



HFMA briefing  
July 2017



# Medicines costs in Scotland



# Contents

<b>Introduction</b>	3
<b>The medicines approval process in Scotland</b>	4
The Scottish Medicines Consortium (SMC)	4
The SMC value for money decision making process	5
The standard process for medicines value for money assessments	5
Very rare and end of life conditions medicines	6
Patient access schemes	8
Individual patient treatment requests and the peer approved clinical system	8
<b>Medicines costs and funding</b>	9
Historic trends of medicines costs in Scotland	9
<b>Financial risks and challenges</b>	12
Rising medicines costs	12
End of life and very rare conditions medicines costs	13
Sub-conditions and sub-populations	14
Extending the appropriate conditions or cohort for already approved very rare and end of life conditions medicines	16
Individual patient treatment requests (IPTRs) and peer approved clinical systems (PACS)	17
The new medicines fund (NMF)	17
Whole health-economy value for money	19
<b>Conclusion</b>	20
<b>Appendix 1 – New medicine approval flowchart</b>	21
<b>Acknowledgements</b>	22

# Medicines costs in Scotland

## The value for money decision-making process for accepting medicines for use in the NHS in Scotland explained, and the financial consequences explored

### Introduction

The Scottish Medicines Consortium (SMC) decides whether new medicines ought to be routinely available for prescribing by the NHS in Scotland based on its assessment of the value for money of those new medicines. Medicines treating relatively common, non-end of life conditions must usually be below a certain price per extra year of perfect health they will give. But where a medicine is designed to treat a very rare, or end of life condition, the SMC adopts a different assessment of its value for money. Under these circumstances less weight is placed on the cost-effectiveness of the medicine and therefore more expensive medicines may be accepted for use in the NHS when treating these types of conditions.

This briefing sets out the background to the SMC's approval process, and how the process differs between very rare or end of life conditions medicines and other medicines. It explains the calculations used in working out the cost and impact, and explains the approval route that can be taken where a medicine has not been accepted for use by the SMC. This background will be useful for healthcare finance professionals in Scotland since it provides the necessary context for assessing the financial risk to their health boards associated with future medicines approvals.

Medicines costs are a material part of all health boards' budgets. This briefing shows how the proportion of health boards' budgets spent on medicines has changed over time and can be extrapolated to future years based on these trends. Growth in medicines costs in hospital and community services is particularly high, at 10.2% and 19.8% per annum respectively on average over recent years. If growth continues at this rate then, given that it significantly outstrips the growth in healthcare funding in Scotland, an increasing proportion of healthcare expenditure will need to be on medicines, and savings will have to be found elsewhere.

This briefing examines a set of financial risks identified through our research that relate to medicines costs in Scotland. We note that as well as the general risk due to rising medicines costs there are some specific financial risks associated with very rare and end of life conditions medicines because of their relatively high cost and high acceptance rates.

In identifying financial risks the briefing will be valuable for finance professionals in their financial planning, and where mitigating actions are available, will be of support in reducing the likely impact of the risks.

# The medicines approval process in Scotland

The SMC makes assessments of new medicines in Scotland and accept them for use, or otherwise, for prescription by clinicians in the NHS in Scotland. We explain below how this process works and how the value for money assessments are made. See also appendix 1 for a summary flowchart showing this process.

## The Scottish Medicines Consortium (SMC)

The approval route for accepting new medicines for use by the NHS in Scotland falls within Scotland's devolved legislative powers and so differs from the routes in other countries in the United Kingdom. This means that the Scottish Government sets the policy that determines the way in which medicines are approved for use within the NHS in Scotland.

The principal body that decides whether a medicine is approved for NHS clinicians to administer in Scotland is the SMC. The SMC describes itself as “a committee made up mainly of clinicians and managers from across NHS Scotland and also representatives of the pharmaceutical industry and public partners”.<sup>1</sup>

There are three stages that a new medicine needs to go through before it can be prescribed by an NHS clinician in Scotland.<sup>2</sup>

- Before the SMC considers accepting a new medicine for use it must first be licensed for use in the UK: this is done either by Medicines and Healthcare Regulatory Agency (MHRA), which covers just the UK; or the European Medicines Agency (EMA), that covers the whole of the European Union.
- Once a medicine has been licensed for use the pharmaceutical company may submit it to the SMC which must then decide whether or not to accept its use by the NHS in Scotland before the next stage.
- If the SMC has accepted a medicine for use by the NHS in Scotland, then each NHS board must decide whether to accept it for use in its area. If a medicine has been accepted for use by the SMC then it is the norm that boards will accept it for use in their area – this avoids there being differing prescribing policies in different geographical areas in Scotland.

The MHRA or EMA's role in the medicines approval process is to assess whether a new medicine works as intended and is acceptably safe. Their focus is the clinical efficacy and safety of a new medicine rather than any wider financial, or economic considerations.<sup>3,4</sup> It is not currently known whether the UK will continue to use the EMA's recommendations after the Brexit process is concluded.

The SMC's role in accepting a medicine for use in the NHS in Scotland focuses on the value for money of the medicine. The SMC describes its purpose as ‘to accept for use those newly licensed medicines that clearly represent good value for money to NHS Scotland’.<sup>5</sup>

---

<sup>1</sup> [www.scottishmedicines.org.uk/About\\_SMC/Who\\_we\\_are](http://www.scottishmedicines.org.uk/About_SMC/Who_we_are)

<sup>2</sup> [www.scottishmedicines.org.uk/files/7523\\_A4-New-Medicines.pdf](http://www.scottishmedicines.org.uk/files/7523_A4-New-Medicines.pdf)

<sup>3</sup> [www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con2031677.pdf](http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con2031677.pdf)

<sup>4</sup> [www.ema.europa.eu/docs/en\\_GB/document\\_library/Leaflet/2014/08/WC500171674.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Leaflet/2014/08/WC500171674.pdf)

<sup>5</sup> [www.scottishmedicines.org.uk/About\\_SMC/What\\_we\\_do](http://www.scottishmedicines.org.uk/About_SMC/What_we_do)

To assess whether a new medicine is good value for money the SMC looks at:

- How effective a medicine is
- Whether there is an already available medicine that is as good or better than the medicine under consideration
- The patient groups that would benefit from the medicine
- An economically and financially focused assessment of the value for money of the medicine.<sup>6</sup>

We look below at the value for money assessment, and in particular how this relates to the cost of the medicine, since this is the part of the decision-making process with the greatest financial consequence for health boards in Scotland.

## The SMC value for money decision making process

The SMC assesses all new medicines in terms of value for money. They will usually only accept a medicine for use if there are not alternatives already available that are either more clinically effective or as clinically effective and cheaper.

If the medicine is for a very rare condition or for treatment of an end of life condition then the assessment can follow a process that is distinct from the process followed by other medicines. We refer below to the 'standard process' and the 'very rare and end of life conditions process' to distinguish between the two.

The SMC's role is to look at the value for money of new medicines, but it should be noted that *value for money* and *affordability* are distinct concepts. A medicine could be very good value for money because it significantly enhances the length and quality of a patient's life, but if it is relatively expensive or is likely to be appropriate for a large cohort of patients it may not be affordable given other requirements for healthcare funding.

## The standard process for medicines value for money assessments

This section summarises how value for money decisions are made by the SMC for drugs which are not for rare or end of life conditions.

