

White paper

THE CHANGING DYNAMICS OF THE UK RETAIL PHARMACEUTICAL MARKET

*What is happening and what are the implications for
Pharma and the NHS?*

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EXECUTIVE SUMMARY

Whilst in 2017 the total UK pharmaceutical market grew more slowly in cash and volume terms than in previous years, the retail sector experienced a cash and volume decline in June 2017. Changing patterns of drug usage suggest that NHS cost-containment measures combined with the drive for medicines optimisation account for the reduced volume of trading.

The main drivers for cost containment are NICE guidance, medicines optimisation and prescribing controls, such as local formularies. Together they are intended to ensure that NHS spending is contained or reduced in order to tackle the predicted funding deficit. A variety of implementation mechanisms and processes has been introduced.

Patterns of drug usage in key areas reflect adherence to NICE guidance and local formularies. Analysis of performance data via the Medicines Optimisation Dashboard has prompted better monitoring and support of patients.

We suggest that the shrinkage of the UK retail pharmaceutical market is likely to be a one-off correction as waste is eliminated from the system and new habits are learned, although it has some way to go yet. Elimination of ineffective (wasteful) use of medicines and better managed treatment with a clear focus on outcomes (i.e. optimised treatment) is in everyone's best interests, especially the manufacturers. Medicines that are prescribed, taken and monitored correctly are likely to achieve the therapeutic target more often with fewer side effects.

RECOMMENDATIONS

- The partnership between the NHS and the pharmaceutical industry needs to continue to develop to ensure the UK remains an attractive market and patients in the UK can access the most appropriate medicine for their diseases.
- It is no secret that the UK pharmaceutical market has historically not been an early launch market, but a market for which new chemical entities see slow and often low uptake. The UK Government's Life Sciences Industrial Strategy acknowledged this by stating that by 2023, the UK should be in the top quartile of comparator countries for speed of adoption and overall uptake of innovative, cost-effective products. If this goal is achieved, UK pharmaceutical market growth will become more "front loaded" to innovative new launches.
- Industry should work with the NHS to find sustainable/mutually beneficial ways forward bearing in mind that NHS cost-containment measures are intended to liberate funds for innovative products that should achieve better health outcomes
- Industry should be aware of and take into account the Medicines Optimisation agenda to ensure positive outcomes

OVER THE LAST 5 YEARS, THE PHARMACEUTICAL MARKET HAS EVOLVED. WHAT IMPACT HAS THIS HAD ON OBSERVED SALES?

List price is a price level for a medicine, either publicly available or estimated from public sources, from which non-publicly available discounts or rebates may be made, meaning the actual price the manufacturer realises is in fact lower. These non-publicly available rebates/discounts can be substantial. They are almost entirely non transparent, with confidentiality agreements as in Patient Access Schemes frequent. The rebate paid to the government as part of the PPRS is also not captured in the list price level data, (nor could it be because it is not assigned on a product by product basis) nor are discounts under the statutory scheme.

In value terms, pre rebate and discount, overall (retail and hospital) the UK pharmaceutical market has expanded at a compound annual growth rate (CAGR) of 6.2%* during the period 2011-2016. This trend continued in 2017 with value growth at YTD Q2 2017 at 3.5% and Moving Annual Total (MAT) Q2 2017 growth at 2.4%.

The expansion has been largely driven by growth in the secondary care sector which has seen strong list price, pre rebate (including patient access schemes) sales growth* over the past 5 years of 12.4% CAGR. Price has been the main driver of growth, reflecting the introduction of innovative medicines for complex conditions in areas such as cancer, respiratory and infectious diseases, supported by NICE appraisals and guidance. This has included rapid growth in the use of biologics for rheumatoid arthritis, psoriasis/psoriatic arthritis and inflammatory bowel diseases. However, it should be noted that price is always a complex issue, and especially so in the specialty secondary care sector because the list price picture will not reflect the patient access schemes which are now so common, especially in oncology, and which allow for substantial discounts.

In comparison, the primary care (retail) sector has expanded much more modestly at 2.1% CAGR (list price) during the 2011-2016 period. Historically, volume has been the main driver of growth in this sector. However, the MAT figures for June 2017 showed a decline in unit and list price growth (-1% and -3% respectively). Closer examination shows that retail market growth peaked in May 2016, and since then there has been a slow-down reflected across all therapy areas, both nationally and regionally.

This report explores the reasons for the observed decline in the UK retail pharmaceutical market.

WHAT IS DRIVING THE DECLINE OF THE RETAIL MARKET?

NHS FINANCIAL POSITION

The NHS is facing a £22bn deficit by 2020.¹ In the last two years, the service has experienced its worst winter pressures ever. The majority of NHS providers are said to be in deficit and by 2020 NHS funding growth will be at an historic 55 year low – despite the combined £12.8bn cash injection realised from the Treasury in 2016/17. In June 2018, Theresa May announced a major new funding initiative, with an average of 3.4% a year real term increase in funding over the next five years. This commitment came with a “financial test” rider that required productivity and efficiency improvements.

MEASURES TO REDUCE SPENDING

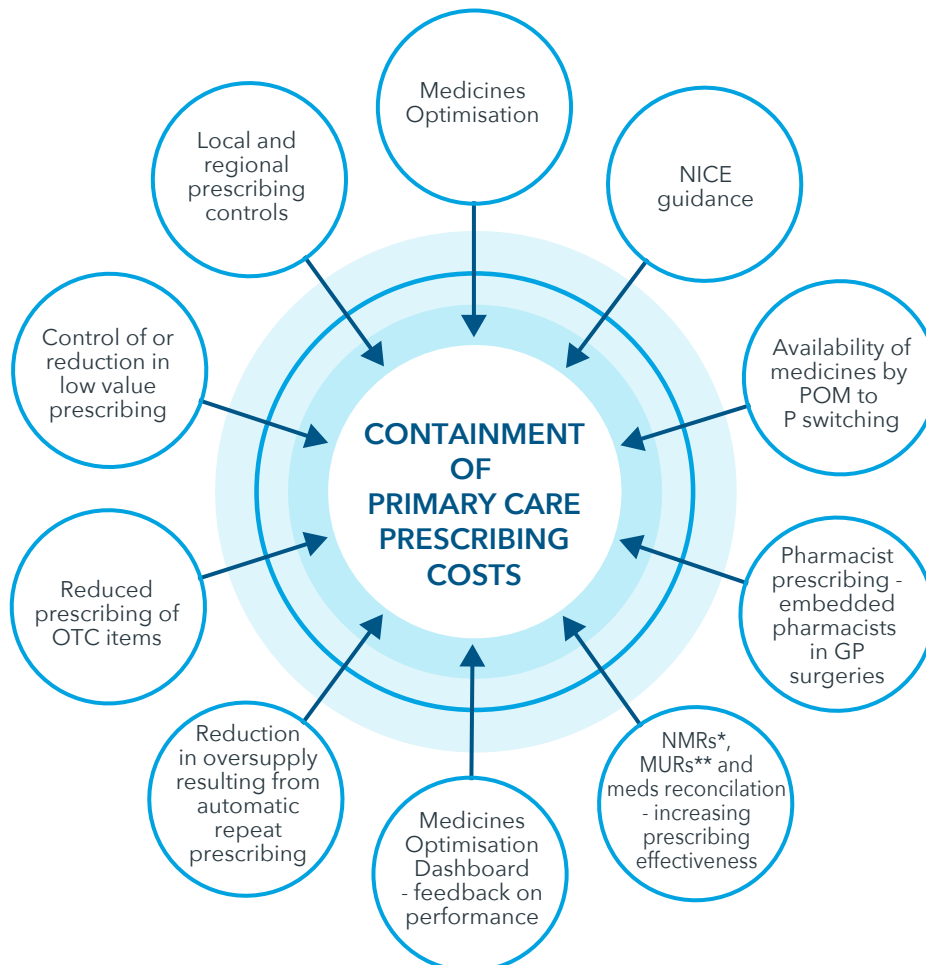
Over the past decade, the NHS has introduced a variety of measures to contain the growth in medicines' expenditure with an increasing focus on the efficient and effective use of medicines. The first three items in the table - NICE guidance, Medicines Optimisation and prescribing controls - are the drivers here and all the other measures are the mechanisms and processes through which MO is implemented and the competing demands are balanced.

