HTA P&P week 9 offline format

1. HTA Policy and Principles Week 9

1.1 Title

Notes:

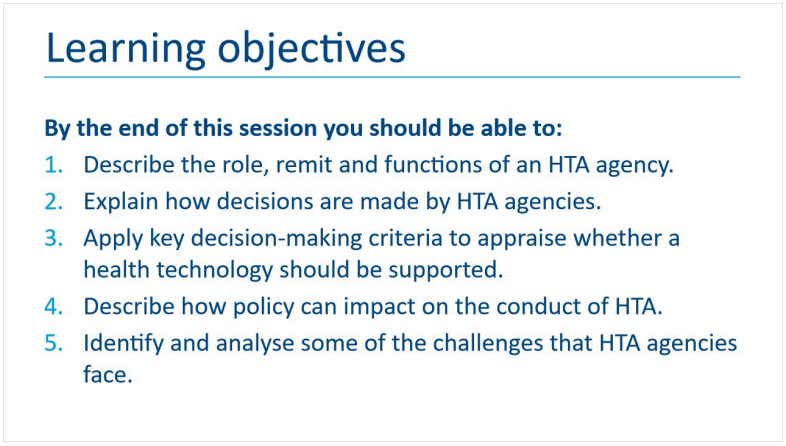
Hello, welcome to the session – HTA and policy in the UK. My name is Louise Craig, a Health Services Researcher at Healthcare Improvement Scotland. Healthcare Improvement Scotland, commonly referred to as HIS, is a health body, funded by the Scottish Government, which has the remit for driving improvements in the quality of care in health services in Scotland. During this session I will describe the HTA function within Health Improvement Scotland, how policy can impact on how HTA is conducted and how the HTA activities within Health Improvement Scotland align within the wider context of health policy in Scotland.

1.2 Role of Healthcare Improvement Scotland

Notes:

Firstly, a short description of the role of Healthcare Improvement Scotland. This organisation has a wide range of functions including providing advice and guidance on healthcare interventions through the undertaking of guidelines and HTA. Healthcare Improvement Scotland encompasses a number of 'brands' including SIGN which has developed clinical guidelines for Scotland since 1993 and the Scottish Patient Safety Programme which improves the safety and reliability of healthcare and reduces harm.

1.3 Learning objectives

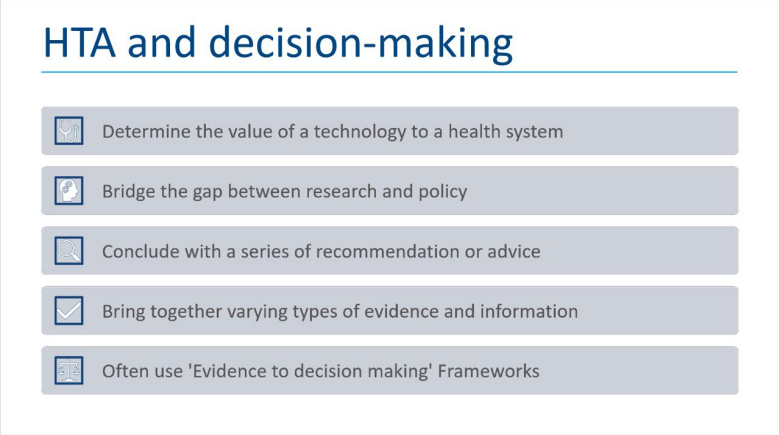


Notes:

By the end of this session you should be able to:

- Describe the role, remit and functions of a HTA agency in informing decision-making in healthcare.
- Explain how decisions are made by HTA agencies about which medicines and technologies should be made available within healthcare systems.
- Apply key decision-making criteria to appraise whether a medicine or technology should be supported within a national healthcare system.
- Describe how NHS policy recommendations can impact on the conduct of HTA
- And lastly, identify and analyse some of the challenges that HTA agencies face when assessing new medicines and technologies in the context of uncertainty.

1.4 HTA and decision-making



Notes:

As you will have come to understand from the earlier sessions of this course, HTA is a process in which the value of a technology to a health system is determined, in order to inform decision-making within that health system. HTA is said to bridge the gap between research and policy.