In assessing the value for money of a new medicine the SMC considers evidence submitted by the pharmaceutical company putting forward the medicine for consideration. The evidence considered in making the value for money decision will primarily be about the cost of the medicine proposed together with an assessment of the expected impact on the health of the recipient of the medicine, though the evidence considered can be wider in scope.

To quantify the value for money of a new medicine the SMC, in common with the approach adopted by the National Institute for Health and Care Excellence (NICE) for England and Wales, takes the ratio of the incremental cost of treatment to the incremental quality adjusted life years (QALYs) it confers on the patient.<sup>7</sup>

A QALY is an attempt to quantify the quality of someone's health – one year at perfect health corresponds to one QALY, three years at only half of perfect health corresponds to 1.5 QALYs etc. The ratio of the incremental cost to incremental QALY is called the 'incremental cost-effectiveness ratio' (ICER), an example calculation is illustrated below.

---

<sup>6</sup> [www.scottishmedicines.org.uk/Public\\_Involvement/New-Medicines-Approval](http://www.scottishmedicines.org.uk/Public_Involvement/New-Medicines-Approval)

<sup>7</sup> See for example pp32-33 of the SMC's May 2017 guide to manufacturers on the new product assessment form, this or subsequent updates can be found: [www.scottishmedicines.org.uk/Submission\\_Process](http://www.scottishmedicines.org.uk/Submission_Process)

### Example ICER calculation

- A full course of a new medicine, needed for six months, costs £15,000 for the average patient
- The medicine can be expected to save the patient's life and there are no alternative treatments
- The patient will have a near perfect quality of life after taking the medicine and on average can be expected to live a further 10 years.

To calculate the ICER, the difference in QALYs for the patient between taking and not taking the medicine needs to be calculated, in this example this is 10 QALYs – being 10 years of near perfectly quality of life each of which equates to one QALY.

The cost of the medicine is £15,000 for the full course and so the ICER is  $£15,000/10 = £1,500$ .

In practice calculations will not be this simple: it is unlikely that a medicine will mean the difference between not living and perfect health to such a degree with such a short course of treatment. The data available to make such calculations are also unlikely to be as clear as we have set out in this example.

The SMC, in its guidance for pharmaceutical companies, states that it notes NICE's policy with respect to the threshold for the ICER when making its decisions. This establishes that where the ICER of a drug is below £20,000 (i.e. where the incremental cost of the medicine divided by the total QALYs it gains is less than £20,000) then the medicine would usually be approved if all other approval criteria are met. Where the ICER is between £20,000 and £30,000 then the SMC will pay closer scrutiny to further factors about the likely benefit of the medicine. Where the ICER is greater than £30,000 then an 'increasingly strong case' would need to be presented about how the new medicine would be a good use of NHS resources.<sup>8</sup>

### Very rare and end of life conditions medicines

The standard process, described above, is available for all medicines in Scotland but an alternate route can be opted for by pharmaceutical companies for medicines that are for treating very rare or end of life conditions. If the medicines fit into these categories, which we define below, then the cost can be greater per QALY gained than under the standard process. This has important implications for medicines costs that health boards in Scotland will incur.

---

<sup>8</sup> See pp32-33 of of the SMC's May 2017 guide to manufacturers on the new product assessment form.

## Definitions

To use the alternative value for money assessment route a medicine must be for treating either a very rare condition or an end of life condition.

Medicines for very rare conditions in Scotland are split into two sub-categories:

- *Orphan medicines* are those used to treat conditions with a prevalence of less than one instance per 2,000 in Scotland (less than 2,500 in a population of 5 million);
- *Ultra-orphan medicines* are those that can be used to treat conditions with a prevalence of less than one instance per 50,000 people in Scotland (less than 100 in a population of 5 million).

An *end of life medicine* is one that is “[...] used to treat a condition at a stage that usually leads to death within 3 years with currently available treatments.”<sup>9</sup>

## Background to differential value for money assessment

In October 2013 the Scottish Government published its response to the Health and Sport Committee’s inquiry into the approval process for new medicines in Scotland.<sup>10</sup> A key passage from that response is:

*“The Committee recognised that existing cost-effectiveness thresholds are not always appropriate for end of life medicine or for medicines to treat very rare diseases. The Cabinet Secretary has therefore directed the SMC to apply different approaches in the evaluation of these medicines, including a rapid review of the wider aspects of value and QALYs in order to increase access to patients to these medicines.”*<sup>11</sup>

There was an explicit policy decision by the Scottish Government to adopt a differing value for money assessment for those end of life and very rare condition drugs that in effect raised or removed the usual ICER thresholds applied.

This means that for these drugs the cost of the medicines can be significantly higher and still be approved for use by the NHS in Scotland.

## The very rare and end of life conditions medicines assessment process

The process for assessment differs further with ultra-orphan drugs (those for conditions expected to affect fewer than 1 in 50,000 people) following a different approvals process to orphan and end of life drugs; but for the purposes of this briefing we pull out the salient points that give rise to the financial impacts that are common to both.

The ICER is still usually calculated,<sup>12</sup> but this is given less weight in the decision-making process than for standard medicines. Instead, greater consideration is given to other potential positive effects of the medicine, effects which are not already included in the calculation of the QALY and cannot

<sup>9</sup> Pp3-4 *PACE (Patient & Clinician Engagement) Overview Document*, SMC  
[www.scottishmedicines.org.uk/files/PACE/PACE\\_Overview\\_Document\\_V2.pdf](http://www.scottishmedicines.org.uk/files/PACE/PACE_Overview_Document_V2.pdf)

<sup>10</sup> *Response to the health and sport committee inquiry into the access to new medicines*, Scottish Government, 2013 [www.parliament.scot/S4\\_HealthandSportCommittee/Inquiries/Scottish\\_Government\\_Response\\_-\\_Access\\_into\\_New\\_Medicines.pdf](http://www.parliament.scot/S4_HealthandSportCommittee/Inquiries/Scottish_Government_Response_-_Access_into_New_Medicines.pdf)

<sup>11</sup> P5, *Response to the health and sport committee inquiry into the access to new medicines*, 2013  
[www.parliament.scot/S4\\_HealthandSportCommittee/Inquiries/Scottish\\_Government\\_Response\\_-\\_Access\\_into\\_New\\_Medicines.pdf](http://www.parliament.scot/S4_HealthandSportCommittee/Inquiries/Scottish_Government_Response_-_Access_into_New_Medicines.pdf)

<sup>12</sup> In some assessments of ultra-orphan medicines the ICER may not be calculated at all, but it will be for end of life or orphan medicines



necessarily be quantified. For example, the SMC might look at the impact the medicine has on a patient's family, or on the ability of a patient to work.

Where the medicine meets the standard ICER criteria that apply to other medicines it may be provisionally accepted by the SMC. Otherwise, the medicine will go through patient and clinician engagement (PACE), where this is not the case under the standard approach.

Under PACE patients and clinicians meet to jointly determine those wider effects that are not easily quantified through the QALYs. The intention is for the approach to be more consultative and for the decision about whether to approve the medicine for use to reflect all relevant considerations.

In December 2016 an independent review by Dr Brian Montgomery was published into the assessment process for very rare and end of life conditions medicines.<sup>13</sup> The review makes recommendations about the approvals process for example on the definitions of the terms 'end of life' 'orphan' and 'ultra-orphan', it might be expected therefore that the process outlined above will change in the near future.