* All prices in this report are list prices (ex-manufacturer) and do not include rebates, discounts and industry repayments under PPRS

Table 1: Key NICE events/milestones in control of NHS prescribing

DATE	EVENT	POSSIBLE EFFECT
2000	NICE Guidance on Blacklisted Drugs / Local Formulary Development	Reduced prescribing of atorvastatin, clopidogrel, dabigatran, pantoprazole, ciclesonide, olanzapine and dexamethasone
2013	Asthma Quality Standard	Better use of inhaled products
2015	NICE Diabetes 1 + 2	Better treatment plan due to monitoring and reporting. Use of treatment algorithms. Fewer patients moving onto complex treatments, insulin and insulin analogues. Patient Outcomes Monitoring by CCG / NHSE.
2015	NICE Medicines Optimisation Medicines Optimisation Dashboard Medicines Use Reviews New Medicines Reviews (NMRs)	Meds Optimisation (both via Dashboards for Primary and Secondary Care) monitored and reported nationally
Multiple	NICE Technology Assessments (TAs) for multiple treatment areas	Add-on therapy for one year after trastuzumab treatment improved rates of disease free survival by 2.3–2.5%
2015	NICE Medicines Optimisation	Respiratory, heart failure, atrial fibrillation, rheumatoid arthritis etc. all have medicines optimisation recommendations

Figure 1: NHS measures to contain primary care medicines expenditure



* New Medicines Reviews (NMRs) ** Medicines Use Reviews (MURs)

Table 2: NHS measures to contain primary care prescribing costs

MEASURE	EFFECT	Click for web link
NICE guidance	NICE Clinical Guidelines and Technical Appraisals are designed to identify products and treatments that represent value for money for the NHS. Medicines that are approved by NICE are required to be put into local formularies	https://www.nice.org.uk/guidance
Medicines Optimisation	Making sure that prescribers and patients use medicines in a way that gives the best possible outcomes	https://www.england.nhs.uk/medicines/medicines-optimisation/
Local and regional prescribing controls (formularies)	Formularies have been introduced to guide and control prescribing. Originally this was at CCG level but increasingly groups are coming together to form area and regional medicines optimisation committees with agreed formularies	http://gmmmg.nhs.uk/
NHSE Plan to reduce low value prescribing	Consultation document has been actioned by most local areas, reducing volume of prescribing. However, most Local Medicines Management Groups / Area Formulary Committees have already actioned a "Do Not Prescribe List" to include medicines of low clinical value as detailed in the published list	https://www.england.nhs.uk/2017/07/medicine-consultation/
Reduction in prescribing OTC medicines	Various schemes to stop prescribing OTC medicines. Nationally, there has been an increased drive to encourage patients to self-treat with OTC medicines instead of getting them on prescription. Some patients who do not pay a prescription charge are reluctant to do this but GPs are being incentivised to encourage this	https://www.pharmaceutical-journal.com/news-and-analysis/news-blog/buy-your-own-drugs-an-unreasonable-request-or-sensible-policy/20068206.article?firstPass=false
Increase in POM to P reclassification	More medicines available OTC. Recent examples include the proton pump inhibitor esomeprazole and sildenafil for erectile dysfunction	https://www.pharmaceutical-journal.com/opinion/insight/why-the-resurgence-of-pom-to-p-reclassifications-in-the-uk-is-a-good-thing/20202645.article
Electronic transfer of prescriptions (ETP) and patient electronic repeat prescription requests	A scheme that allows patients to request repeat prescriptions has stopped the oversupply made when repeat prescribing was less controlled when paper prescriptions were used	http://psnc.org.uk/our-news/faqs-on-pharmacy-management-of-repeat-meds-requests-published/
Pharmacists embedded in GP surgeries	Pharmacists are undertaking medicines use reviews (MUR) and repeat prescribing in GP Surgeries. Some 500 have been in post since 2016; 900 should be in post by March 2018 and 1300 in the longer term. Pharmacists are less likely to prescribe a medicine of limited value and are more likely to de-prescribe a medicine if it is ineffective for a particular patient	https://www.pharmaceutical-journal.com/news-and-analysis/news/nhs-report-promises-over-1300-pharmacists-in-gp-surgeries-by-2019/20202554.article
New Medicines Reviews (NMRs)	Recent studies have shown that NMRs and MURs save significant funding and improve patient outcomes by the more effective use of medicines through patient engagement, support and education and appropriate intensification of treatment	https://www.pharmaceutical-journal.com/news-and-analysis/news/new-medicines-service-could-save-nhs-5176m-economic-evaluation-finds/20203374.article

NICE GUIDANCE

NICE guidance includes Clinical Guidelines, Technology Appraisals and Quality Standards. The NICE Guidance on Type 1 and 2 diabetes (2015) and Asthma Quality Standard (2013) and Medicines Optimisation (2015), together with guidance on the treatment of chronic obstructive pulmonary disease (COPD), heart failure, atrial fibrillation and rheumatoid arthritis have played a critical role in optimising medicines use. For example, the NICE Guidance for diabetes and asthma gives a structure to treatment pathways with treatment goals and measurements. It is also framed to support and empower patients to achieve treatment goals with first or second line medicines and therefore progress more slowly to newer, more expensive treatments.

MEDICINES OPTIMISATION

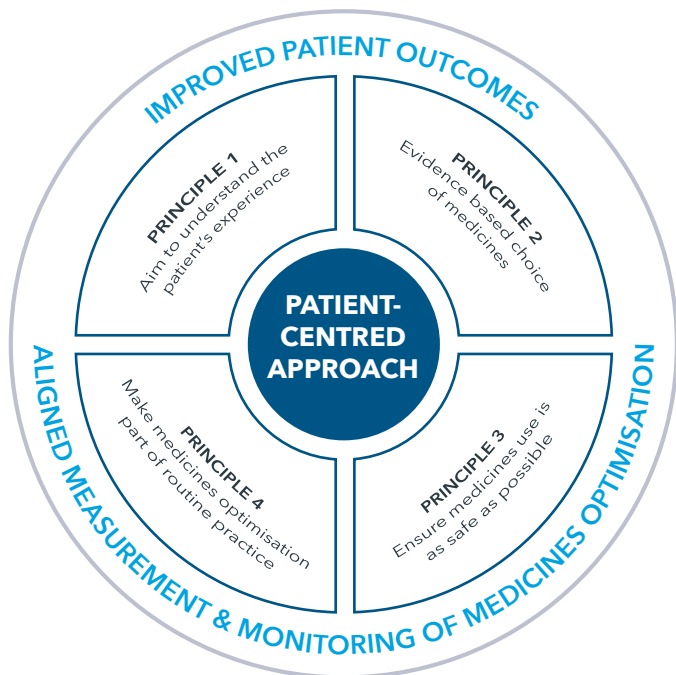
Helping patients to make the most of medicines. RPS May 2013*

Medicines optimisation encourages safe, effective and economical use of medicines using an evidence-based, patient-centred approach with an emphasis on improved outcomes. Medicines optimisation is applicable to all therapy areas and involves a variety of measures including de-prescribing of ineffective medicines and supporting patients with New Medicines Reviews (performed by community pharmacists) and Medicines Reconciliation at transfers of care.

In 2015, the Medicines Optimisation Dashboard was introduced across primary and secondary care to provide feedback on performance. The Dashboard

* <https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Policy/helping-patients-make-the-most-of-their-medicines.pdf>

Figure 2: Principles and outcomes of medicines optimisation prescribing costs



Source: <https://www.england.nhs.uk/medicines/medicines-optimisation/>

monitors and compares prescribing and medicines management across therapy areas and provides a local / CCG level indication of effectiveness of medicines' use (<https://apps.nhsbsa.nhs.uk/MOD/AtlasCCGMedsOp/atlas.html>).

It produces, on a quarterly basis, a dashboard of medicines' usage. Given that it explicitly shows each CCG's place in the ranking it effectively focusses the priorities of CCG and Secondary Care Medicine Optimisation leads. It is issued to all CCG and Trust boards, including, of course, Directors of Finance.

In 2015 Lord Carter delivered a series of recommendations to the Government in respect of £20billion in efficiencies that could be delivered by 2020, in secondary care, if NHS procurement of anything, from toilet rolls to pharmaceuticals, was improved.² He created a Model Hospital as a way of reducing or eliminating unwarranted variation in running cost and performance between trusts. NHS Improvement has now developed a Model Hospital

digital information service to enable providers to explore and compare their productivity and efficiency in a variety of critical domains. (<https://improvement.nhs.uk/resources/model-hospital/>). Hospital pharmacies would be monitored on this.

