented as changes in either volumes or prices over time. For branded medicines an overall assessment of volumes is challenging. This is because the measure of volume for different medicines can be radically different. A medicine may range from a single tablet to several thousand units in a suspension, and "counts" of these cannot simply be combined for a single volume measure. Instead we concentrate on assessing volume growth rates for those medicines that contribute the most to overall increases in the value of medicines expenditure.

**Figure 7: UK Top 250 branded medicines by sales value: share of total market sales and annual growth MAT September 2016**




Source: Source IQVIA Analysis Manager accessed on 23 November 2016
Note: MAT - Moving annual total.

Using data from IQVIA Health, at list prices, for the twelve months to the end of September 2016, we observe that the branded medicines market is concentrated. The total sales of branded medicines were £14,993m in the year to September 2016 (MAT Sep)[14]. The sales of the top 250 branded medicines (by sales) were £11,573m representing 77% of the total branded market in the 12 months to September 2016. They accounted for 88% of the value of growth in the market between the 12 months to September 2015 and the 12 months to September 2016 (see Figure 7 above). It is therefore reasonable to use this sample as the basis to assess growth in branded sales overall and to draw conclusions about the contribution of changes in volume growth rates.

Of the sales of the top 250 branded medicines, 20% (£2,399m) belonged to products launched over the past 5 years, which, in turn, explain more than 90% (£1,009m) of £1,105m of growth in the 12 months to September 2016 (see Figure 8 overleaf). This demonstrates the importance of "new products" on medicines bill growth overall.

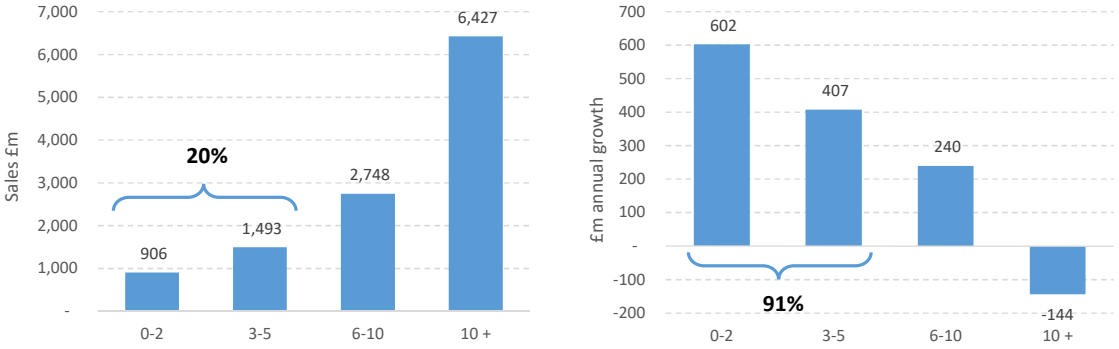
The pattern is similar in both primary and secondary care. In primary care, products launched in the last 5 years accounted for £493m (9%) of sales out of £5,265m, and £237m (96%) out of £248m of growth in the 12 months to September 2016. For secondary care, products launched over the past 5 years accounted for £1,905m (30%) sales out of £6,308m, and £773m (90%) out of £857m of growth in the 12 months to September 2016 (see Figure 9 overleaf). Both primary and secondary care markets have seen successful launches in new therapy areas in recent years:

- in primary care, new classes of diabetes medicines, launches of novel oral anti-coagulants (NOACs), and new generation asthma medicines have driven growth;

[14] MAT: Moving Annual Total, that is the total value of a variable, such as sales in this example, over the course of the previous 12 months.

- in secondary care, new treatments for hepatitis C have been entering the market since 2014, there has been an important new treatment for macular degeneration, and a number of new cancer medicines have been introduced.

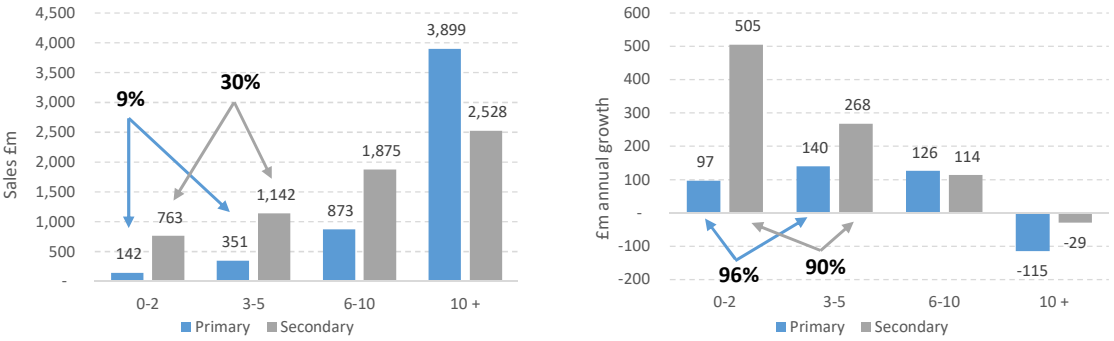
**Figure 8: UK Top 250 branded medicines sales – All channels**




(a) By product age £m (b) By absolute growth

Notes: MAT 9/2016 – All channels (primary + secondary care)
Source: Source IQVIA Analysis Manager accessed on 23 November 2016