## Patient access schemes

Where a medicine for an end of life or very rare condition is assessed by the SMC and not approved, there is scope for the pharmaceutical company to review its pricing structure and subsequently seek approval again from the SMC. This process is known as the 'patient access scheme' and may result in drugs being approved for use but at a lower price than was originally suggested by the pharmaceutical company.

For the purposes of this briefing it is sufficient to note that there are further chances at approval by the SMC if pharmaceutical companies choose to pursue it.<sup>14</sup>

Pharmaceutical companies are also able, prior to any consideration by the SMC, to offer a pricing structure for any medicine (not just those for very rare or end of life conditions) through the patient access scheme.

## Individual patient treatment requests and the peer approved clinical system

Where a medicine is not accepted for use by the SMC, patients may still be able to access the medicine through the NHS in Scotland via an individual patient treatment request (IPTR), or through the peer approved clinical system (PACS). PACS is the process currently used for seeking access to ultra-orphan medicines that have not been accepted for use by the SMC.

The IPTR/ PACS process allows for an individual application for a medicine that has not been accepted for use by the SMC. The medicine might not have been accepted for use by the SMC following its being actively considered by them, or it might not be accepted for use simply because the pharmaceutical company has not submitted the medicine to the SMC for consideration.

Each health board will have its own IPTR or PACS policy, but in general terms these are designed to allow patients and their clinicians to present a case for the use of a drug that has not been accepted for use by the SMC. Each case needs support from the clinician and will depend on the patient's circumstances and their need or benefit for the specific medicine given those circumstances. Where a medicine is approved for a particular patient through this route it would not mean that the medicine can then be routinely prescribed for other patients, each request is considered on a case by case basis.

---

<sup>13</sup> *Review of Access to New Medicines*, Brian Montgomery, 2016 [www.gov.scot/Publications/2016/12/9192/0](http://www.gov.scot/Publications/2016/12/9192/0)

<sup>14</sup> More detail on the patient access schemes can be found here:

[www.scottishmedicines.org.uk/files/PAS/NHS\\_Scotland\\_Patient\\_Access\\_Scheme\\_\\_PAS\\_\\_Guidance\\_V3.0\\_Final.pdf](http://www.scottishmedicines.org.uk/files/PAS/NHS_Scotland_Patient_Access_Scheme__PAS__Guidance_V3.0_Final.pdf)



Importantly for the focus of this briefing, the cost of the medicine should not be a consideration when deciding whether an IPTR or PACS application is successful. The implication of this is that where a medicine is not accepted for use by the SMC on value for money grounds it may nevertheless be approved through the IPTR or PACS route.

## Medicines costs and funding

### Historic trends of medicines costs in Scotland

Medicines costs in Scotland are published as part of the Information Services Division's (ISD's) Scottish health service costs dataset. In publishing these costs the ISD distinguishes between hospital drugs, community drugs costs and family health services drugs costs – we group the latter two together here as primary care drugs costs.<sup>15</sup>

Table 1 sets out the costs of hospital drugs from 2012/13 until 2015/16 and compares it with primary care drugs costs. The table also shows the growth rates in both sets of drugs costs as well as the total costs for primary care and hospital care based on the ISD data.

**Table 1: Historic primary care and hospital drugs costs and costs growth<sup>16</sup>**

	2012/13	2013/14	2014/15	2015/16
<b>Hospital drugs costs - £000</b>	313,929	341,411	387,992	419,858
<b>All hospital costs - £000</b>	5,812,862	5,944,883	6,145,754	6,384,216
<b>Primary care drugs costs - £000</b>	1,055,871	1,080,377	1,174,140	1,255,253
<b>All primary care costs £000</b>	4,050,199	4,150,639	4,299,309	4,459,047
<b>Hospital drugs cost growth</b>		8.8%	13.6%	8.2%
<b>All hospital costs growth</b>		2.3%	3.4%	3.9%
<b>Primary care drugs costs growth</b>		2.3%	8.7%	6.9%
<b>All primary care costs growth</b>		2.5%	3.6%	3.7%

Source: Information Services Division - Scottish health services costs to 31 March 2016

Healthcare costs are increasing in Scotland, but table 1 shows how the rate of growth of drugs costs outstrips the rate of growth of overall costs. For example, all hospital costs in 2015/16 rose by 3.9% but hospital drugs costs rose by 8.2%, similarly primary care costs rose by 3.7% in 2015/16 but primary care drugs costs rose by 6.9%.

If we take the data from table 1 on the costs of drugs and the costs of whole services we can calculate a compound average growth rate – i.e. the average year on year growth rate over the three years in the data above (table 2).

<sup>15</sup> In so doing we follow the ISD's note here on the split of primary care into community and family health services: [www.isdscotland.org/Health-Topics/Finance/Costs/](http://www.isdscotland.org/Health-Topics/Finance/Costs/). We follow the ISD's use of 'drugs' rather than 'medicines' when referring to their data or extrapolation from their data.

<sup>16</sup> [www.isdscotland.org/Health-Topics/Finance/Costs/](http://www.isdscotland.org/Health-Topics/Finance/Costs/), the presentation and growth analysis presented here are produced by the HFMA from the data obtained.

**Table 2: compound average growth rate of services and drugs**

	Compound average growth rate
<b>Hospital drugs costs</b>	10.2%
<b>All hospital costs</b>	3.2%
<b>Primary care drugs costs</b>	5.9%
<b>All primary care costs</b>	3.3%

What is stark from table 2 is that the costs of drugs in Scotland are on average increasing at a far greater rate than the costs of hospital services as a whole (10.2% versus 3.2%). They are also growing at a far faster rate than primary care drugs costs (10.2% versus 5.9%). This increase in drugs costs is replicated in other countries too though – for example NHS England noted recently “The NHS drugs bill grew by over 7% last year, with particular growth in hospital-driven prescribing. This was considerably faster than growth in the overall NHS budget.”<sup>17</sup>

At table 3 we show how future costs would look across hospital and primary care services if the compound annual growth rates remain at these levels from 2016/17 to 2019/20.