In 2016, four Regional Medicines Optimisation Committees (RMOCs) were introduced to focus on driving optimal use of medicines that are not on the NICE work programme, making decisions on access to medicines on behalf of the region and addressing national initiatives such as the uptake of biosimilars across England.

They are also mandated to address the variation that exists across the 209 CCGs in respect of local formularies-such as those compiled by the Greater Manchester Medicines Management Group (GMMMGM) and other projects delivered as part of Devo-Manc . Many are very much in their formation period so their impact on growth is likely to be small at this stage, but can be expected to increase through 2018 and beyond.

MO is an important element of Sustainability and Transformation Partnerships (STPs). Once the structural and organisational transformations are complete it is the ongoing MO activities that should deliver long-term benefits in terms of costs and health outcomes. Table 3 shows how the feedback metrics in the MO dashboard are intended to influence prescribing.

PRESCRIBING CONTROLS

The prescribing control measures that are determined by RMOCs cascade down to CCGs, acute trusts, accountable care organisations and other NHS provider organisations and are the responsibility of the Heads of Medicines' Management and Trust Chief Pharmacists.

The transition from Primary Care Trusts (PCTs) to Clinical Commissioning Groups (CCGs), following the Health and Social Act 2012, will have impacted current growth. Most of the former PCT medicines optimisation teams were transferred to the new CCGs. However, the numbers employed in those teams were sharply reduced and they had a very clear mandate over and above medicines optimisation, namely to ensure prescribing budgets remained in balance.

Table 3: Metrics used in the Medicines Optimisation Dashboard and intended effects

METRIC	INTENDED EFFECT ON PRESCRIBING
Antibiotic Use	
Overall antibiotic use	Reduction in antibiotic use
Use of broad spectrum antibiotics	Improvement in antibiotic use
Community Support	
% Electronic Prescribing items	Reduction in unnecessary repeat prescribing volume
% Repeat prescribing on EPS	
% Pharmacies conducting MUR	Effective medicines use. Reduction in polypharmacy and de-prescribing of ineffective medicines
% Pharmacies conducting NMS	
% Practices enabled for EPS	
Number of MUR per 1000 items	
Number of NMS per 1000 items	
CVD / CHD	
% Oral anticoagulants	Reduction in polypharmacy and de-prescribing of ineffective medicines
Heart Failure outcome measures	
Atrial Fibrillation outcome measures	
NSAID use	
Diabetes	
Number of emergency admissions	Focus on patient outcomes by increasing patient support and effective use of first line medicines
Diabetes outcome measures	
Mental Health	
Antidepressant outcome measures	Decreased use of hypnotics and effective mental health support
Hypnotic use	
Osteoporosis	
Osteoporosis outcome measures	Reduction in bone Calcium regulator use
Patient Experience	
Use of electronic repeat prescription services	Patients are in control of repeat prescription requests resulting in a reduction off waste
Respiratory	
Asthma outcome measures	Focus on patient outcomes by increasing patient support and effective use of first line medicines.
Emergency asthma admissions	
COPD Outcome measures	
COPD emergency admissions	

Furthermore, not only were they encouraged not to build in growth to the budget at this time, but the Directors of Finance within CCGs were asked to achieve a reduction in expenditure of 0-2%.

Most of England’s 209 CCGs are moving away from having their own formularies and are increasingly becoming part of area or regional medicines management groups with joint formularies. Drugs are categorised as red, amber, green and brown and GPs are not allowed to initiate medicines in the red, amber or brown categories. Formulary committees have introduced this into local prescribing and prescribing software tools such as Blueteq™, Scriptswitch™ and Map of Medicine™ ensure that consultants and GPs do not deviate from the formularies.

UNFULFILLED OPPORTUNITY

There is mounting evidence from patient support groups that large numbers of patients are not filling their prescriptions because of high prescription charges.² Reports suggest that as many as 30% of those eligible to pay prescription charges have skipped prescriptions or reduced their own doses (PCC report). As a result, significant numbers of people become sick and require time off work, there are additional GP visits and avoidable hospital admissions. In addition to under-treatment and wasted NHS time this could distort the retail pharmaceutical market.

DYNAMICS OF THE UK RETAIL MARKET

TRADING FIGURES IN THE LIGHT OF NHS COST-CONTAINMENT/OPTIMISATION MEASURES

Changes in the retail pharmaceutical market can be shown in several ways. In this section we will consider:

- Changes in Moving Annual Totals (to June 2018)
- Changes in usage patterns for the top 50 Anatomical Therapy Classes (MAT June 2017 and June 2018)
- Therapy area growth dynamics over the past four years
- Case studies to illustrate major changes in key therapeutic areas

Whilst at a macro level it can take weeks, months or years for the full effect of the NHS cost containment initiatives to be seen, subtle changes may already be emerging in all of the UK nations. As of June 2018 (MAT), most have shown a declining unit growth rate, suggesting that some of the NHS and government initiatives have started to influence primary care dispensing behaviour (see Figure 3).

AT THE THERAPY LEVEL

Changes in usage patterns for the top 50 therapeutic classes tell an interesting story - 76% of these show a decline. The largest effects are seen in non-narcotic analgesics, antibiotics, emollients, anticoagulants (particularly warfarin) and treatments for diabetes and respiratory disease. Likely contributory factors to these are the encouragement to purchase over the counter versions of medicines and the drive to reduce unnecessary antibiotic prescribing, a worldwide initiative designed to reduce antibiotic resistant bacteria problems.

The sharp fall in numbers for Vitamin K antagonists (anticoagulants) is due to widespread switching from warfarin to the Direct Oral Anticoagulants (DOACs) (formerly known as NOACs), which involves a change from three or four packs of warfarin tablets of different strengths, to a single pack of one strength of a DOAC, per patient.

Figure 3: Retail market trends for England, Scotland, Wales and Northern Ireland (Standard Units, MAT June 2018)

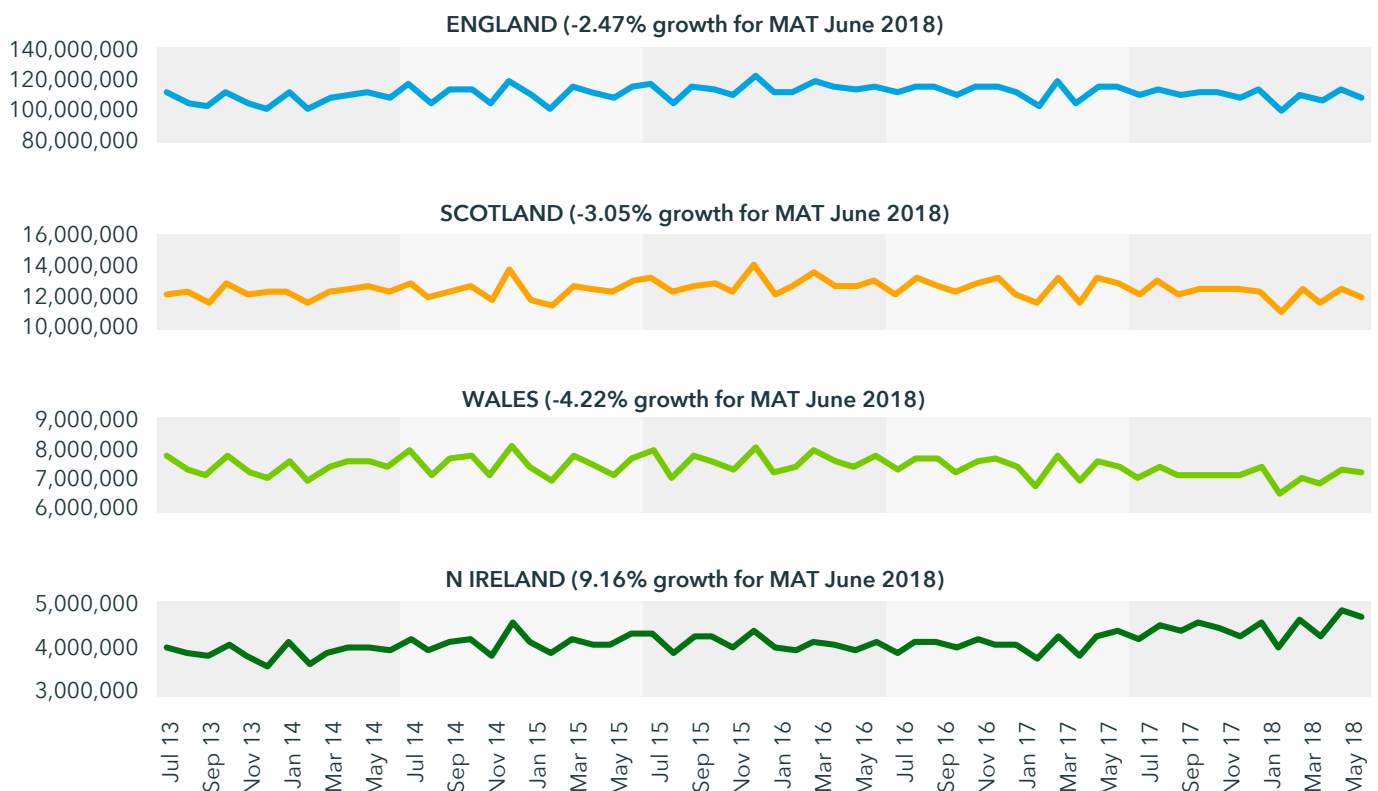


Table 4: Top 50 therapeutic classes (units)