**Figure 9: UK Top 250 sales – Primary and Secondary Care**



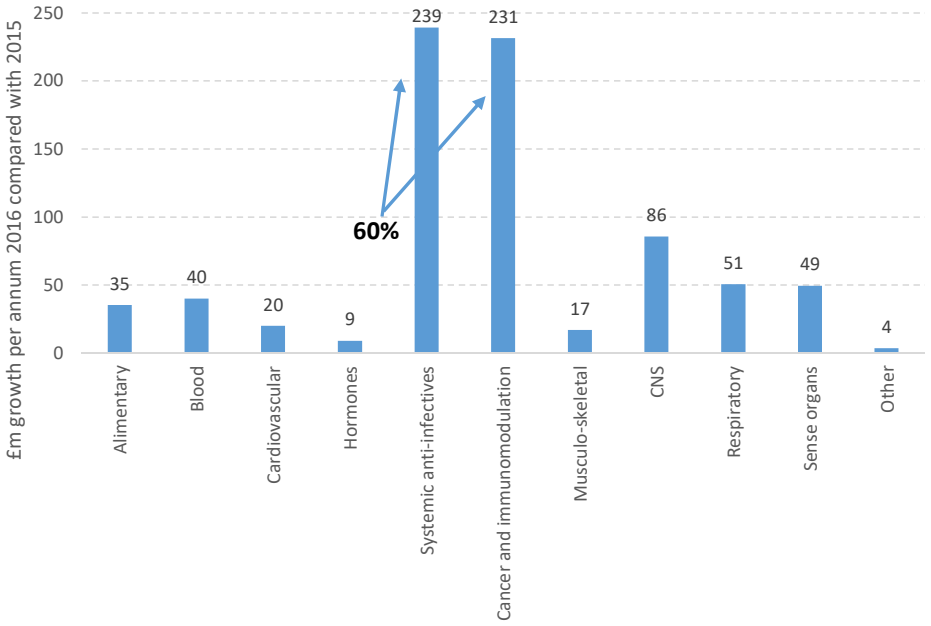

(a) By product age £m (b) By absolute growth

Notes: MAT 9/2016
Source: Source IQVIA Analysis Manager accessed on 23 November 2016

We can take a closer look as to the products that most affected sales and its growth in the 12 months to September 2016. In terms of ATC classification[15], Figure 10 shows that 60% of the absolute cash growth for the top 250 branded medicines was attributable to two therapy classes: systemic anti-infectives (£239m), and cancer and immunomodulation (£231m).

[15] The Anatomical Therapeutic Chemical (ATC) Classification System is used for the classification of active ingredients of drugs according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties.

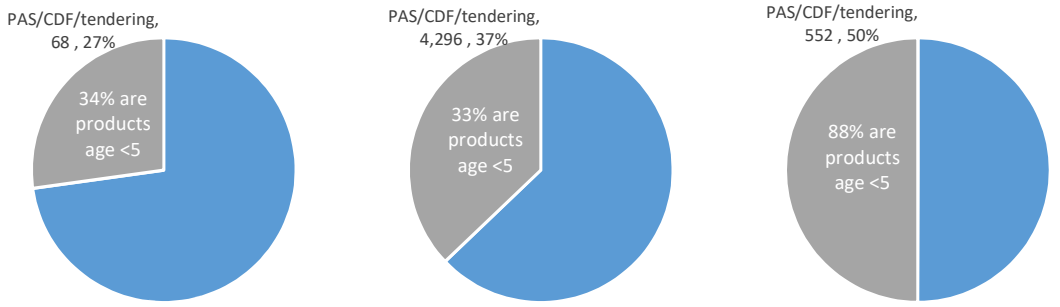
**Figure 10: UK 2016 growth £m secondary care branded medicines by ATC1 class**




Notes: MAT 9/2016
Source: Source IQVIA Analysis Manager accessed on 23 November 2016

However, most of the medicines that have a significant impact on growth are not sold at list prices. 27% of the top 250 medicines are associated with one or more of a PAS, CDF or NHSE tendering process. These products account for 37% of the top 250 market sales and 50% of the absolute growth of the top 250 products (see Figure 11 below).

**Figure 11: UK Medicines associated with PAS, CDF or NHSE tendering processes[16]**




(a) Count of top 250 products

(b) Top 250 sales £m

(c) top 250 sales by absolute growth £m

Notes: MAT 9/2016 – All channels (primary and secondary care)
Source: Source IQVIA Analysis Manager accessed on 23 November 2016

This analysis uses expenditure or "cash" growth. Comparing this "cash growth" with volume growth, we find almost all "discounted" medicines have volume and value growth

[16] Note that Direct-acting Antiviral Agents (DAAs) for the treatment of Hepatitis C virus (HCV) account for 2% of products and 23% of growth. This indicates their importance but also that the effects we describe are not simply the result of the NHS handling the DAAs for HCV.

in the same range. This supports our view that volume increases in "discounted" medicines are having a significant impact on growth[17].

## *3.2 The branded medicines market in 2017*

The analysis undertaken by NHS Digital indicated a slowdown in branded medicines growth in 2017. For the 12 months to March 2017 overall growth declined from approximately 8% per annum for the previous three years to 3.5%. The slowdown was seen in both primary care and secondary care markets. Primary care growth slowed from 3.8% to -1% and secondary care growth slowed from 13.7% to 9%.

IQVIA data for 2017 provides supporting evidence of the slowdown in growth. The IQVIA calendar 2016 figures in Table 1 show an overall growth rate of 4.7% broadly consistent with 3.5% figure for the 12 months to March 2017 reported by NHS Digital. The IQVIA data shows a greater contribution to the trend from the primary care market (minus 2.8% compared with minus 1% reported by NHS Digital) and secondary care growing at a rate of 10% compared with the 9% seen in the NHS Digital analysis.

**Table 1: UK Branded Market Growth At list prices for 2014-2017**

| | 2014 £m per annum | 2015 £m per annum | 2016 £m per annum | 2017 £m per annum |
|---|---|---|---|---|
| **Total market** | **16875** | **18568** | **19433** | **20225** |
| *of which branded* | *12944* | *14089* | *15079* | *15987* |
| *of which generic* | *3932* | *4479* | *4354* | *4238* |
| **Primary care** | **9663** | **10318** | **10360** | **10035** |
| *of which branded* | *6934* | *7141* | *7395* | *7368* |
| *of which generic* | *2729* | *3178* | *2965* | *2667* |
| **Secondary care** | **7213** | **8250** | **9074** | **10190** |
| *of which branded* | *6010* | *6948* | *7684* | *8619* |
| *of which generic* | *1202* | *1302* | *1389* | *1571* |

| | Growth 2015/2014 | Growth 2016/2015 | Growth 2017/2016 |
|---|---|---|---|
| **Total market** | **10.0%** | **4.7%** | **4.1%** |
| *of which branded* | 8.8% | 7.0% | 6.0% |
| *of which generic* | 13.9% | -2.8% | -2.7% |
| **Primary care** | 6.8% | 0.4% | -3.1% |
| *of which branded* | 3.0% | 3.6% | -0.4% |
| *of which generic* | 16.4% | -6.7% | -10.1% |
| **Secondary care** | 14.4% | 10.0% | 12.3% |
| *of which branded* | 15.6% | 10.6% | 12.2% |
| *of which generic* | 8.2% | 6.7% | 13.1% |

Source: IQVIA Analysis Manager: accessed 07/02/2018. Excludes ATC classes K&T and note combines two Analysis Manager databases and some growth may be due to reporting differences.