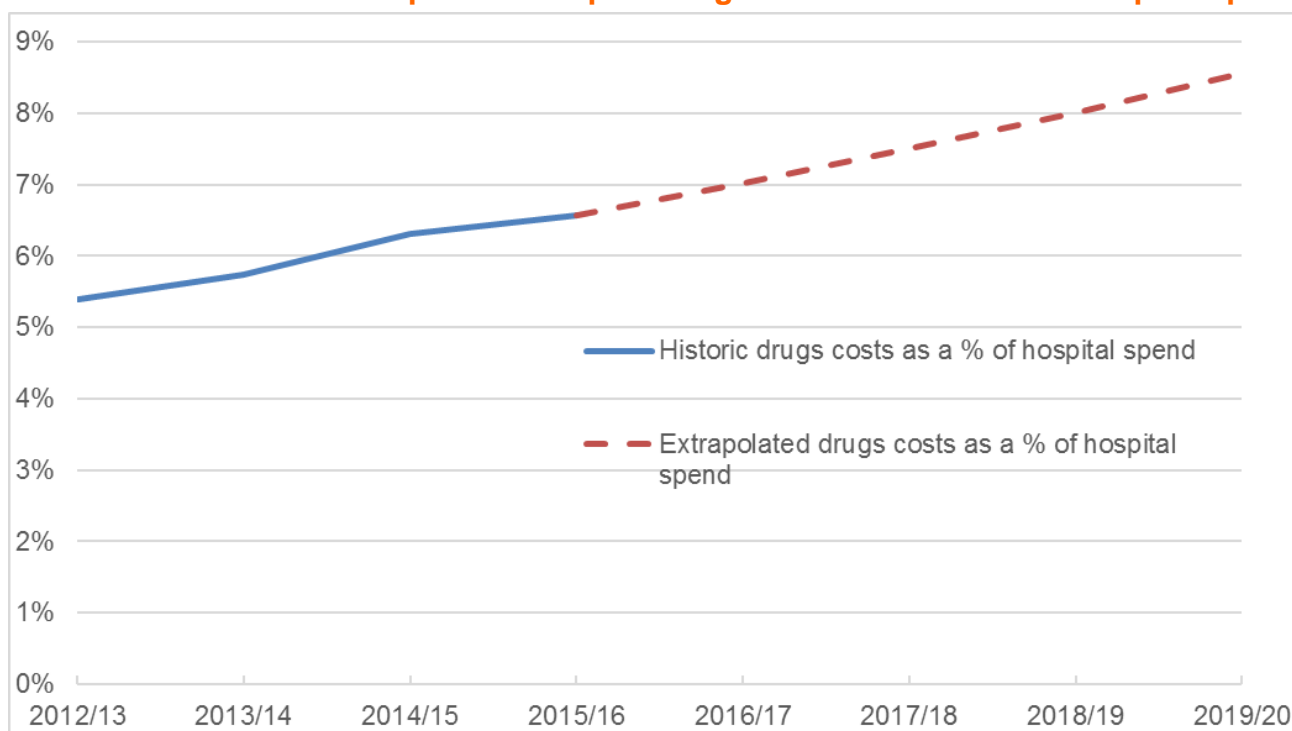
**Table 3: Extrapolated costs of services and drugs 2016/17 to 2019/20**

	2016/17	2017/18	2018/19	2019/20
<b>Hospital drugs costs - £000</b>	462,587	509,664	561,532	618,679
<b>All hospital costs - £000</b>	6,586,885	6,795,988	7,011,730	7,234,319
<b>Primary care drugs costs - £000</b>	1,329,753	1,408,676	1,492,283	1,580,852
<b>All primary care costs £000</b>	4,604,303	4,754,291	4,909,165	5,069,085
<b>Assumed hospital drugs cost growth</b>	10.2%	10.2%	10.2%	10.2%
<b>Assumed all hospital costs growth</b>	3.2%	3.2%	3.2%	3.2%
<b>Assumed primary care drugs costs growth</b>	5.9%	0.0%	0.0%	0.0%
<b>Assumed all primary care costs growth</b>	3.3%	3.3%	3.3%	3.3%

If the trends in table 3 are followed, and drugs costs growth continues at 10.2% per annum in the hospital sector, then the costs of drugs within the hospital sector as a proportion of the total costs of the hospital sector will increase significantly. Drugs costs in hospitals in 2012/13 were 5.4% of all hospital costs, but chart 1 shows that this will increase to 8.5% by 2019/20 if they continue to grow at the rate they have historically.

<sup>17</sup> P41 *Next steps on the NHS five year forward view*, NHS England, March 2017

**Chart 1: Historic and extrapolated hospital drugs costs as a % of total hospital spend**



Because of the nature of the medicines and the conditions that they treat a greater proportion of end of life and very rare conditions medicines are likely to be used in a hospital setting rather than in primary care. Dr Brian Montgomery's review of the end of life and very rare conditions approval process noted that there has been an increase in acceptance rates for very rare and end of life medicines since the inception of the new process in 2014, and it also notes the potential cost pressure that this will give rise to.<sup>18</sup> Later in this briefing we note the financial risks arising from this.

### Primary care drugs costs analysis

In primary care the costs of drugs are a greater proportion of total costs, 26.1% in 2012/13, and if they and total primary care costs rise as shown in table 3 this will increase to 31.2% by 2019/20. We have added together both community services and family services drugs costs as primary care, in the analysis above, both sets of costs are incurred outside of hospital services.

A further sub-division of primary care drugs costs into community services drugs costs and family health services costs<sup>19</sup> reveals that the average growth rate in the costs of community drugs was 19.8% between 2012/13 and 2015/16, with family health drugs growth at 3.7%. This is shown in table 4.

<sup>18</sup> See, for example, section 6.4.5 p24, section 6.6.6 p29, or sections 7.2 and 7.3 p45 *Review of Access to New Medicines*, Brian Montgomery, 2016

<sup>19</sup> ISD defines 'community services' and 'family health services' as:

- community services - home visits by district nurses, for example, or prevention services such as breast screening and health promotion
- family health services - services provided by the family doctor (GP) service and the "High Street" dentists, opticians and pharmacists

**Table 4: Primary care drugs costs and growth**

	2012/13	2013/14	2014/15	2015/16	
<b>Community services drugs - £000</b>	130,588	139,368	184,762	224,377	
<b>Family health services drugs - £000</b>	925,283	941,009	989,378	1,030,876	
<b>Total primary care drugs - £000</b>	1,055,871	1,080,377	1,174,140	1,255,253	
					<b>Compound average growth rate</b>
<b>Community services drugs growth</b>		6.7%	32.6%	21.4%	19.8%
<b>Family health services drugs growth</b>		1.7%	5.1%	4.2%	3.7%
<b>Total primary care drugs growth</b>		2.3%	8.7%	6.9%	5.9%

This growth of community services drugs costs over recent years is notable. There can be a differential VAT treatment on drugs dispensed through community services rather than in hospitals which can make community services drugs cheaper than when they are prescribed in hospital,<sup>20</sup> this may have led to part of this growth. The data are not available to point definitively to the cause of this growth, but interviewees for this research noted a general trend to prescription in the community (either because of favourable VAT treatment or because of quality benefits for patients), as well as a general rise in new medicines, not just those for end of life or very rare conditions.

Where some of the growth in community services costs in recent years is attributable to a shift from prescribing in hospitals then this may have offset some of the growth in hospital drugs costs that would otherwise have occurred. Consequently, the underlying growth rate in hospital drugs costs used to extrapolate future hospital drugs costs may be understated, and finance professionals may wish to consider the overall growth in both hospital and community services drugs where this is relevant to their health board.

## Financial risks and challenges

There are a number of financial risks arising from medicines costs and funding availability in Scotland. This section sets out those risks and, where available, the mitigating actions that might be taken to partially address them.

### Rising medicines costs

In general, medicines costs are rising at a greater rate than overall healthcare costs, as shown in table 1.

The total funding allocated to territorial health boards in the 2017/18 draft budget was £9,355m, a 2.8% increase over 2016/17's £9,102m.<sup>21</sup> This increase in funding includes some funding earmarked for new investment though and so the increase in general funding for health boards will be lower than this.

Health boards should continue to plan for rising medicines costs, and for them rising at a rate greater than the overall funding envelope. At projected rates there would be a need for there to be savings elsewhere in the system to offset these rising costs.

Noting the Montgomery review's assertion that there is a risk around the sustainability of funding medicines for end of life and very rare conditions we look in subsequent sections at specific risks arising from this class of medicines.