TOP 50 ANATOMICAL THERAPY CLASSES	MAT 06/17 ('000s)	MAT 06/18 ('000s)	GROWTH 17/18	PROPOSED REASON FOR DECLINE
ANTIDEPRESS.& MOOD STAB.	109,347	111,789	2.23%	
ANTIULCERANTS	106,394	105,237	-1.09%	Reduction in OTC prescribing
NON-NARCOTIC ANALGESICS	113,357	104,021	-8.24%	Medicine Optimisation - NSAIDs and OTC reduction
CHOLEST&TRIGLY.REGULATOR	101,302	101,233	-0.07%	Reduction in OTC Prescribing
ACE INHIBITORS PLAIN	68,714	66,918	-2.61%	Medicines Optimisation - NICE Cardiac Guidance
BETA BLOCKING AGENT PLAIN	61,582	61,408	-0.28%	Medicine Optimisation - NICE Cardiac Guidance
BIGUANIDE ANTIDIABETICS	62,756	61,146	-2.57%	
CALCIUM ANTAGONISTS PLAIN	58,641	58,803	0.28%	
THYROID PREPARATIONS	51,595	50,845	-1.45%	Medicines Optimisation - NICE Respiratory Guidance
DIURETICS	51,250	48,172	-6.01%	Medicines Optimisation - NICE Cardiac Guidance
PLATELET AGGREG INHIBITRS	46,880	43,725	-6.73%	Medicines Optimisation - NICE Cardiac Guidance
B2-AGONISTS	41,714	39,620	-5.02%	Respiratory Guidelines
ANTI-EPILEPTICS	32,649	33,424	2.37%	
ANGIOTENSIN-II ANTAG,PLAIN	31,559	31,485	-0.23%	Medicine Optimisation - NICE Cardiac Guidance
EMOLLIENTS & PROTECTIVES	33,514	30,589	-8.73%	Reduction in OTC prescribing
DRUGS FOR CONSTIPATION	29,795	28,938	-2.88%	Reduction in OTC prescribing
PLAIN CORTICOSTEROIDS	25,434	24,671	-3.00%	Asthma Guidelines - reduction in need for rescue therapies
ANTIRHEUMATIC NON-STEROID	26,081	23,960	-8.13%	Reduction in OTC prescribing (has this gone up in OTC activity?)
NARCOTIC ANALGESICS	22,863	22,965	0.45%	
BROAD SPECTRUM PENICILLIN	25,391	21,818	-14.07%	Antimicrobial Stewardship
B2-AGON+CORTICOID COMBS	21,663	21,769	0.49%	
SULPHONYLUREA A-DIABS	21,878	20,401	-6.75%	Medicines Optimisation - NICE Diabetes Guidance
ANTIHISTAMINES SYSTEMIC	20,942	20,093	-4.05%	Reduction in OTC Prescribing
VITAMIN K ANTAGONISTS	23,214	19,786	-14.77%	Medicines Optimisation - NICE Respiratory Guidance
DIABETES TESTS	17,567	17,912	1.96%	
MIOTICS+ANTIGLAUCOMA PREP	17,780	17,739	-0.23%	Medicine Optimisation
HORMONAL CONTRACEPT SYST	17,794	17,716	-0.44%	Medicine Optimisation
BPH PRODUCTS	16,473	16,528	0.33%	Medicines Optimisation - Reduction in Polypharmacy
TRANQUILLISERS	16,275	15,586	-4.23%	
MED/NARROW SPECT PENICILL	15,067	15,320	1.68%	Antibiotic Stewardship
HUMAN INSULIN+ANALOGUES	15,933	15,020	-5.73%	Reduction in treatment progression - NICE Diabetes Guidance
ANTIHYPERTENS(NON HERB)PL	14,338	14,566	1.60%	Medicine Optimisation - NICE Cardiac Guidance
ANTIPSYCHOTICS	14,149	13,980	-1.19%	Medicines Optimisation - Reduction in antipsychotics in the elderly
TOPICAL NASAL PREPS	14,165	13,931	-1.65%	Reduction In OTC Prescribing
TOP CORTICOSTEROIDS PLAIN	13,599	13,464	-0.99%	Reduction in OTC prescribing
HYPNOTICS & SEDATIVES	13,274	13,120	-1.16%	Medicines Optimisation - Local targets
HAEMATINICS,IRON & COMBS	12,958	12,170	-6.08%	Reduction in OTC prescribing
MACROLIDES & SIMILAR TYPE	12,215	11,836	-3.10%	Antimicrobial Stewardship
TOP A-RHEUMATICS & ANALG	11,842	11,445	-3.35%	Reduction in OTC Prescribing
ANTI-GOUT PREPARATIONS	11,784	11,280	-4.27%	Medicine Optimisation - Reduction in Polypharmacy
OTH ANTI-ANAEM+FOLIC ACID	11,617	10,935	-5.87%	Reduction in OTC Prescribing
VIT A & D INC. COMBS	10,406	10,637	2.22%	Reduction in OTC prescribing
BONE CALCIUM REGULATORS	9,865	10,557	7.01%	Medicine Optimisation - reduction in Polypharmacy
CORTICOIDS	9,833	10,433	6.10%	
ANTICHOLINERGICS PLAIN	11,001	10,184	-7.43%	Asthma Guidelines

Table 4: Top 50 therapeutic classes (units) *continued*

TOP 50 ANATOMICAL THERAPY CLASSES	MAT 06/17 ('000s)	MAT 06/18 ('000s)	GROWTH 17/18	PROPOSED REASON FOR DECLINE
TETRACYCLINES & COMBS	10,444	10,017	-4.09%	Antimicrobial Stewardship
ERECTILE DYSFUNCTION PRD	10,061	9,917	-1.44%	Medicines Optimisation - Viagra moving to OTC
ANTACIDS ANTIFLATULENTS	10,247	9,820	-4.16%	Reduction in OTC prescribing
DIRECT FACTOR XA INHIBS	9,856	9,820	-0.37%	
URINARY INCONTINENCE PRD	10,341	9,646	-6.73%	

Source: IQVIA, Prescription Based Services (PBS)