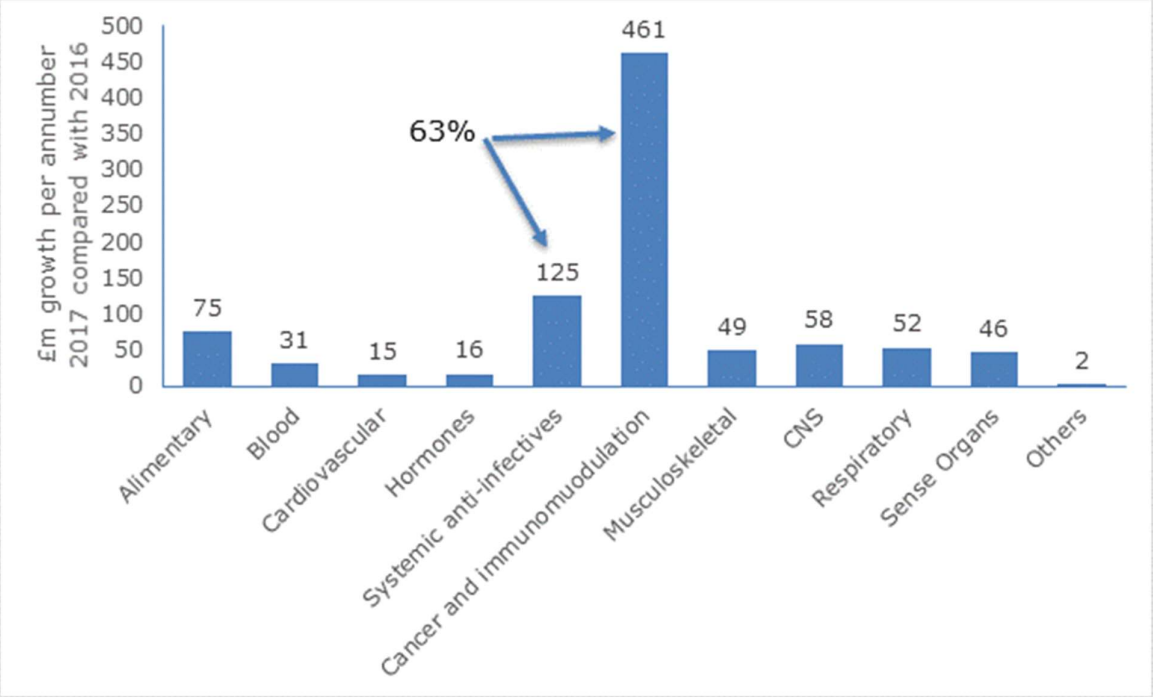
Overall 2017 growth rates in the Table 1 analysis of IQVIA data are broadly comparable with 2016, 4.1% for 2017 compared with 4.7% for 2016. Underlying this is an increasing

[17] Of course, another factor maybe the growth in list prices of new medicines, which are typically set by reference to other European or global markets. This may require greater discounting to achieve NICE's cost-per-QALY threshold. The effect is still the same, however, growth at net prices is lower than growth at list prices.

decline in the primary care market, with both brands and generics having a negative growth rate, offset by an increased growth rate in secondary care, for both branded and generic medicines.

Growth in the secondary care branded market by therapy area is consistent with previous years, with nearly two-thirds of growth attributable to the two ATC1 classes Cancer and Immunomodulation, and Systemic Anti-invectives (mainly HIV and hepatitis C). Figure 12 shows the contribution of growth by ATC1 class and shows a similar pattern to previous years. As previously noted, these are therapy classes that attract greater than average levels of discounts and therefore growth at prices net of discounts will be lower.

**Figure 12: UK 2017 growth £m secondary care branded medicines by ATC1 class**



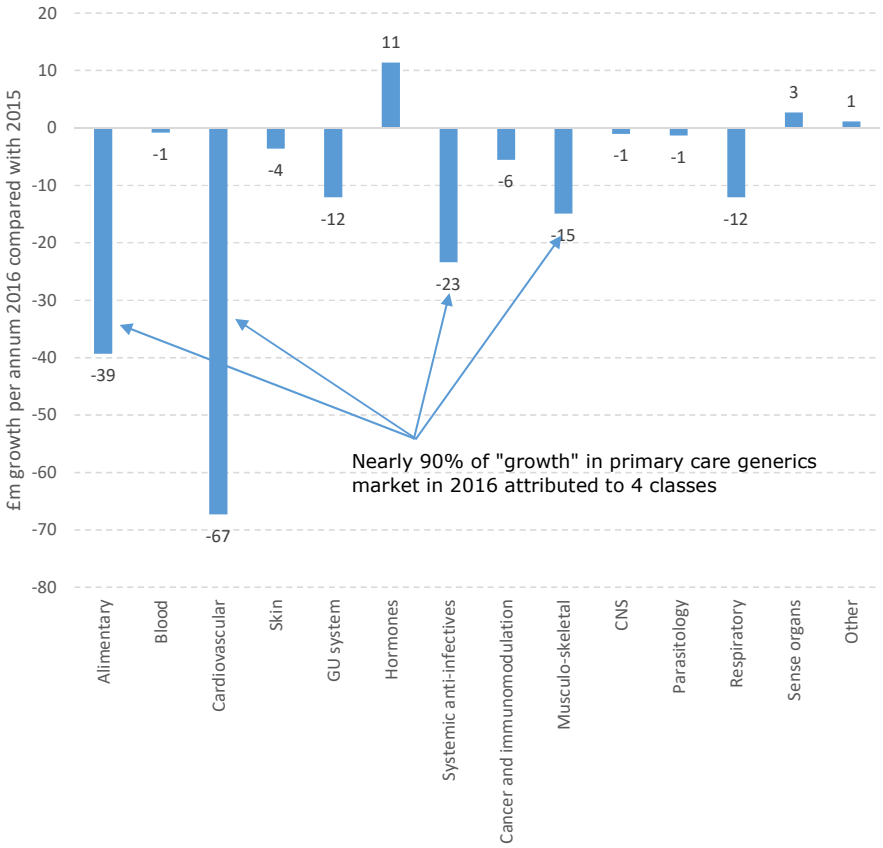

Within the Cancer and Immunomodulation class the two subclasses with the greatest rates of growth were Anti-TNF medicines, contributing £100m to growth, and monoclonal antibodies contributing £169m. The former subclass is now subject to significant bio-similar competition meaning that discounting levels are likely to be substantial.