<sup>20</sup> See for example this note from HMRC: [www.gov.uk/government/publications/vat-notice-70157-health-professionals-and-pharmaceutical-products/vat-notice-70157-health-professionals-and-pharmaceutical-products#pharmaceutical-goods-supplied-with-or-without-medical-treatment](http://www.gov.uk/government/publications/vat-notice-70157-health-professionals-and-pharmaceutical-products/vat-notice-70157-health-professionals-and-pharmaceutical-products#pharmaceutical-goods-supplied-with-or-without-medical-treatment)

<sup>21</sup> [www.gov.scot/Publications/2016/12/6610/7](http://www.gov.scot/Publications/2016/12/6610/7)

## End of life and very rare conditions medicines costs

Because medicines for very rare conditions have, by definition, a low potential patient cohort that they are appropriate for, their cost of development by pharmaceutical companies is often higher than other medicines and so the cost to the health service per patient will also often be higher.

In interviews carried out for this briefing with healthcare finance professionals in Scotland it was noted that there is concern about the rising costs of end of life and very rare conditions medicines and about the long term affordability of these. These concerns are echoed in both the Montgomery review and in Audit Scotland's wide-ranging 2016 report on the NHS in Scotland.<sup>22</sup>

Audit Scotland's report and the Montgomery review have both noted the high acceptance rate of end of life and very rare conditions medicines, and that this rate appears to be significantly higher than the approval rate for these medicines was before the new approach was introduced. Audit Scotland said:

Between May 2014 and March 2016, the SMC approved 75 per cent of medicines (for treating very rare and rare conditions and for use at end of life). This compares to 48 per cent of medicines approved by the SMC between 2011 and 2013 (for cancer medicines and those for treating rare conditions).<sup>23</sup>

Given this apparently higher acceptance rate and the costs of such medicines, there is a risk that medicines costs will continue to grow at a high rate.

This increase in medicines costs is borne out by the analysis earlier in the briefing, but there is a risk of a compounding effect in future years that has not been reflected into our earlier analysis and which might have a further material impact on these medicines' costs. Because the SMC's new approval route came into effect only in May 2014 the data from ISD, which includes up to financial year 2015/16, will only be showing two years' effect of this new approach. But, as we set out below, both the increasing use of those medicines approved since 2014, and the new medicines that are being approved each year, may have an ever-increasing impact on medicines costs.

There is an initial lag between a medicine being accepted for use by the SMC and its being prescribed by clinicians at the expected steady-state yearly rate – starting from a baseline of zero patients per year it will take perhaps two or three years, according to interviewees, for the prescribing rates to reach their full level as new patients are prescribed the medicines. It would follow that the full effect of medicines approved in 2014 and 2015 is not reflected in the 2015/16 figures for the cost of medicines the ISD have reported, and therefore the extrapolated growth in costs of drugs of 10.2% for hospital services may be too low.

The assessment process for end of life and very rare conditions medicines remains in place, and so new medicines are being accepted for use by the NHS in Scotland monthly. Most of these will increase the formulary list of medicines for routine use and so will lead also to an increase in medicines costs. This cause of increase will also not be fully reflected in the extrapolated growth figures presented earlier in this briefing – and so this too might mean that the forecast growth figures are lower than the actual growth.

Health boards will, in many cases, already be planning for these cost increases. Pharmacy and finance departments will financially model the predicted costs of new medicines based on assumed uptake rates that reflect the increasing use of new medicines over time as more patients are

---

<sup>22</sup> Section 6.6.6 p29 *Review of Access to New Medicines*, Brian Montgomery, 2016; p22 Audit Scotland, *NHS in Scotland*, 2016

<sup>23</sup> P22 *NHS in Scotland*, Audit Scotland, 2016

prescribed them. Data are available from the SMC,<sup>24</sup> from boards' own historic accounts, and from pharmacist and clinician projections of patient numbers on the costs of medicines and likely patient numbers in the future. Use of these data to predict future costs of currently available medicines in financial modelling will help boards plan for the increased costs they will face, but there will be uncertainty over a number of the variables that impact the model.

### Variation in patient numbers for very rare conditions medicines

Where medicines have high per patient costs, accurate modelling of patient numbers can be particularly important as small changes in numbers can result in a large change in costs. Where patient numbers are very low materially accurate prediction of these numbers will be more difficult. The following example looks at how costs might vary from those expected.

Suppose a health board covers a population of 300,000, and a new ultra-orphan medicine is approved (an ultra-orphan drug is one where the expected prevalence of the condition it is designed to treat is less than one in every 50,000 people). Suppose that the drug is expected to be appropriate for one in every 60,000 people in any one year, then that health board should expect to have five patients per year in its population of 300,000 ( $300,000 / 60,000$ ). If the drug costs £80,000 per patient then the expected cost would be £80,000 \* 5 patients = £400,000 per year at full roll-out of the medicine.

However, there is a nearly 40% chance that there would be more than five patients requiring the medicine in an area, with each additional patient above the expected value leading to an additional £80,000 expenditure per year.<sup>25</sup>

Health boards ought to not only form an expectation of the cost of the medicines they require but also an assessment of the potential variance from this expectation so that financial risks can be appropriately evaluated. To do this for multiple end of life and very rare condition medicines is a complicated task.

When assessing the risk that patient numbers for very rare conditions might vary materially from the expected level, health boards ought to consider whether their board is likely to have a greater prevalence of a condition in the population it serves than the Scottish average. This might happen either because of characteristics of the population in the area it covers or because it is home to a hospital with a particular expertise in treating a very rare or end of life condition.

### Sub-conditions and sub-populations

Medicines that count as *orphan* or *ultra-orphan* do so in virtue of the prevalence of the condition they are intended to treat in the population – fewer than one in every 2,000 people for orphan status and fewer than one in every 50,000 people for ultra-orphan status.

---

<sup>24</sup> The SMC produces regular horizon scanning reports:

[www.scottishmedicines.org.uk/About\\_SMC/What\\_we\\_do/Horizon\\_Scanning](http://www.scottishmedicines.org.uk/About_SMC/What_we_do/Horizon_Scanning). These provide data on new medicines coming in the next year, likely costs and uptake rates. The reports are updated quarterly.

<sup>25</sup> We assume that each member of the population has a 1 in 60,000 chance of requiring the medicine in a year, and so there is a 61.6% chance that five or fewer patients in a population of 300,000 will require it and so a chance of 38.4% that more than five will require it. In calculating this we have made the simplifying assumption that any one individual in the population has a 1 in 60,000 chance of requiring the medication for the condition in any one year, and that each member of the population's chance of requiring the medication is independent of any other member requiring it. In reality this may under-estimate the risk in some cases, for example where there is a genetic cause for a condition one member of a family might be more likely to have the condition if another of their family members also has it.



## Medicines for sub-conditions

If medicines are developed which treat sub-conditions of already existing conditions then the prevalence of those who can benefit from the medicine that treats the sub-condition will be lower than those who can benefit from the medicine that treats the condition itself.

For example, suppose that medicine A treats condition X, and that a small minority of types of condition X are found not to benefit from medicine A but these sub-conditions do benefit from medicine B – then there will be fewer who benefit from medicine B than who benefit from medicine A.

In the example it is possible that medicine A is neither an orphan nor ultra-orphan drug but that medicine B is. Consequently, medicines A and B would have different assessment routes and the ICER threshold for medicine B would be higher than the thresholds under the standard value for money approach.