PRESCRIBING OF MEDICINES AVAILABLE OVER-THE-COUNTER

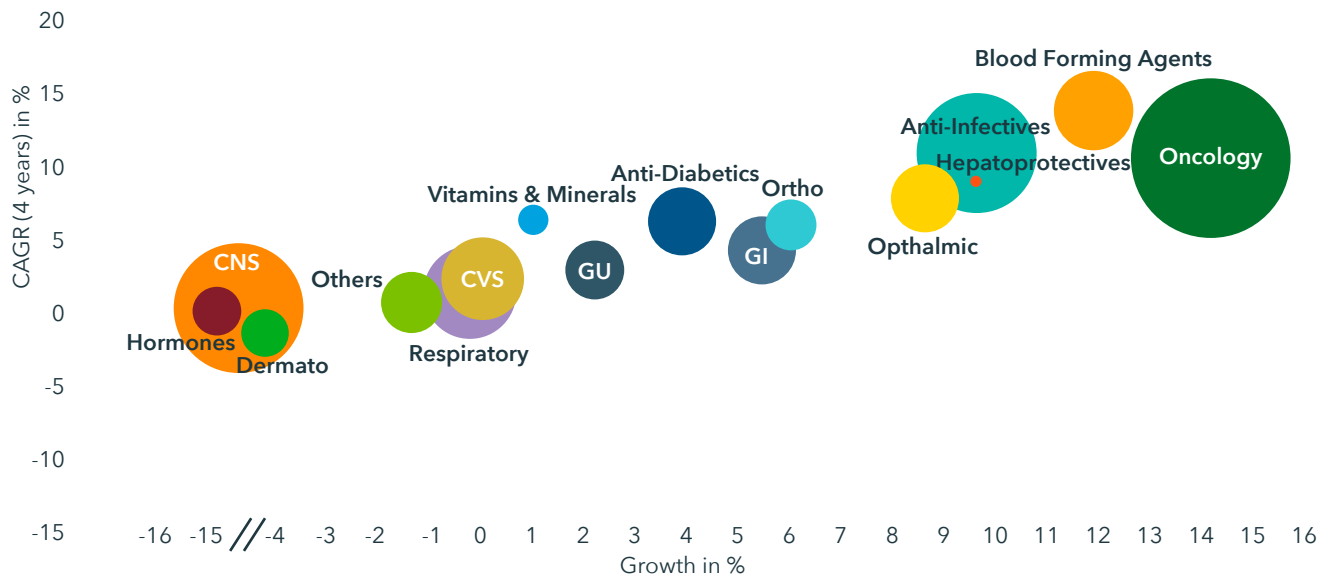
The drive to stop prescribing over-the-counter (OTC) medicines seems to be contributing to the decline in the number of such items dispensed. When looking at OTC cash sales from the grocery segment, in a market worth £1.5BN (full year December 2017), we see an acceleration on the previous year of 2.4% (full year December 2017).⁸

CASE STUDIES: DIABETES AND RESPIRATORY

When looking at the total UK retail market, diabetes and respiratory products account for 23.2% of cash sales (pre-rebates discounts and industry repayments under PPRS) and 13.9% of unit sales (IQVIA, XBPI, MAT June 2018). Given the size of their contribution, the slowdown in growth through 2016/17 can clearly be seen (see figure 4).

The changing patterns of drug usage in these two areas illustrate the interplay between guidelines, MO activities and prescribing control measures.

Figure 4: Relative market sizes of major therapeutic areas and growth (IQVIA XBPI/HPAI, Values (GBP in millions), MAT June 2018)



Source: xxxx

CASE STUDY: DIABETES

According to NHS Digital and IQVIA prescription data, the diabetes therapeutic class accounts for 9.5% of the primary care prescribing costs. This includes medication and diagnostic tests. Complications from sub-therapeutic treatment contribute an even greater cost in admissions to secondary care.

In June 2017 it was apparent that usage of sulphonylureas and insulin had decreased while usage of biguanides had increased.

The NICE Guidance on Type 2 Diabetes in Adults (2015)⁴ provides for increased patient support in diet and exercise before pharmacological intervention but also supports patients to take their medicines effectively once the treatment pathway is escalated to first line pharmacological treatment. This means more patients can be maintained on first line treatments before moving to second line and then, in turn, are maintained on this treatment level for longer before further treatment escalation.

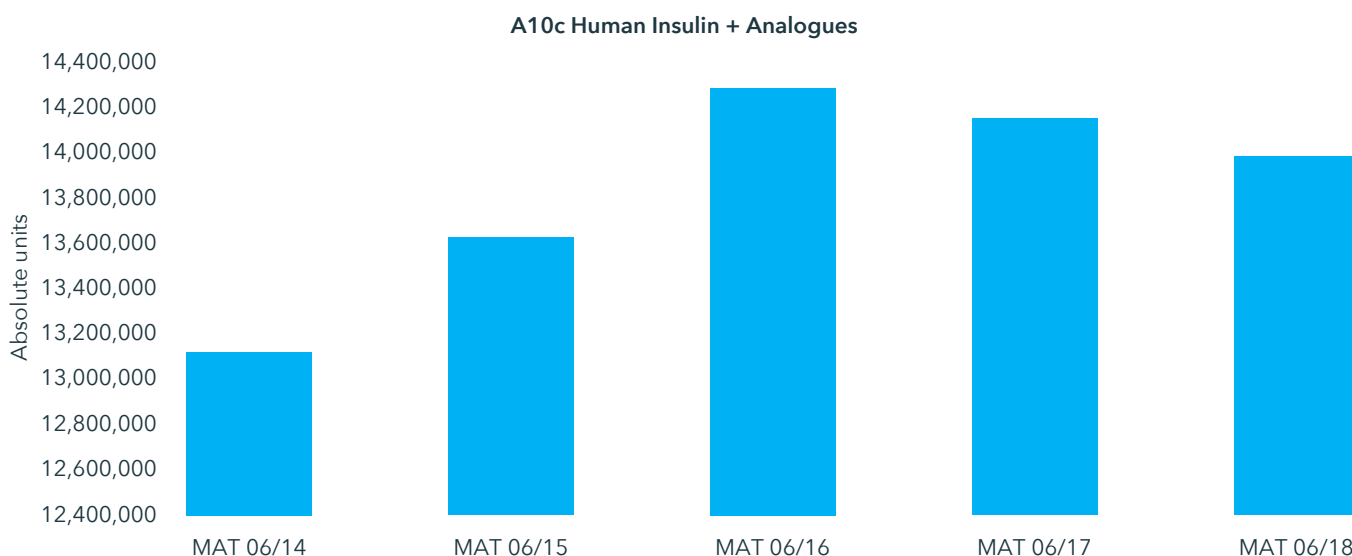
Treatment algorithms, pathways and treatment progression options are documented and prescribers are supported in decision-making by commissioners. Patient care is individualised – the Guideline advises:

Adopt an individualised approach to diabetes care that is tailored to the needs and circumstances of adults with type 2 diabetes, taking into account their personal preferences, comorbidities, risks from polypharmacy, and their ability to benefit from long term interventions because of reduced life expectancy. Such an approach is especially important in the context of multi-morbidity. Reassess the person's needs and circumstances at each review and think about whether to stop any medicines that are not effective.

Take into account any disabilities, including visual impairment, when planning and delivering care for adults with type 2 diabetes.”

Source: NICE guideline NG28⁴

Figure 5: Usage of human insulin and analogues 2014-2018 (by MAT, units)



Source: IQVIA, Prescription Based Services (PBS)

Following the publication of NICE Guidance on Type 2 diabetes management in 2015⁴ there has been an intensification of monitoring of outcomes, discontinuation of inappropriate treatments and the introduction of a formalised treatment plan for diabetes patients. The effects of the guidance have taken 12 to 24 months to become apparent.

The proportion of patients achieving satisfactory haemoglobin A1c (HbA1c) levels is routinely monitored and fed back to prescribers and CCGs. This is an absolutely crucial monitoring metric, as it will indicate whether longer times to insulin treatment are appropriate (a sign of better pre-insulin diabetes management) or inappropriate (a sign of reluctance to move to insulin because of lack of education, awareness or training).