## *3.3 The generic medicines market in 2016*

Using IQVIA reported numbers in Table 1, we can see that the total value of the generics market (primary and secondary care) shrank by 2.8% in 2016 compared with 2015. The main factor driving this is a reduction in the value of the primary care generics market of 6.7% over the same period.

Almost all the of this reduction in growth in primary care generic medicines is associated with four classes of medicines; cardiovascular, alimentary, musculoskeletal systems and systemic anti-infectives. This is shown in Figure 13 where the contribution to 2016 growth of each broad therapy area of generic medicine is plotted.

**Figure 13: UK 2016 growth £m primary care generics by ATC1 class**




Note: "Nervous system", CNS.
Source: Source IQVIA Analysis Manager accessed on 1 June 2017.

The reduction in the total value of growth for many classes, reported in Figure 13 can be broken down into changes in "volumes" and "prices". Table 2 reports these changes by ATC1 class for 2016. The first column lists class names. These are ranked by 2016 total sales (reported in the second column) to highlight the classes contributing most to the evolution of total sales. Column 3 reports overall growth in 2016, as a %. Column 4 "Growth 2016 cu "volume" is a measure of volume growth, calculating total counting units (cu) growth per ATC1 class[18]. The last column is a measure of "price" growth, measuring the change in total value of sales in the class divided by counting units i.e. cost per counting unit[19]. For many ATC1 classes there is either low or negative volume growth outweighed by even greater negative growth in "prices". Hence, for almost all classes, overall growth in 2016 has been negative.

[18] As we noted earlier it is not straightforward to aggregate different types of medicine. Counting Units approximate broadly to one "dose" e.g. a single tablet, vial, or inhaler puff.
[19] Note an element of the average change in cost per counting unit will be a change in the mix of medicines dispensed by therapy area. If the share of relatively "cheaper" medicines dispensed increases then the average cost per counting unit will decline.

**Table 2: UK market for generics by broad class (sales in 2016, growth £m, growth in counting units and price per counting unit)**

| ATC 1 | 2016 sales £m | Growth 2016 £m% | Growth 2016 cu "Volume" | Growth 2016 cost per cu "Price" |
|---|---|---|---|---|
| CNS | 990.6 | 0% | 2% | -17% |
| **Cardiovascular** | 489.9 | -12% | **1%** | **-15%** |
| **Alimentary** | 450.9 | -8% | **2%** | **-8%** |
| Hormones | 362.9 | 3% | 2% | 0% |
| **Systemic anti-infectives** | 166.2 | -12% | **-3%** | **-13%** |
| GU system | 109.8 | -10% | 8% | -16% |
| Blood | 109.8 | -1% | -2% | 2% |
| **Musculo-skeletal** | 103 | -13% | **-3%** | **-14%** |
| Respiratory | 81.4 | -13% | 3% | 3% |
| Skin | 48.1 | -6% | -13% | 123% |
| Sense organs | 41.2 | 7% | 4% | -13% |
| Cancer and immunomodulation | 37.3 | -13% | 6% | -25% |
| Parasitology | 15.9 | -7% | -3% | -19% |
| Other | 5.3 | 28% | 23% | 111% |

Source: Source IQVIA Analysis Manager accessed on 1 June 2017.

Looking at primary care Prescription Cost Analysis (PCA) data for England for the same period, the pattern of negative generics market growth consists of low volume growth out-weighed by a greater reduction in "prices". Table 3 below shows that total NIC for medicines prescribed and dispensed as a generic has declined in value (Net ingredient cost NIC), by 1.3%, with volumes (prescription items) increasing by 2.3% and cost per prescription item ("prices") falling by 3.5%.

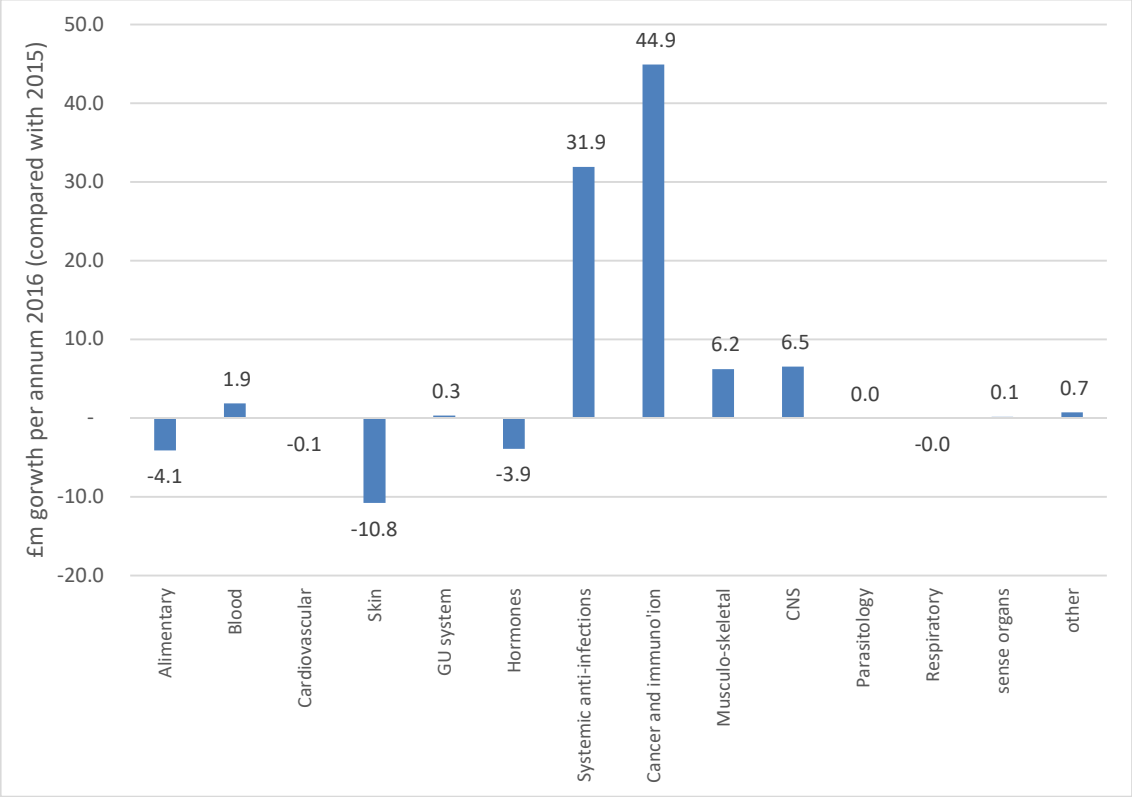
**Table 3: Primary care generic medicines sales growth, volume and value, England (using PCA data)**

| | 2015 | 2016 | Change |
|---|---|---|---|
| NIC £ | 3,486,394,156 | 3,439,800,703 | -1.30% |
| Rx items | 807,059,110 | 825,557,786 | 2.30% |
| cost per Rx item £ | 4.32 | 4.17 | -3.50% |