## Medicines for sub-populations

Similarly, if a medicine is developed that treats a sub-population of those who have a particular condition (i.e. all have the same condition rather than a sub-condition, but the medicine does not treat all who have the condition), then the prevalence of those who are treatable by that medicine would be lower than were the medicine able to treat the whole population.

A medicine such as this, that is targeted at a specific sub-population, may be more clinically effective than one targeted at a whole population with a condition; but, as with those medicines that target sub-conditions, this medicine may in effect be an orphan or ultra-orphan medicine where a medicine that targeted all those with a particular condition would not count as either an orphan or ultra-orphan medicine.

## Impact of medicines targeted at sub-conditions or sub-populations on acceptance rates

The effect is that it may be easier for medicines for sub-conditions or sub-populations to be approved because the lower prevalence of patients treatable by these medicines may mean they are in the orphan or ultra-orphan status and so not subject to the standard ICER threshold.

The Montgomery review noted that there is likely to be an increasing amount of medicines that are targeted in these ways over the coming years:

*“While the definitions [of ‘orphan’ and ‘ultra-orphan’] appear to have supported increased access it is anticipated that therapeutic innovations such as genomics and precision medicine, which are likely to impact within the next few years, could see many more medicines classed as orphan or ultra-orphan and the current definitions may lack necessary specificity going forwards.”<sup>26</sup>*

It is a recommendation of the Montgomery review that the criteria for being counted as orphan or ultra-orphan medicines are revisited.

The EMA, who also use the term ‘orphan’ but not ‘ultra-orphan’, set additional criteria that a medicine targeted at a sub-condition or sub-population must fulfil. These criteria must be fulfilled if the medicine’s prevalence is to be calculated based on the numbers with the sub-condition (rather than the whole condition) or on the numbers in the sub-population (rather than the whole population with the condition).

Without discussing the clinical technicalities of these criteria<sup>27</sup> we note that the SMC do not currently employ these same criteria and so there are in principle a greater number of medicines that could be treated as orphan or ultra-orphan medicines than there would be were the EMA criteria to be used.

---

<sup>26</sup> P17 *Review of Access to New Medicines*, Brian Montgomery, 2016

<sup>27</sup> For a precis of these criteria and the impact they have on EMA decisions then see [www.ncbi.nlm.nih.gov/pmc/articles/PMC3907589/pdf/1750-1172-9-13.pdf](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3907589/pdf/1750-1172-9-13.pdf) , in particular page 2.



If, as the Montgomery review suggests, there is an increase in the development of targeted medicines then, when combined with the relaxation of the £30k ICER threshold for orphan and ultra-orphan medicines there is a possibility that more such medicines are accepted for use by the SMC over the coming years.

The financial risk following from this is that these drugs may be relatively expensive, and that where the SMC criteria remain unchanged the costs of medicines to health boards may grow at an even higher rate than we have extrapolated earlier in this briefing.

The SMC advised us during our interviews that how these drugs are defined is one of the areas that is being looked at in response to the Montgomery review. Healthcare finance professionals in Scotland should continue to engage with the SMC and the Scottish government on this issue.

## **Extending the appropriate conditions or cohort for already approved very rare and end of life conditions medicines**

Where a medicine is accepted for use by the SMC it is accepted in relation to a particular condition (or sub-condition). From here the medicine ought to be added to a health board's formulary, enabling appropriate clinicians working for the health board to prescribe the medicine for the conditions indicated.

There is a divorce between the assessment of the safety and efficacy of a new medicine, which is undertaken by the MHRA or the EMA, and the value for money assessment undertaken by the SMC. Because of this it is possible that the set of conditions or the cohort of patients for which it is appropriate to use a medicine be extended after the SMC accepts it for use, although this would require a further submission to the SMC.

While the decision to extend the range of conditions or cohort for which a medicine can be prescribed will be made for clinical reasons there is a consequent financial risk stemming from this decision. Where a medicine has been approved under the end of life or very rare conditions approach the ICER threshold will have been relaxed from the typical £30,000 and so the medicine might be relatively expensive.

In principle, a relatively expensive medicine may be appropriate for a relatively small cohort where it is intended for very rare conditions or prescribed for a relatively short amount of time where it is intended for end of life conditions. However, by extending the range of conditions or cohort for which a medicine can be prescribed, this cohort or time-period will be extended, and if per patient per year costs remain the same the total costs of the medicine may increase substantially.

### **Examples of extending the cohort of patients**

Nivolumab is an example of an end of life/ very rare conditions medicine that has been accepted for use by the SMC through the end of life and orphan process. The SMC has made separate, subsequent decisions to accept its use in different situations,<sup>28</sup> and so while any individual decision will apply to a small group of potential patients, the decisions taken in aggregate will apply to a larger group of patients. There is a financial risk from this and future similar decisions that relatively expensive medicines accepted for use by the SMC become prescribable for a relatively large number of a patients and so lead to a material financial impact on health boards' medicines budgets.

It need not just be a medicine that has been approved for use by the SMC that might have the range of conditions or cohort for which it can be prescribed extended. For example, Ivacaftor, a medicine used to treat cystic fibrosis has not been accepted for use by the SMC but has been endorsed for use by the Scottish Government and is regularly prescribed. Through our interviews we understand that Ivacaftor was initially licenced for use in those with a specific mutated gene, but has

---

<sup>28</sup>[www.scottishmedicines.org.uk/General/SMC\\_Advice\\_Site\\_Search\\_Results?q=%28nivolumab%29+AND+path%3A%2Fcontent%2FSMC\\_Advice%2FAdvice\\*+AND+type%3APAGE&p=0&style=smc\\_advice\\_results](http://www.scottishmedicines.org.uk/General/SMC_Advice_Site_Search_Results?q=%28nivolumab%29+AND+path%3A%2Fcontent%2FSMC_Advice%2FAdvice*+AND+type%3APAGE&p=0&style=smc_advice_results) – lists the SMC's advice notes on this medicine.

subsequently been extended for use in children and those with other, less uncommon, genetic mutations. Ivacaftor has been reported to cost circa £180,000 per patient per year,<sup>29</sup> and so the costs to health boards where the patient group for whom it is prescribed is extended can grow over time.

Health board finance professionals will need to work closely with their pharmacist and other clinician colleagues to understand where there is likely to be an extension of the range of conditions for a medicine. This is particularly important where a medicine is more expensive and the extension in use is likely to give rise to a significant increase in the numbers for whom it is prescribed. The SMC horizon scanning publications will provide advance notice of medicines the use of which is likely to be extended.

## Individual patient treatment requests (IPTRs) and peer approved clinical systems (PACS)

As we note above, where a medicine is not approved by the SMC for use, clinicians are able to apply for its use by patients on a case by case basis through the IPTR route.

The Montgomery review states that IPTR applications tend to be successful, with 85% of patients in 2015/16 being “deemed to have circumstances that exempt them from the SMC’s decision”.<sup>30</sup> In our interviews for this briefing, respondents noted that part of the reason for a high success-rate for IPTR applications was because clinicians did not make the applications unless they thought there were good grounds for doing so, so only those applications deemed likely to succeed were made in the first place.