HTAs generally conclude with a series of recommendations or advice which are directed towards decision-makers makers. The types of evidence and

information used within HTAs to reach these recommendations can vary and may be based on traditional trials, or in more recent time the use of real-world evidence. HTAs will consider clinical and cost effectiveness evidence but may also consider other factors too such as the patient and carer perspectives, ethical and legal issues and in some cases service redesign.

Over recent years there have been a move towards using specific “evidence to decision making” frameworks to enable a more structured and transparent approach to decision making. I will be able to provide an example from the perspective of Health Improvement Scotland later on. You can read a bit more about the use of such frameworks in a recent paper by Morgan and colleagues, which is in your reading list.

1.5 NHSScotland - Policy Context

Notes:

Let’s now look at healthcare policy at a high level in Scotland as this sets the context in which HTA occurs within NHSScotland.

Firstly, the overall policy context in which the HTA is being introduced is important. The policy context can influence the prioritisation of topics for

HTA, and also the subsequent implementation of their recommendations into practice.

This slide shows some of the most recent relevant policy documents in NHSScotland. The Healthcare Quality Strategy provides an overarching strategic direction for NHSScotland. Other policy documents include the Prescription for Excellence which is our national vision for pharmaceutical care and the cancer action plan for Scotland, both of which have been updated recently.

I don't plan to go through each of these documents but it may be worth looking at them in your own time in particular the recommendations that are made. One thing that you are likely to notice is that all the healthcare policies drive the delivery of three quality ambitions – safety, patient-centredness and effectiveness. These values are very much embedded in the strategy for Health Improvement Scotland and hopefully as we move through this lecture it should become clear how these values are underpinned by the HTA.

1.6 HTA within Healthcare Improvement Scotland

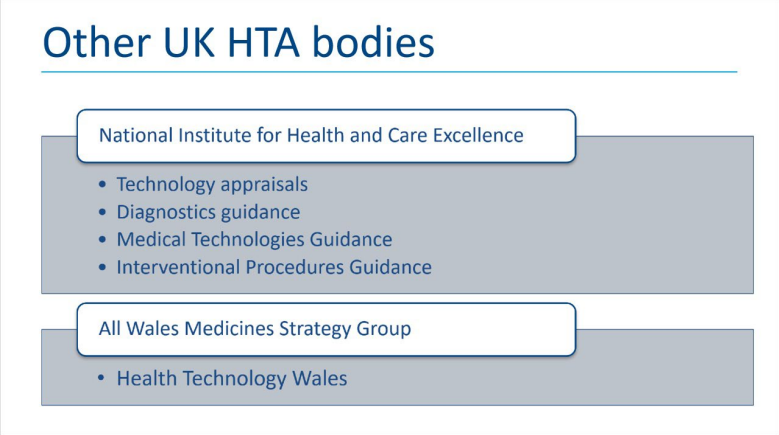
Notes:

There are two groups, supported by Healthcare Improvement Scotland, which assess the clinical and cost effectiveness of health interventions. The

Scottish Medicines Consortium, referred to as SMC, appraises information on the health benefits and cost to the NHS as supplied by manufacturers, of newly licensed medicines. Those medicines judged to represent good value are accepted for routine patient use as quickly as possible. The Scottish Health Technologies Group, referred to as SHTG, is an advisory group set up to provide advice to NHS Boards when considering selected non-medicines health technologies, such as devices, diagnostics and interventional procedures. I am going to talk more about these two groups shortly.

The outputs of both these groups have a status of 'required to consider' for NHS Scotland. They are not mandatory because each of the 14 territorial healthboards in NHSScotland has autonomy to decide how to spend their budget, but boards would generally be expected to implement the evidence-based advice being offered.