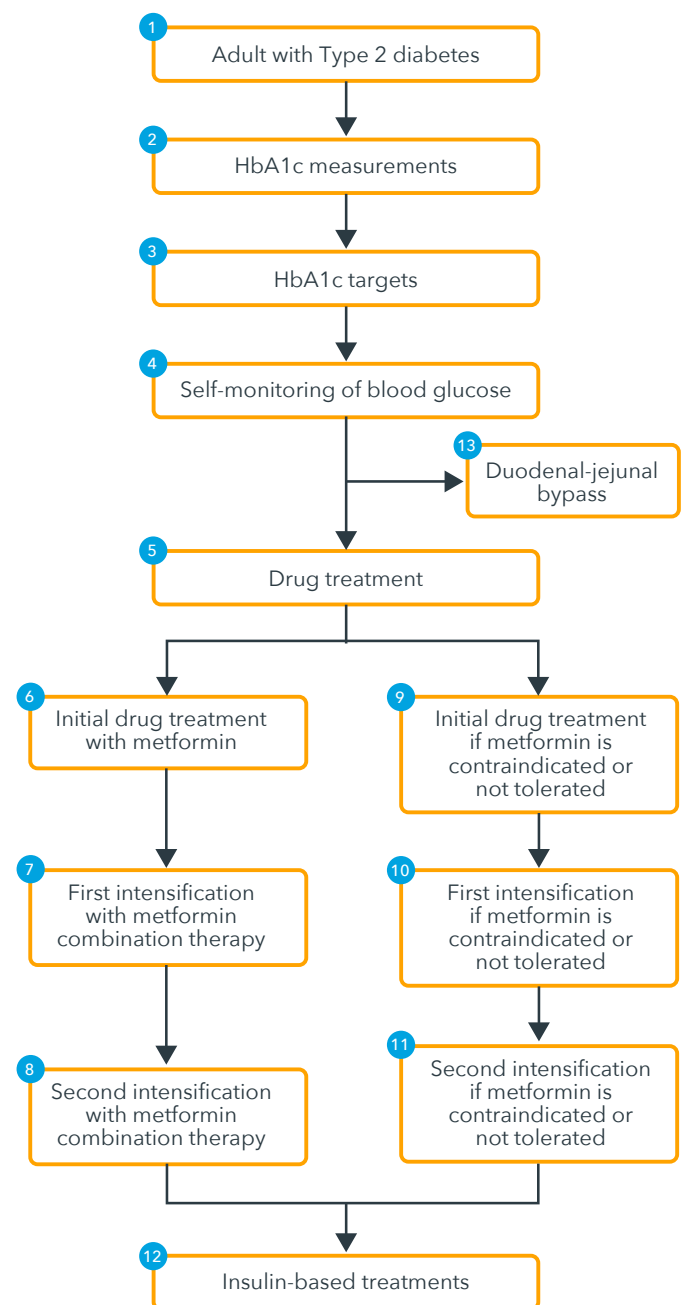
Fewer patients move onto the more complex treatments of biphasic insulin and insulin analogues, usage of which reached a peak in 2016 (see figure 5). This could be a function of the introduction of more concentrated treatments, such as Toujeo, as well as a significant increase in the number of new treatments which are available as options before patients reach insulin, which grew strongly from 2008.

In addition, there has been an increase in the use of newer sodium-glucose co-transporter-2 (SGLT2) inhibitors and once-daily insulin regimens such as insulin glargine (Toujeo®) and insulin degludec (Tresiba®), with MAT June 2018 unit growth at 84.3% and 86.4% respectively. As these products are administered once daily, their use results in fewer prescriptions and therefore slower growth in cash and unit terms.

The changing patterns of drug usage in Type 2 diabetes suggest that there is now good adherence to the NICE Type 2 diabetes pathway (see figure 6) with increased patient support, decreased over-prescribing and more effective use of medicines. The net result is that more patients are being managed effectively at the early stages of the pathway, systematically progressing through dual ('first intensification') and triple therapy ('second

intensification'), if required. This is a trend that is likely to be welcomed by patients who will generally try to avoid escalation to insulin for as long as possible. Those who do progress to insulin, are more likely to be using long-acting once-daily insulin analogues than older insulin products.

Figure 6: The NICE Type 2 diabetes pathway



Source: Managing blood glucose in adults with type 2 diabetes pathway. NICE. January 2018

CASE STUDY: RESPIRATORY

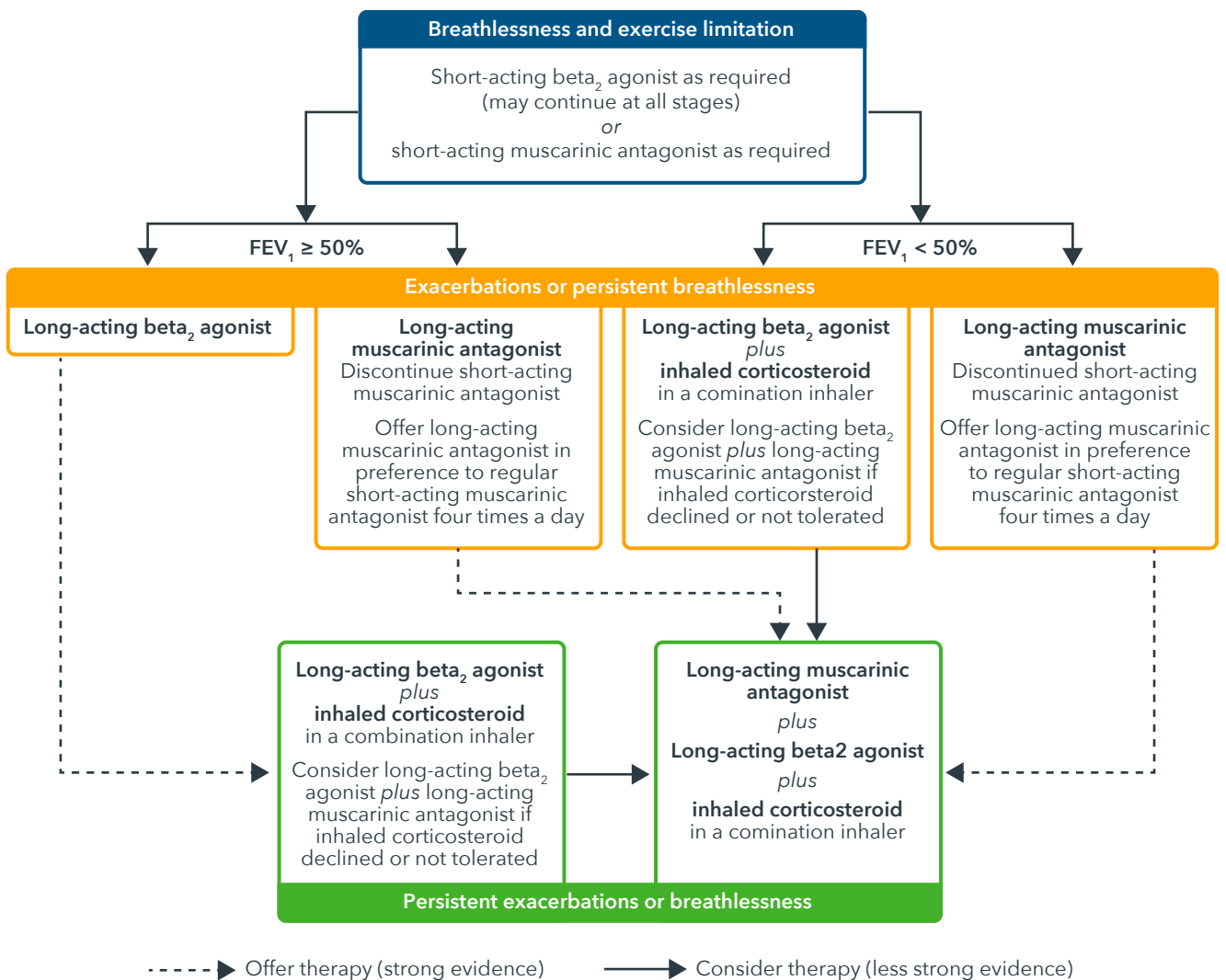
Respiratory conditions, including COPD and asthma, account for about 10% of primary care prescribing costs (Estimating the economic burden of respiratory illness in the UK, 2017, www.blf.org.uk)

The total costs for respiratory disease, including GP visits, secondary care admissions and reductions in productivity, are considerably higher. They are estimated to be £80m to £90m per month.⁵

The BNF Guidance on the management of COPD describes the treatment pathway and options for treatment escalation (see figure 7). This, in combination with the NICE Asthma Guidance 6 and the medicines optimisation drive, has resulted in the development of more regional joint formularies and an increase in the cost-effective use of inhaled therapies.

Figure 7: BNF Guidance based on NICE Guidance

Use of inhaled therapies in chronic obstructive pulmonary disease



Advice on the use of inhaled therapies in chronic obstructive pulmonary disease is based on the recommendations of the National Institute for Health and Care Excellence (2010). management of chronic obstructive pulmonary disease in adults in primary and secondary care. London: NICE. Available from www.nice.org.uk/CG101 Reproduced with permission

Source: <https://bnf.nice.org.uk/treatment-summary/chronic-obstructive-pulmonary-disease.html>

Table 5 shows the changing pattern of respiratory medicines usage. These are predominantly changes within therapeutic class to cheaper products and a shift from single-agent corticosteroids to long-acting beta agonist (LABA) combination products, in line with the recommended NICE/BNF guidance.

When the drug classes are considered, the effects of local medicines optimisation based on acquisition cost and patient acceptability can be seen. There is a general reduction in the use of branded and more expensive inhalers.