Source: NHS Digital (2017)

Figure 14 below shows that in secondary care, two classes, Systemic Anti-infectives, and Cancer and Immunomodulation, account for almost all growth in generic medicines volumes. They are both markets with recent instances of medicines moving off-patent. The sub-classes underlying growth are, however, different to those found in the secondary care branded market. Around two-thirds of growth in Systemic Anti-infectives is attributed to Antibiotics and Anti-bacterials. For Cancer and Immunomodulation approximately one quarter of growth is for a medicine used to counteract transplant rejection.

**Figure 14: UK Secondary care generic medicines value growth for key therapy classes 2016 over 2015**




## *3.4 Recent developments in the generic medicines market*

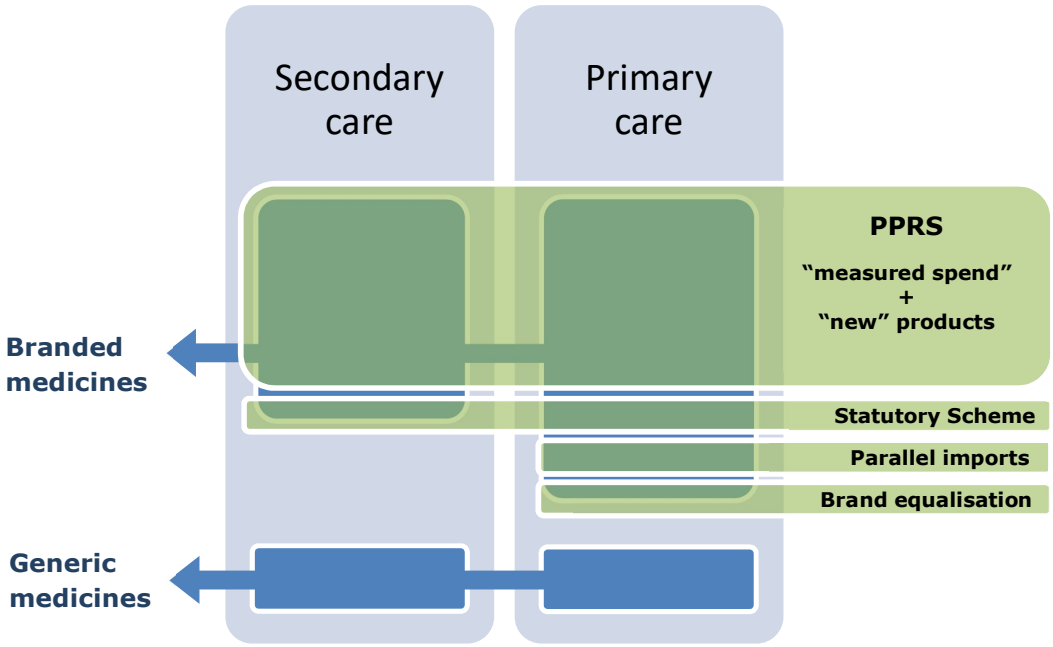
The analysis we show in Table 1 shows a continued decline in the generic market in 2017 at list prices using IQVIA data, with secondary market growth offset by continued decline in primary care. However, there were significant price rises for some primary care generics in 2017/18. In January 2018 the National Audit Office (NAO) announced[20] "an investigation of the extent of, and response to, increased expenditure on generic drugs in the NHS." This reported in June 2018[21] and found that the price increases came from a small number of medicines for which pharmacists found themselves unable to purchase at the Drug Tariff Price. They were forced to seek "concessionary pricing". The DHSC agreed to 709 price concessions in 2017-18 as compared to 282 in 2016-17. The NAO estimated that this cost £315m over and above the Drug Tariff prices for those medicines. Ten medicines accounted for "around half of this net spend." The DHSC identified "three main underlying causes" which were (i) regulators "suspending the licences of three manufacturers of generic medicines" (ii) "a fall in the value of sterling" and downward pressure on prices in other countries leading to market exit to an extent that "the reduced capacity and competition then increased prices within the UK market."

[20] National Audit Office Press Release Posted 22nd January 2018.
[21] Available at https://www.nao.org.uk/wp-content/uploads/2018/06/Investigation-into-NHS-spending-on-generic-medicines-in-primary-care.pdf

# 4 MOVING FROM LIST PRICE TO NET EXPENDITURE

We have analysed trends using IQVIA list prices. We now seek to move from list prices to net prices. To do this we draw on analysis of spending by regulatory component. A typology is set out in Figure 15.

**Figure 15: The components of the medicines spend and relevant regulatory instruments**




Source: Own elaboration.

We begin by describing each of these elements.

## *4.1 The PPRS and rebate mechanism*

In the UK, for the majority of companies supplying branded medicines, prices are managed through a price, profit and expenditure control system known as the Pharmaceutical Price Regulation Scheme (PPRS). The PPRS is a voluntary agreement with the branded pharmaceutical industry. Companies that choose to participate in the scheme agree to have both costs and sales values associated with medicines sold to the NHS audited. From this, profitability is assessed against agreed benchmarks. There is a restriction on price increases other than in exceptional circumstances, or when there are offsetting reductions in prices elsewhere.[22]

For the 2014 PPRS an additional agreement was reached to set a cap on the growth of the branded medicines bill, known as "measured spend". Under the current PPRS, companies make rebate payments to the DHSC when growth exceeds the agreed limit, known as the "allowed growth rate". The allowed growth rates were set at zero % for

[22] For details of the current PPRS see DHSC (2014) available at https://www.gov.uk/government/publications/pharmaceutical-price-regulation-scheme-2014

2014 and 2015, 1.8% for 2016 and 2017 and 1.9% for 2018. Averaging out the allowable growth over the 5 years gives 1.1% per annum, which is a significant real terms reduction in net branded spend by PPRS member companies. As the PPRS scheme progressed a payment percentage for each year was calculated. This was based on expected growth rates in measured spend for the year based on growth in previous years of the scheme. For example, an anticipated rate of growth in measured spend in 2016 was based on actual growth in 2014 and 2015. This level of anticipated measured spend was compared with the allowed growth rate. A rebate payment percentage was calculated which would deliver anticipated required growth rates. This mechanism was amended in December 2016, with the payment percentage for 2017 set at 4.75% to deliver an agreed anticipated level of rebate. The rebate payment in 2018 will be set between 2.38% and 7.80% depending on the growth in 2017 measured spend. Between 2014 and 2016 total payments made under the scheme were £1,779m[23].