1.7 Other UK HTA bodies



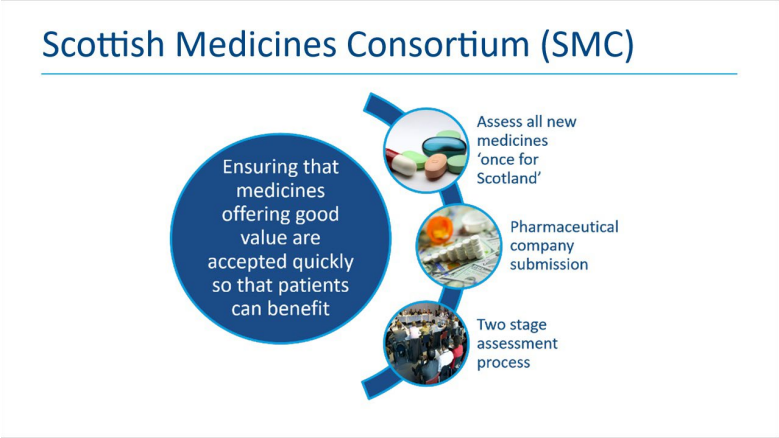
Notes:

Just a brief mention of the other publicly funded HTA bodies in the UK helping to inform healthcare practice. People are probably quite familiar with NICE, the National Institute for Health and Care Excellence in England. NICE has quite a wide range of functions, but one of its original and main functions is HTA. They produce a range of outputs relating to health interventions, and I've listed some of these on the slide. Interestingly, unlike Scotland, some of

the NICE advice comes with a funding mandate, based upon healthcare providers making available the technology in question with a certain period of time.

In Wales, the All Wales Medicines Strategy Group advises the Welsh Government about the use, management and prescribing of medicines in Wales. Health Technology Wales is the Welsh equivalent to the Scottish Health Technology Group and looks at non medicine technologies and provides advice to the NHS in Wales.

1.8 Scottish Medicines Consortium (SMC)



Notes:

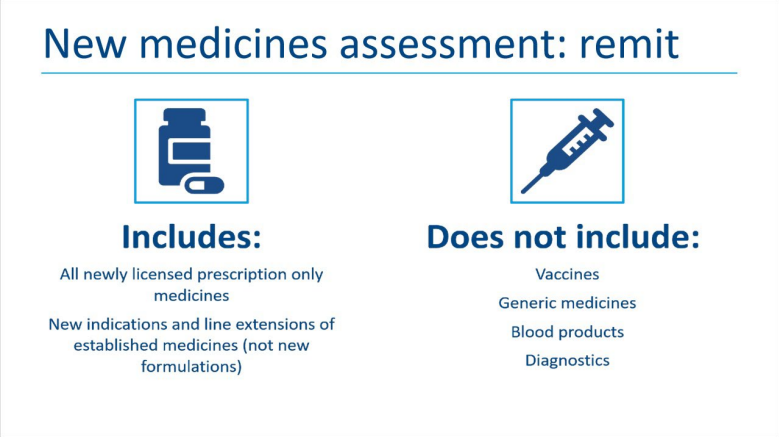
Just moving back to HTA within Health Improvement Scotland. Firstly, I will cover the role of SMC which is to evaluate new medicines and provide advice to NHSScotland on their clinical and cost effectiveness.

SMC provides a 'once for Scotland' HTA function by advising on the use of medicines to be applied consistently and fairly across Scotland, addressing (or minimising) the risk of variation in access and outcomes.

The pharmaceutical company submission focuses on health benefits and justification of price relative to current clinical practice.

There is a two-stage assessment process involving two committees, one called the New Drugs Committee and the other is called the Scottish Medicines Consortium decision-making committee.

1.9 New medicines assessment: remit

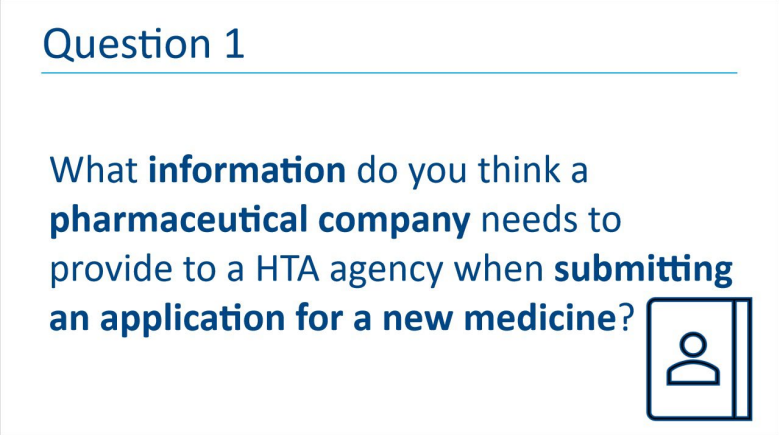


Notes:

The SMC remit is confined to prescription only medicines. SMC do not assess:

- vaccines
- generic medicines which are medicines have the same properties as an already launched brand-name medicine
- pharmacy and general sales list medicines
- blood products, and
- diagnostics.