There are not reliable data on the overall financial implications of IPTR decisions, but because the IPTR process is designed so that the cost of the medicine under consideration is not relevant to the decision there is potential for high costs arising from each medicine approved through this process. These costs may be significantly higher than the standard approach ICER threshold of cost-effectiveness. This is because the medicines may also have been deemed not to be value for money under the very rare and end of life conditions approach and so cost substantially more than £30,000 for every extra QALY gained.

The Scottish Government have advised that IPTR is to be replaced by PACS, but currently PACS only applies to ultra-orphan medicines. Many of the same principles apply here and there is a financial risk that significant costs may be incurred for medicines that have not been accepted for use by the SMC. Finance professionals will need to be linked closely with clinical colleagues if they are to forecast where material changes in pharmaceutical costs are likely to arise because of IPTR or PACS applications.

Because the IPTR and PACS processes are on a per patient basis the implications of a single decision are unlikely to be financially material to an overall medicines budget, though costs can be in excess of £300,000 per year for some medicines. Furthermore, the high rate of success of IPTR applications raises the risk that in aggregate these decisions over a financial year are material to budgets, and consequently an allowance for these decisions’ costs ought to be included in any medicine costs financial forecasts.

## The new medicines fund (NMF)

The Scottish Government recognises that there is a financial cost associated with approving, often more expensive, medicines for very rare and end of life conditions. To help with the financial impact of paying for these medicines the Scottish Government established the new medicines fund (NMF), which replaced the similar rare conditions medicines fund. In a letter to health boards in Scotland in December 2015 the Scottish Government explains the purpose of the fund:

<sup>29</sup>[www.heraldsotland.com/news/14386202.Criticism\\_as\\_single\\_drug\\_accounts\\_for\\_over\\_85\\_per\\_cent\\_of\\_rare\\_conditions\\_budget/](http://www.heraldsotland.com/news/14386202.Criticism_as_single_drug_accounts_for_over_85_per_cent_of_rare_conditions_budget/)

<sup>30</sup> P21 *Review of Access to New Medicines*, Brian Montgomery, 2016

*“The Scottish Government announced the New Medicines Fund in October 2014 to expand and replace the Rare Conditions Medicines Fund. The New Medicines Fund is intended to ensure that availability of funding is not a barrier to NHS Board implementation of policy intentions on increased patient access to licensed orphan, ultra-orphan and end of life medicines and that no NHS Board is better or worse off financially on the basis of clinical decisions on prescribing these medicines.*

*For 2015/16 initial funding of £80m has been allocated to territorial NHS Boards. This funding continues to cover costs incurred by NHS Boards for increasing patient access to licensed orphan, ultra-orphan and end of life medicines. The funding is available for acquisition costs of these medicines and can also be used to cover appropriate supporting services to enable implementation should this be required.”<sup>31</sup>*

The NMF is funded through Scotland’s portion of the payments from pharmaceutical companies to the Department of Health under the pharmaceutical price regulation scheme (PPRS). The PPRS is a scheme designed to help control the cost of medicines in the UK and is negotiated with pharmaceutical companies. Under the PPRS, if costs of medicines are above a set level then pharmaceutical companies agree to pay a proportion of that difference to the Department of Health. Because this is a UK wide scheme then the Department of Health apportions part of this payment to Scotland, as well as the other devolved nations.

Because of the way in which the PPRS money is determined, the receipts to the UK Government fluctuate (as drug spend fluctuates) and consequently so too does the NMF. While the Scottish Government will seek to provide an estimate of the total NMF for the financial year ahead, in practice the total value of the fund will not be known until the year-end. The year-end total can vary materially from the estimate at the beginning of the year because of the uncertainty in PPRS receipts, though within the wider total Scotland medicines bill this variation will not be material. In 2016/17 boards were advised to plan for a total NMF of £60m for Scotland (because of the forecast PPRS receipts) but it ended up being £53m; the overall medicines bill was around £1.7bn in 2015/16 or £644m across just community and hospital services.

The current PPRS agreement was agreed with pharmaceutical companies until the end of the 2018 calendar year, as yet there is no agreement from 2019 onwards, or from the fourth quarter of the 2018/19 financial year. However, this should not be taken to imply that the NMF will cease at the end of 2018, a new PPRS may be negotiated and the Scottish Government may choose to continue the NMF. Currently while there is no certainty about what the new PPRS (if there is one) might look like and consequently what can be expected in terms of the NMF in Scotland it is not the Scottish Government’s intention to cease this fund.

The view of many we spoke to when conducting interviews for this briefing was that even if very rare and end of life conditions medicines costs had not exceeded the value of the NMF in previous financial years they were likely to this year. That prediction was based on the assumption that the value of the NMF would be in the range £30-£40m, were it to fall below this then the costs would further outstrip their dedicated source of funding. The Montgomery review (published in December 2016), also noted that while the NMF had been sufficient to date there was uncertainty about whether it would be large enough in future years to meet the costs of end of life and very rare conditions drugs.<sup>32</sup> This was corroborated by the interviews with clinicians and accountants working in healthcare in Scotland that were conducted for this briefing.

Finance professionals in Scotland should build uncertainty about the level of NMF funding into current and future years’ budgets and should reflect the fact that costs of medicines that the fund is designed to pay for are likely to exceed its value. In the absence of additional funding into the

---

<sup>31</sup> Total funding for 2015/16 was £85m after PPRS receipts were known.

<sup>32</sup> Section 6.6.6 p29 *Review of Access to New Medicines*, Brian Montgomery, 2016

healthcare system, savings and economies will have to be found elsewhere within health boards' finances.

## Whole health-economy value for money

The SMC's approach to assessing very rare and end of life conditions medicines in a way that is more flexible around the ICER threshold than under the standard approach was the result of a policy decision by the Scottish government.

Those medicines for very rare and end of life conditions are often more expensive than drugs for less rare conditions. Because of this, were the standard process used by the SMC for these medicines, with its ICER thresholds, they would often not be accepted for use. As the Montgomery review notes, end of life medicines, in common with those for very rare conditions, were, prior to the new SMC approach in 2014, being disproportionately not accepted for use primarily because of cost.<sup>33</sup> From this, the decision to improve access to these medicines through the new SMC approach outlined earlier in this briefing followed, as did an increase in expenditure on these types of medicines.

The Montgomery review notes in its findings that the new approach by the SMC has achieved the Scottish government's aims of improving access to end of life and very rare conditions medicines (although less so for the ultra-orphan drugs for extremely rare conditions, but access to these is increasing via IPTR and PACS).<sup>34</sup>

At a system-wide level there is an inevitable trade-off between improving access to medicines to treat those at the end of their life or with very rare conditions, and in funding other interventions that the Scottish healthcare system could provide.

Recent research by Sarah Karlsberg Shaffer et al suggests that typically health boards in Scotland do not follow the cost per QALY criterion (or at least not solely) when making decisions about which services they should invest in or disinvest from.<sup>35</sup> Rather, the research suggests, health boards consider a range of criteria such as the impact on waiting times and patient safety; and that frequently reliable QALY data on service impact will not be available in any case.

Nevertheless, there may be a wider policy debate that health boards wish to be involved with if they feel that budget pressures mean that a different approach to very rare and end of life conditions medicines assessments could benefit their local health economy and provide better value for money. Some of the interviewees we spoke to for this research felt that an increase in expenditure on end of life and very rare conditions medicines has meant that resources are diverted away from interventions that would have greater QALY benefits.