Table 5: Unit usage of respiratory medicines 2017- 2018

PRODUCT	MAT 06/17 ('000s)	MAT 06/18 ('000s)	GROWTH MAT JUNE 18	HYPOTHESIS FOR CHANGE IN GROWTH
Adrenoceptor Agonists				
SEREVENT	649	491	-24.20%	This group of medicines has been optimised to the cheapest available option with a reduction in branded products (apart from Easyhaler, which has improved patient outcome in those patients who cannot effectively use standard inhalers)
BRICANYL	1,191	1,072	-10.00%	
VENTOLIN	27,279	25,831	-5.30%	
SALAMOL	6,773	6,385	-5.70%	
SALBUTAMOL	3,872	4,086	5.50%	
EASYHALER SALBUT	527	566	7.40%	
LABA Combinations				
SERETIDE	6,900	5,374	-22.10%	Reduction in use of the more expensive Symbicort and Seretide with an increase in cheaper products in the same class
SYMBICORT	4,806	4,230	-12.00%	
SIRDUPLA	1,288	1,161	-9.80%	
FLUTIFORM	1,059	1,104	4.30%	
DUORESP SPIROMAX	1,423	1,649	15.80%	
FOSTAIR	4,866	6,237	28.20%	
RELVAR ELLIPTA	1,158	1,667	43.90%	
ANORO ELLIPTA	393	652	66.00%	
INCRUSE ELLIPTA	721	1,158	60.70%	
Antimuscarinic Bronchodilators				
SPIRIVA	6,358	4,062	-36.10%	Reduction in Spiriva and Atrovent producing a rise in Seebri and Braltus use instead. Eklira is a new product with a small market share Braltus is a new branded generic taking share from Spiriva
ATROVENT	792	576	-27.30%	
EKLIRA GENUAIR	583	565	-3.20%	
SEEBRI BREEZHALER	543	631	16.30%	
BRALTUS	248	2,089	740.70%	
Corticosteroids				
FLIXOTIDE	635	562	0	General reduction in the single component steroid inhalers because of the increase in combination products which are more cost effective and have greater patient acceptance
QVAR	1,980	1,883	0	
CLENIL MODULITE	7,020	6,829	0	
Leukotriene antagonists				
MONTELUKAST	3,524	3,742	0	

Source: IQVIA, Prescription Based Services (PBS)

SUMMARY/CONCLUSION

The medicines' usage figures show a change in the rate of growth of the retail pharmaceutical market and we believe this is largely attributable to the combined effects of medicines' optimisation and cost containment measures which are only now beginning to work through the system. If this is the correct explanation then it is likely to be a one-off correction as waste is eliminated from the system and new habits are learned, although it might have some way to go yet. When all waste has been eliminated and new habits have been learned, underlying growth could continue but the rate might be slower than in the past because previous figures reflected a combination of appropriate and inappropriate prescribing. It should be remembered that one of the reasons for the NHS measures to contain expenditure is to liberate funds for innovative products that will improve health outcomes.

WHAT ARE THE IMPLICATIONS OF THIS FOR THE PHARMACEUTICAL INDUSTRY AND NHS?

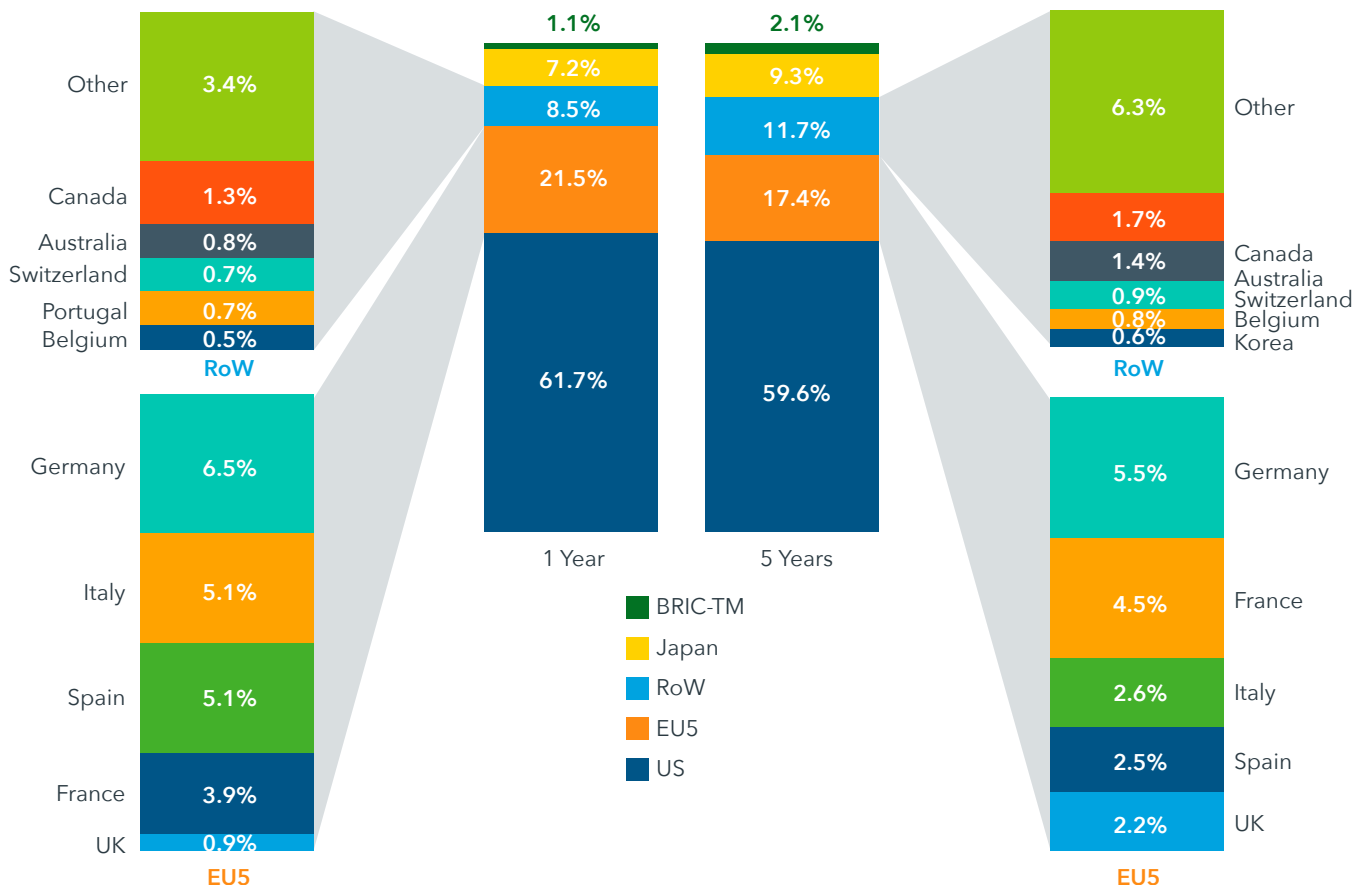
The findings of this report need to be considered against the wider social and political context.

INDUSTRY

The position of the UK as a launch country is a complex question. When looking at new launches, 90% of the first five year sales come from seven countries - US, EU5 and Japan. Therefore, the UK is important as the developed world matters, however, whilst the UK is within the top seven countries, it is ranked at number seven. Several factors play into this.

The UK has the third-highest number of new chemical entities launched as reference country, after US and Germany, however, it has the lowest uptake of new medicines at years 1 and 5 (see figure 8).

Figure 8: Proportion of cumulative 1-year and 5-year sales of new launches 2005-2015 by country



Source: IMS Health MIDAS LC US \$ Q1 2005-Q1 2016. Country contribution is calculated based on the accumulative sales of NAS (new active substances) launches from 2005 to 2015

Specialty products (both new launches and existing products) are driving the growth we do see. The original Cancer Drugs Fund has facilitated this and was in place from 2010-2016 and was generally seen to have improved medicines access. The reason for the UK's prominent position is that companies choose to launch in the UK early for reasons other than commercial return, including, but not limited to, getting a good list price for reference pricing purposes, NICE backing and the prestige of UK institutions.

The 2016 vote to leave the European Union has generated further uncertainty amongst global pharma in respect of UK as a reference country, as one of the consequences will be the relocation of the EMA offices.