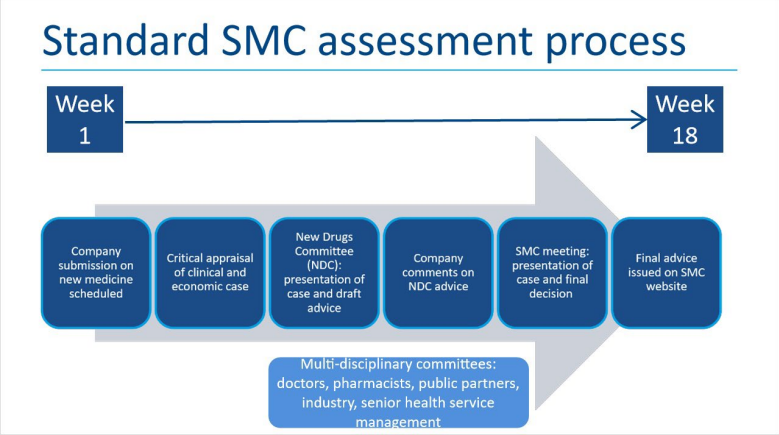
1.10 Question 1



Notes:

So before we go on and talk about the process of assessment please pause and make a note of the information that you think a pharmaceutical company needs to provide to an HTA agency when submitting an application for a new medicine?

1.11 Standard SMC assessment process



Notes:

The work of SMC is complex and there is an 18 week time line for standard straight

forward submissions from scheduling of a submission to publication of advice. A longer timeline, of 22 - 26 weeks, is required for submissions for end of life and orphan medicines that require a Patient and Clinician Engagement (PACE) meeting and for some other situations. In periods where a high number of submissions are received we may need to prioritise submissions to meet the needs of patients, prescribers and the healthcare system.

So lets start at the beginning of the assessment process outlined on the slide. The company submits an application for a new medicine. This application can be over 300 pages long with many appendices. Following on from the previous question posed on the slide the application contains information on the clinical evidence for the new medicine including both direct and indirect evidence, the safety profile and clinical effectiveness issues including the generalisability and relevance to the Scottish population. The application also contains the economic evaluation conducted by the company including medicine costs and any resource implications. It is reviewed by the dedicated assessment team which consists of health services researchers, pharmacists and health-economists. Clinical experts outside of Health Improvement Scotland are also consulted.

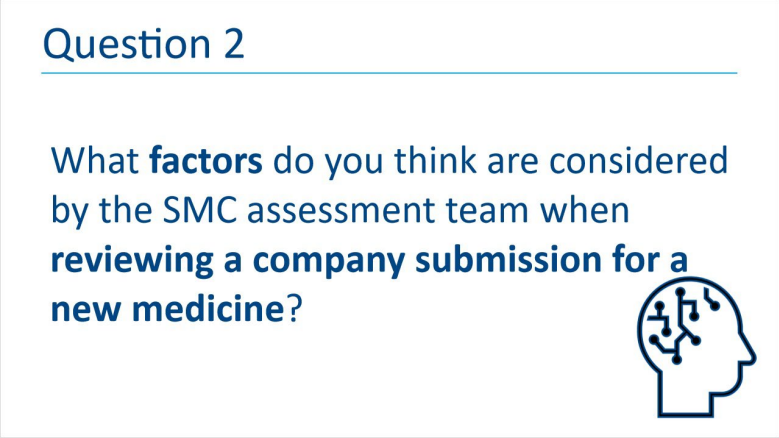
The information is compiled by the assessment team into a draft advice document which then goes to a multidisciplinary New Drugs Committee, where the emphasise is on the critical appraisal of the company submission and draft advice produced.