---

<sup>33</sup> P7 *Review of Access to New Medicines*, Brian Montgomery, 2016

<sup>34</sup> P5 *Review of Access to New Medicines*, Brian Montgomery, 2016

<sup>35</sup> *Local health care expenditure plans and their opportunity costs*, Sarah Karlsberg Schaffer et al, Health Policy, 2015

## Conclusion

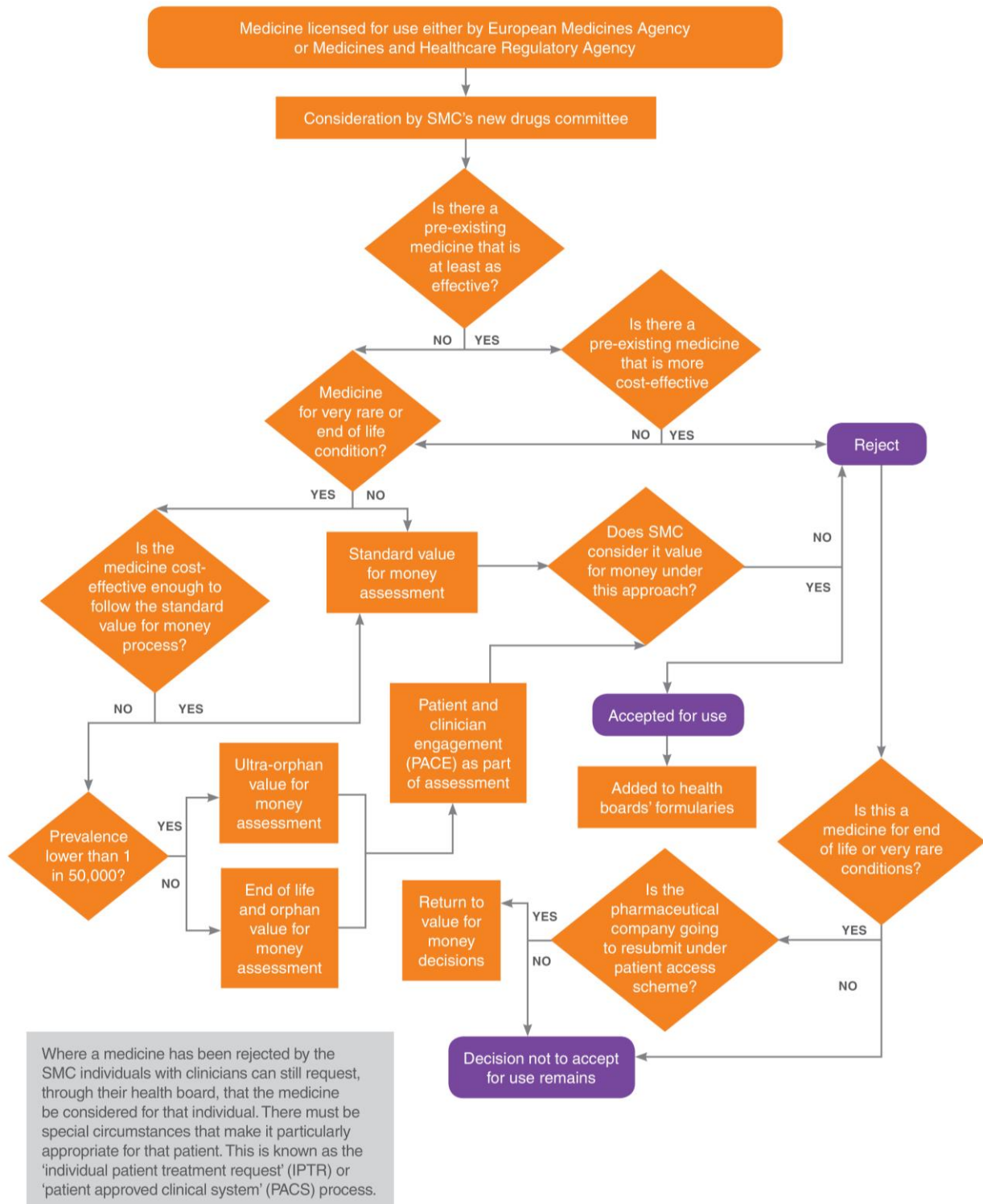
If medicines costs in Scotland, particularly in hospital and community services, continue to grow at the rate they have done in previous years they will absorb an increasing proportion of health boards' budgets. Healthcare finance professionals should plan for this rise in costs as far as possible, and where there is uncertainty in either the future costs or future funding this uncertainty should be made explicit in financial forecasting where it could materially affect financial performance.

Health boards should continue to make use of the horizon scanning publications from the SMC to forecast future costs of new and incoming medicines. In forming these forecasts finance professionals will wish to work closely with clinicians, particularly for those medicines for very rare or end of life conditions that have high per-patient costs, to understand the likely number of patients per year in their health board area.

Health boards may wish to engage directly with the SMC and the Scottish government to the extent that they have views about how the future very rare and end of life assessment process will be developed in light of the Montgomery review. Similarly, health boards are likely to want to work with the Scottish government to plan for the future of the NMF when it's current funding source ceases at the end of 2018.



# Appendix 1 – New medicine approval flowchart<sup>36</sup>



<sup>36</sup> **N.B.** this flowchart is a simplification of the new medicines approval process designed to show how the value for money decisions fit into the process and how the route varies. For a detailed account of the process readers should consult guidance at the SMC's website [www.scottishmedicines.org.uk](http://www.scottishmedicines.org.uk)

## Acknowledgements

We would like to thank all the staff at health boards, the Scottish Government, and the SMC who helped with the research, data, and took part in interviews with us as well as helping to review any earlier draft of this briefing. We would also like to thank members of the HFMA's Policy and Research Committee who helped review an earlier draft of this document.

Specifically, we are grateful to the support from the following individuals

- Alison Campbell, public health pharmacist, NHS Great Glasgow and Clyde
- David Garden, head of financial planning, NHS Highland
- Anne Lee, chief pharmacist, SMC
- Derek Lindsay, executive director of finance NHS Ayrshire and Arran
- Julie McKinney, head of internal financial performance, directorate for health finance at the Scottish government
- Alan MacDonald, chair, SMC

The author of this briefing was Duncan Watson, HFMA research manager, under the direction of Emma Knowles, head of policy and research, HFMA.





## About the HFMA

The Healthcare Financial Management Association (HFMA) is the professional body for finance staff in healthcare. For more than 60 years, it has provided independent and objective advice to its members and the wider healthcare community. It is a charitable organisation that promotes best practice and innovation in financial management and governance across the UK health economy through its local and national networks.

The association also analyses and responds to national policy and aims to exert influence in shaping the wider healthcare agenda. It has a particular interest in promoting the highest professional standards in financial management and governance and is keen to work with other organisations to promote approaches that really are 'fit for purpose' and effective.

© Healthcare Financial Management Association 2017. All rights reserved.

HFMA  
1 Temple Way, Bristol BS2 0BU  
T 0117 929 4789  
F 0117 929 4844  
E [info@hfma.org.uk](mailto:info@hfma.org.uk)

Healthcare Financial Management Association (HFMA) is a registered charity in England and Wales, no 1114463 and Scotland, no SCO41994. HFMA is also a limited company registered in England and Wales, no 5787972. Registered office: 110 Rochester Row, Victoria, London SW1P 1JP

[www.hfma.org.uk](http://www.hfma.org.uk)