## *4.2 The Statutory Scheme*

Companies choosing not to enter the PPRS are subject to a Statutory Scheme that has operated on the basis of reductions to the published 'list' prices of branded medicines. Following the agreement of the PPRS beginning 2014, the government consulted on and then imposed a 15% price cut in list prices on companies subject to the Statutory Scheme. Since 2014, however, the savings delivered by the Statutory Scheme have been lower than the DHSC anticipated. This is mainly due to discounting in secondary care markets. If companies already offer discounts on list prices, then a reduction in list price will not necessarily lead to a reduction in the net price paid by the NHS. The DHSC did consult on a proposal to move the Statutory Scheme to using actual prices paid rather than list prices as the basis for a price cut, but decided this would not be feasible.

To address this, the Health Service Medical Supplies (Costs) Act 2017[24], which came into force on 27 April 2017, amended the NHS Act 2006 to allow the cost of medicines under the Statutory Scheme to be controlled in a similar way to the expenditure control used in the PPRS, i.e. using a levy on sales to limit the cost of health service medicines. The DHSC has introduced regulations for a levy of 7.8% on Statutory Scheme members in 2018.

## *4.3 Components of the medicines spend*

Membership of either the PPRS voluntary or Statutory Scheme entails a requirement for companies to supply information on sales to the DHSC. The quality of data provided is ensured through adherence to auditing processes. As a consequence, the DHSC has accurate summary information concerning the net value of each company's sales.

***Measured spend base***

Companies participating in the voluntary scheme provide net sales information for medicines supplied directly to the UK market. This is comprised of three elements:

i. "new" products defined as branded medicines launched after 1 January 2014;
ii. medicines supplied through primary care under brand equalisation arrangements;

[23] See https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/669216/PPRS_Aggregate_net_sales_and_payment_information_November_2017.pdf

[24] See the Impact Assessment for the consultation to reform the Statutory Scheme https://www.gov.uk/government/consultations/revisions-to-statutory-scheme-for-pricing-branded-nhs-medicines

iii. all other branded medicines.

PPRS rebate payments are made only on "measured spend" which excludes ii. As noted above, branded medicines supplied under brand equalisation arrangements are dispensed against a generic prescription and reimbursed at a generic price. From the point of view of UK pricing and reimbursement arrangements they are essentially "generic" medicines, so they are recognised by the DHSC as part of the generic medicines bill rather than the branded medicines bill and they are excluded from net PPRS sales, i.e. excluded from the measured spend.

"New products" are included in the calculation of measured spend in order to assess the overall rebate due, but excluded from the calculation of the amount of rebate paid by each company. This is to avoid a disincentive to launch new medicines onto the UK market.

Companies that are part of the PPRS but have an NHS turnover of less than £5m per annum are exempt from making the PPRS rebate payment. They are however subject to the same requirements for the provision of information.

***Parallel imports***

An additional consideration when assessing the branded medicines bill is medicines supplied through parallel imports. Parallel Imported medicines (PI) are branded medicines supplied to the UK by wholesalers using a Parallel Importer's license. The PI market exists as a consequence of a combination of freedom to trade within the European Union as part of the Single Market, and a difference in prices for branded medicines between the UK and some European Union national markets. As measured spend, and the level of rebate paid, relates to medicines supplied to the NHS from UK-based companies who are members of the PPRS, parallel traded supply is excluded from the measured spend assessment[25].

## *4.4 Moving from list prices to net expenditure*

Returns from PPRS and Statutory Scheme companies provide accurate information on the total net spend on branded medicines in the UK. By reconciling data supplied to the DHSC with list price sales data from IQVIA Health, it is possible to get a better estimate of the value of branded medicines sold to the NHS and understand the trends underlying growth. This approach also provides an estimate of total NHS expenditure on medicines (i.e. both brands and generics) in the UK.

Table 4 overleaf sets out a reconciliation between DHSC net reported total expenditure on branded medicines and an IQVIA Health estimate of the medicines bill at list prices.

[25] Parallel trade is influenced by the £/€ exchange. If the € goes down relative to the £, then medicines priced in € are cheaper in £ and so parallel trade into the UK increases. In Quarter 1 2013 the average rate was 1.18 €/£, and in Quarter 1 2018 it was 1.13 €/£. However, for 2015 the quarterly average was above €/£1.35 reaching €/£1.39 in Q4 representing a 15% depreciation against the £, making parallel imports more attractive. The lowest quarterly €/£ exchange rate was Q4 2017 at €/£ 1.11.

**Table 4: Reconciliation between DHSC reported branded spend and IQVIA Health Medicines bill**

| | | Value £m for 12-month period | | | Growth% | |
|---|---|---|---|---|---|---|
| | | **2014** | **MAT Q1 16** | **MAT Q1 17** | **MAT Q1 16** | **MAT Q1 17** |
| *a* | Measured spend base (net) | 8,317 | 8,548 | 8,905 | 2.78% | 4.18% |
| *b* | Measured spend (+ PI + less than £5m voluntary + Statutory branded sales (net)) | 9,600 | 10,573 | 10,954 | 10.14% | 3.60% |
| ***c*** | **Residual / discount** | **-2151** | **-2,463** | **-2,854** | **14.50%** | **15.87%** |
| d | IQVIA value Measured spend (+ PI + less than £5m voluntary) + Statutory branded sales (net) | 11,751 | 13,036 | 13,808 | 10.94% | 5.92% |
| *e* | Excluded due to data | | 252 | 339 | | 34.52% |
| *f* | Brand equalisation | 1,048 | 1,174 | 1,134 | 12.02% | -3.41% |
| *g* | Generic products | 3,923 | 4,485 | 4,313 | 14.33% | -3.84% |
| *h* | IQVIA Estimate for whole market based on list prices | 16,722 | 18,948 | 19,595 | 13.31% | 3.41% |

Source: DHSC and ABPI.