In 2017, NHS England introduced a new budget impact threshold for medicines that would exceed £20mn in any one of their first three years. The pharma industry is strongly opposed to the budget impact test and the ABPI asked for a judicial review, however this was rejected in October 2017.

Finally, there is frustration in the pharma industry in respect of overall uptake speed and variation in that uptake of NICE-approved medicines, many of which are included in the primary care growth decline.

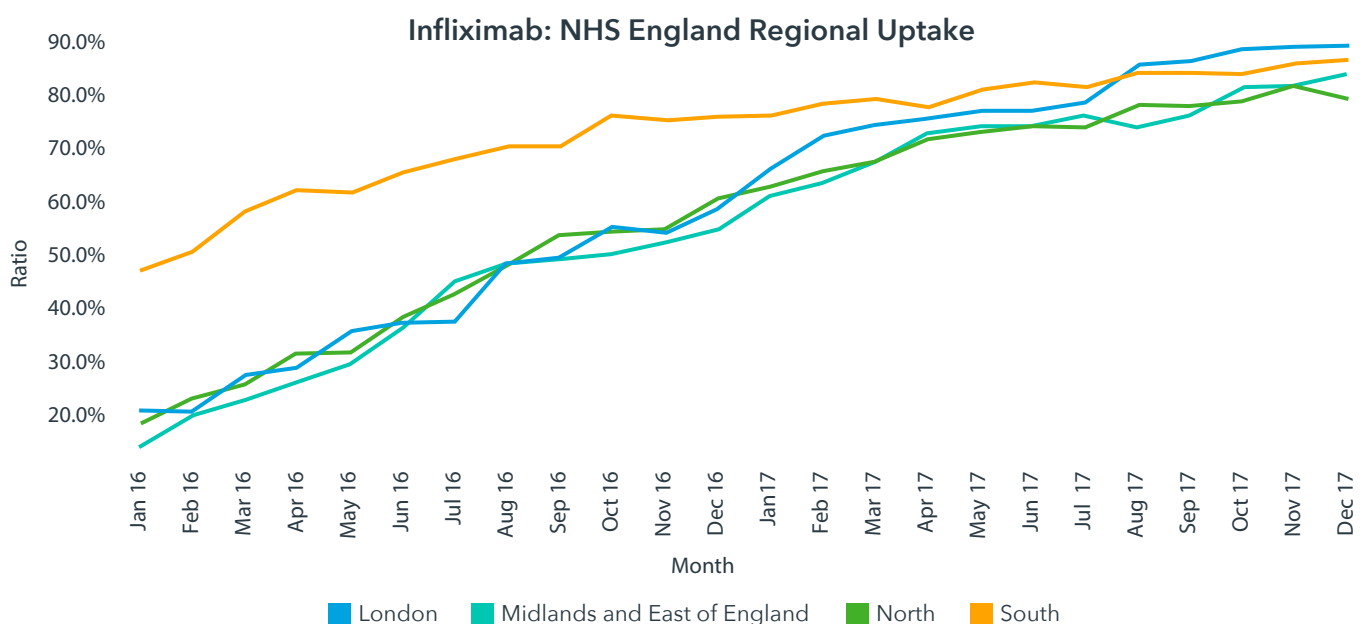
Given the clamp-down on the independence of prescribing choice by clinicians, many pharma companies have cut the number of primary and secondary care sales teams, replacing them with CCG - hospital account managers in an attempt to make the funding case for their medicines.

THE NHS

From an NHS perspective, the previously unsustainable growth in expenditure on medicines is now showing a modest decrease in primary care of -2%, even at the top level of list price, with continued significant growth in secondary care although this has decreased from around 12 to 14% over the last eight years to 6% last year. We believe that the main reasons for these findings include:

- driving efficiencies in medicines use by supporting patients and monitoring their outcomes,
- discontinuing medicines if they are not working, of little clinical value or if they can be bought from pharmacies or are on the General Sales List and
- the use of lower-cost medicines within the same therapeutic class, including using generic and biosimilar medicines effectively on the loss of exclusivity. We note that biosimilar uptake is still not optimised nationally or regionally and opportunities for savings still exist in a number of suppliers (see figure 9).

Figure 9: Biosimilar uptake by region, December 2017 (ref: IQVIA NHS Medicines Use Dashboard (available within the NHS only))



In addition, the decrease in antibiotic use is due to a focus on reducing the risk of antimicrobial resistance through diligent antibiotic stewardship.

In future it is possible that further cost-containment measures could be introduced by Regional Medicines Optimisation Committees, Area Medicines Management Groups as part of the Sustainability Transformation Partnerships (STPs).

WHAT DOES THE FUTURE OF PRIMARY AND SECONDARY CARE PHARMACEUTICAL MARKETS LOOK LIKE?

The total UK pharmaceutical market, forecast to expand at a CAGR of 4.1% over 2017-2022 in list price, pre-rebate and discount value terms, will be mainly propelled by the arrival of premium-priced innovative medicines together with a growing and ageing population, which will in turn drive the NHS drugs bill over the next five years. Based on slower than expected standard unit growth in both the retail and hospital sector in 2017, volume growth in the UK is expected to show actual decline over the forecast period, with a CAGR of just -0.4% in 2017-2022 compared to 1.7% in 2012-2017.

However, the value growth of new product launches will be kept firmly in check by the influence of NICE evaluations. In April 2017 NICE imposed budget impact tests as part of the reform of its appraisal process and this new policy may allow the fast-track appraisal of a few new drugs. Policy changes also mean the prioritisation framework for non-routinely commissioned specialty medicines, which restricts reimbursement to a number of shortlisted drugs within a pre-set budget, will also act as a drag on value growth acceleration over the next five years. Furthermore, subjecting highly specialised medicines to a threshold of cost-per-QALY of up to £300,000 under the NICE reforms, will curb future reimbursement in therapies for rare diseases.

The Cancer Drugs Fund (CDF), which became effective from mid-2016, will curb rates of increase in cancer drugs spending, as it presents a fixed annual budget, which, if exceeded, triggers manufacturer paybacks. It is important to note, the new 'managed access' approach to the CDF, may present the industry with an opportunity to receive early reimbursement funding for drugs that demonstrate potential in early-stage clinical studies.

Factoring in the numerous additional strategies to control the spiralling NHS medicines bill, hospital sector value growth is therefore forecast to decelerate to a CAGR of 8.2% in the 2017-2022 period (compared with 12.7% in 2012-2017).

The retail sector CAGR in value terms is also set to decelerate (at -1.0%) over the next five years (compared with a CAGR of 2.1% in 2012-2017). Volume growth is expected to follow a similar trend with a forecast CAGR of -0.5% compared to 1.7% historically. The main constraints in the sector include NHS England's proposed ban of some 18 treatments, which have been classified as '*ineffective, over-priced and low value treatments*' by NHS England. An estimated saving of about £141 million per annum is expected as a result of this move. Further savings of about £645 million are also targeted by restricting prescribing of OTC medicines. The targeted savings form a key building block of the NHS England's ten point efficiency plan contained in the *Next Steps on the NHS Five Year Forward View*, published in March 2017.⁷

Generic competition and biosimilar penetration will also slow overall market growth in values over the prognosis period.

CONCLUSIONS

Four key messages emerge from this report:

- 1 Market growth as seen over the last eight years is unsustainable.** The financial pressures facing the NHS mean that funding for new medicines has to be found primarily from within existing resources.
- 2 The combined effects of medicines' optimisation and cost containment measures are beginning to work through the system** and exert downward pressure on the primary care pharmaceutical market. This should allow more patients to be treated effectively.
- 3 The decrease in the size of the retail market is likely to be a one-off correction** as waste is eliminated from the system and new habits are learned - although it has some way to go yet.
- 4 Elimination of ineffective (wasteful) use of medicines and better managed treatment with a clear focus on outcomes (i.e. optimised treatment) is in everyone's best interests,** especially the manufacturers. Medicines that are prescribed, taken and monitored correctly are likely to achieve therapeutic target more often with fewer side effects.

RECOMMENDATIONS

The partnership between the NHS and the pharmaceutical industry needs to continue to develop to ensure the UK remains an attractive market and patients in the UK can access the most appropriate medicine for their diseases.

- **Industry should work with the NHS to find sustainable/mutually beneficial ways forward** bearing in mind that NHS cost-containment measures are intended to liberate funds for innovative products that should achieve better health outcomes.
- **Industry should be aware of and take into account the Medicines Optimisation agenda to ensure positive outcomes.**

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