In Table 4:

- Rows *a* and *b*, shaded in grey, are a summary of net price sales data supplied to the DHSC.
- Rows *d* through *g*, shaded blue, report IQVIA Health list price data on the UK market for various components of the medicines bill.
- Row *h*, also shaded blue, is IQVIA Health reported sales at list prices for the total UK medicines bill.

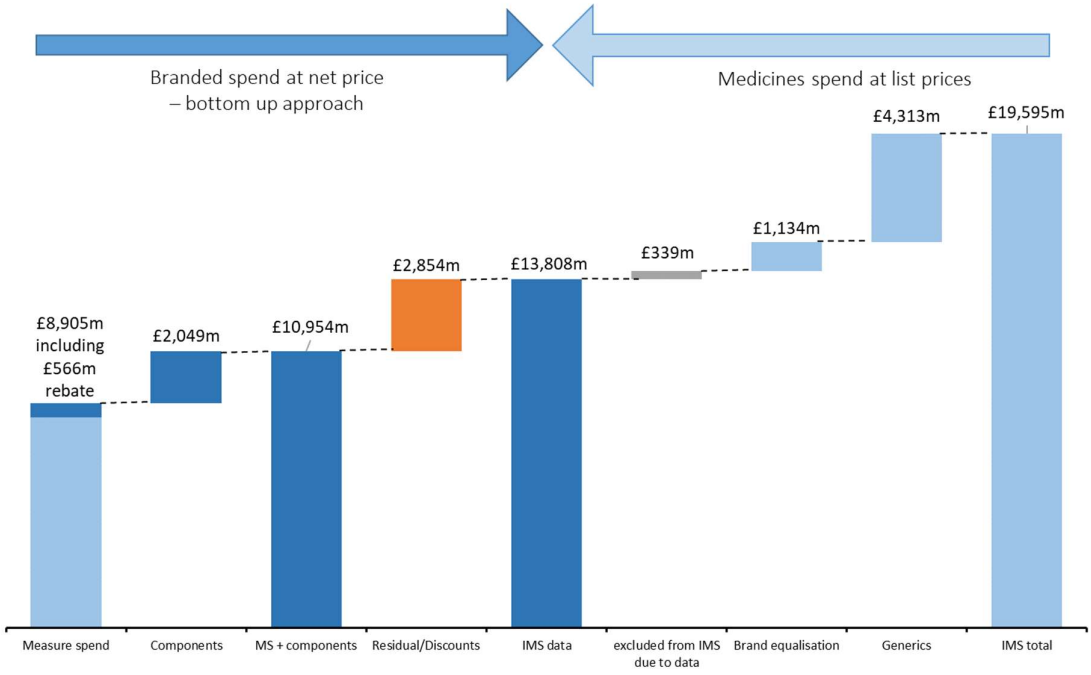
Figure 16 presents the same data in graphical form for the year 2016/17

In order to reconcile with DHSC returns on branded sales, medicines not included in the returns need to be excluded. These are generic medicines and branded medicines supplied through brand equalisation arrangements (columns *g* and *f*, respectively). An additional element are sales excluded from measured spend where voluntary company sales cannot be measured (column *e*). By subtracting these elements from the total bill the remaining sample of medicines should match the medicines included in the DHSC summary net price branded sales data (i.e. the basket of medicines in both should be the same). This is shown in row *d* and should include the same medicines underlying the DHSC measure of the net value of sales in column *b*. The difference between row *b* and *d* is shown in row *c* and labelled as "Residual". The difference between the two can be attributed to (a) the difference between list and net prices and (b) the scope of products covered.

As can be seen, the faster rate of growth in row *d* (5.92%% in 2016/17) than in DHSC net reported values (row *b* and 3.60% in 2016/17) can be attributed to an increasing difference between list and net prices. In addition, companies included in the voluntary scheme have been making rebate payments. As we noted above, between 2014 and 2016 total payments made under the scheme were £1,779m. These rebate payments are not included in Table 4, i.e. measured spend is shown before rebate payments.

The move from line *d* to line *b* is via line *c*, termed "Residual". This is mainly discounts, and has been increasing substantially. The NHS is getting better at extracting discounts from list prices from companies, for example via Patient Access Schemes, the Cancer Drugs Fund, and NHSE tendering. Note that the residual will also include payments to distributors.

**Figure 16: "Waterfall" reconciliation between DHSC reported branded spend and IQVIA Health Medicines bill for Q1 2017, i.e. the 12 months to March 2017**




Source: Own elaboration based on DHSC and ABPI data.

The move from line *b* to line *a* reflects primarily the effect of parallel trade and of the Statutory Scheme. We noted earlier that the DHSC has taken powers to change the way it manages the Statutory Scheme. There are no price or expenditure cap controls on parallel trade. The assumption in relation to parallel trade seems to be that the margins made by pharmacists and wholesalers will be clawed back through the discount clawback mechanism we discussed earlier in Section 2, and that no expenditure control and rebate mechanism is needed for the wholesalers and others who hold licences to parallel trade.

Thus line *b* seems to be the best estimate of net branded expenditure. It takes account of discounts. However, it does not take account of the PPRS rebate payments or the primary care "clawback" mechanism, both of which reduce the cost of branded medicines. It also does not take account of the payments to distributors by manufacturers which are included in the residual and are a cost to the NHS.

# 5 NHS MEDICINES EXPENDITURE AS A SHARE OF TOTAL NHS SPENDING

A common means of contextualising medicines bill expenditure and growth is to express this as a share of total healthcare expenditure. For the UK, where most health care is publically funded and provided, this metric can be expressed as medicines expenditure as a share of total NHS expenditure. An example can be found earlier, in Figure 4, where, for England only, NHS Digital estimate that the share of medicines expenditure is 14.3% of total NHS expenditure in England; with a growing share in recent years suggesting medicines growth faster than NHS expenditure growth.

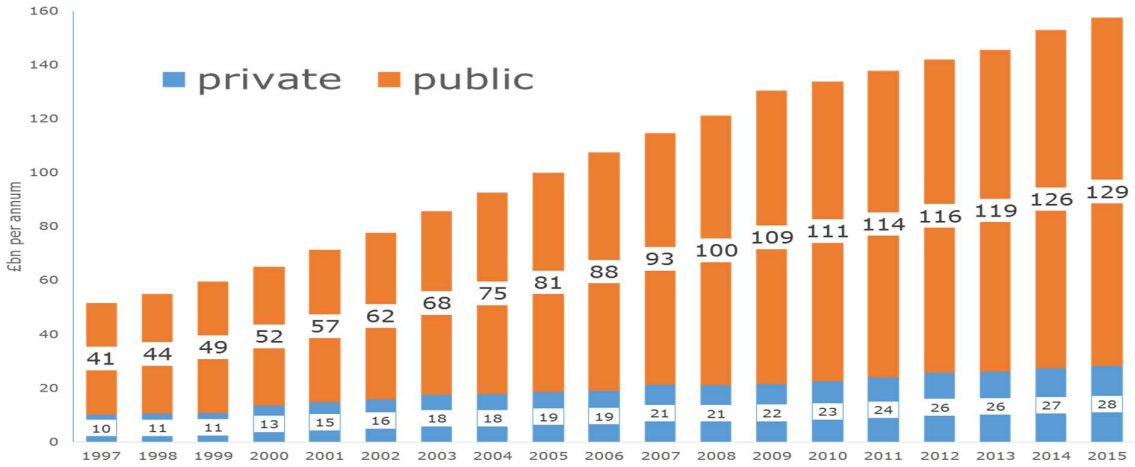
The Office for National Statistics (ONS) produce figures for total "Expenditure on healthcare in the UK"[26]. This includes an estimate for public and private expenditure. The ONS approach supplies a robust estimate of total healthcare expenditure but we cannot use its estimates of medicines expenditure because medicines dispensed as part of an inpatient episode of care, a significant share of total expenditure, are not separately identified[27]. Figure 16 plots ONS UK public and private healthcare expenditure since 1997.

NHS Digital calculates medicines expenditure by combining PCA data for primary care with IQVIA Analysis Manager data for hospitals. To derive a comparable figure for the UK using this approach, we combined PCA data for each UK country and added IQVIA Analysis Manager for hospital sales. Using this measure a benchmark of share of NHS sales at list prices can be derived using ONS Public Healthcare Figures. This is shown in Table 5.

[26] This data uses Office of Economic Co-operation and Development (OECD) guidance from the OECD System of Health Accounts (SHA) in 2000 (SHA 2000). This guidance was superseded by the revised OECD 2011 SHA (http://www.oecd.org/els/health-systems/a-system-of-health-accounts-2011-9789264270985-en.htm) We use the SHA 2000 definition as it is closer to NHS spend. The key differences between the two definitions are the inclusion in the 2011 SHA of health-related social care and of long term care (health). For a reconciliation see page 42 of UK Health Accounts: 2015(https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthcaresystem/bulletins/ukhealthaccounts/2015).

[27] See, for example "UK Health Accounts: methodological guidance" available at https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthcaresystem/methodologies/ukhealthaccountsmethodologicalguidance#methodological-guidance-for-government-expenditure which states that " pharmaceuticals and non-durable medical goods covers expenditure on GP-dispensed drugs".

**Figure 16: "Expenditure on health care in the UK" series by public and private expenditure, 1997 to 2015 (current prices unadjusted for inflation)**




Source: ONS

**Table 5: UK Medicines expenditure at list prices as a share of total NHS Expenditure (medicines at list prices)**

| | PCA primary care sales £bn | IQVIA Hospital sales £bn | Total medicines expenditure £bn | NHS "public" expenditure £bn | Medicines share of total NHS expenditure at list prices |
|---|---|---|---|---|---|
| | UK | UK | UK | UK | UK |
| 2013 | 10.56 | 6.60 | 17.17 | 119.4 | 14.4% |
| 2014 | 10.84 | 7.59 | 18.43 | 125.6 | 14.7% |
| 2015 | 11.34 | 8.64 | 19.98 | 129.4 | 15.4% |

Source: Authors' calculations

As previously noted the use of PCA Net Ingredient Cost data accurately reflects the reimbursement or list cost of medicines but does not capture "clawback" and hence overstates the actual "prices" paid. In addition IQVIA hospital sales estimates value at list prices. If, instead of these list prices, a level of discounting is assumed, constant over the period, the reported share of NHS expenditure is reduced.

Table 4, where IQVIA list price sales are compared with Department of Health suggests that the total level of discounting is increasing (shown in the line "Residual"). Adjusting hospital sales reported at list prices in Table 4 by the value of this residual[28] produces the results reported in Table 6 below for 2014 and 2015. As can be seen the rate of

[28] Note this has been applied to secondary care sales only as relevant primary care discounting (brand equalisation) has been excluded from the calculation of "residual."

growth in share, as well as the absolute level share, has reduced as the value of the "residual" increases. This approach understates the value of medicines expenditure from the point of view of the NHS as the value of "residual" will include some costs associated with distribution.

**Table 6: UK Medicines expenditure as a share of total NHS Expenditure (with constant discount rates applied to list prices)**

| | PCA primary care sales £bn | IQVIA Hospital sales less "residual" £bn | Total medicines expenditure £bn | NHS "public" expenditure bn | Medicines share of total NHS expenditure |
|---|---|---|---|---|---|
| | UK | UK | UK | £bn | £bn |
| 2014 | 10.84 | 5.44 | 16.27 | 125.6 | 13.0% |
| 2015 | 11.34 | 6.11 | 17.45 | 129.4 | 13.5% |

Source: Authors' calculations

On this basis the share of medicines expenditure in overall UK NHS expenditure in 2015 was around 13.5%, almost a percentage point less than the 14.3% that NHS Digital reported for 2015 /16 for England. We can see, however, that absolute share and growth in share for medicines expenditure in the context of total NHS expenditure is sensitive to data sources, geographical coverage, and the assumptions used.

# 6 FINAL REMARKS

We have sought to identify underlying trends in medicines expenditure in the period of the current PPRS agreement 2014-18. In particular we have highlighted the challenges of interpreting different data sources and the importance of looking at trends in discounts.

Overall, whilst hospital branded and generic medicines expenditure is growing at a much faster rate than primary care medicines expenditure, it is not clear from the data we have examined whether or not the underlying trend in the overall growth of medicines expenditure is higher than that of overall NHS expenditure. Headline NHS Digital list price growth rates have fallen, and overestimate underlying growth in net expenditure as they do not take account of increasing rates of discount obtained by the NHS, or of the rebate payments for branded drugs in the PPRS. The latter, the largest component of medicines expenditure, is, as we noted, subject to a 5 year cap with a cumulative average growth rate of 1.1% per annum.

It is important to stress that we are analysing data to understand trends since 2014. We are not making any predictions about future trends in either list price or net expenditure.