The case is presented to SMC, which is the multidisciplinary decision-making committee which makes a final decision either to accept or not recommend a medicine. The primary output is a published document, the Detailed Advice Document, known as the DAD. This is a summary document, which aims to describe the strengths and weaknesses of the evidence considered and the rationale for the decision.

Once a decision is made, it is shared in confidence with NHS boards and the pharmaceutical company four weeks before it is published to ensure that steps can be taken to prepare for the introduction of the new medicine in health boards.

Summary of figure: the flow-chart consists of 6 boxes which each illustrate each of the key milestones in the SMC assessment process as follows: company submission; critical appraisal of clinical and economic evidence; New Drugs Committee, company comments on NDC advice; SMC meeting and the final advice issued on the SMC website.

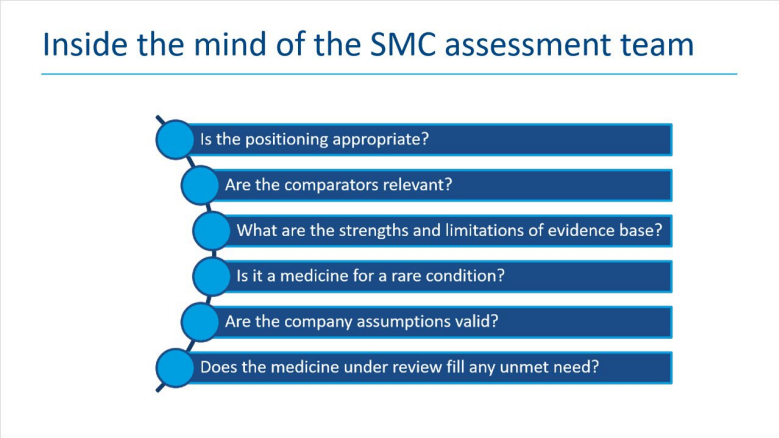
1.12 Question 2



Notes:

So just going back slightly to the point where the assessment team first receive the application from the pharmaceutical company – please pause and make a note of some factors that you think are considered by the SMC assessment team when reviewing a company submission for a new medicine?

1.13 Inside the mind of the SMC assessment team



Notes:

I am sure it will not be surprising to hear that the assessment is focused on determining the clinical and cost effectiveness of the new medicine.

The assessment team often apply the PICO framework: P-population; I-Intervention; C-comparator; O-outcomes. This basic framework is often applied in the initial stages of the assessment to help formulate thinking and raise important questions around the decision problem.

One area the assessors will consider is whether the positioning is appropriate. For example, the submitting company may advise that the proposed positioning is narrower than the marketing authorisation to reflect how the medicine may fit into the therapeutic pathway within NHSScotland.

Whether the comparator posed by the company is relevant to NHSScotland is often a challenging issue as the company may have included a comparator that is not routinely used. It may be that there is no consensus what the comparator is due to lack of agreed standard of care or variation in practice or there may be a lack of comparators due to the rarity of the disease. Our clinical experts also help with this.

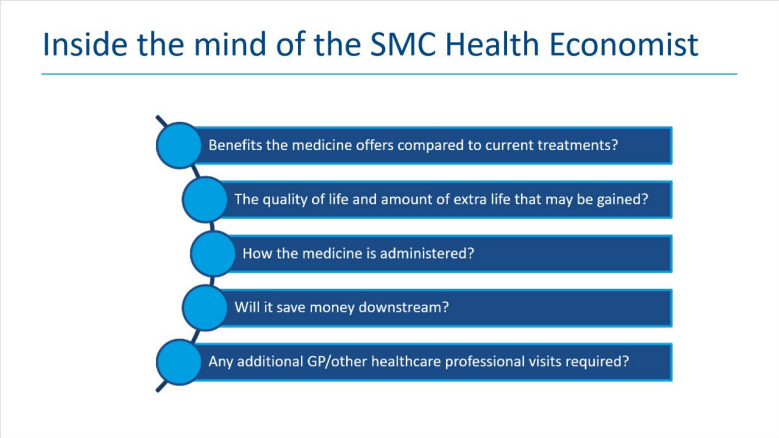
In terms of the evidence base the key question here is how well does the medicine work compared with standard practice? The clinical evidence is critically appraised to highlight the strengths and weaknesses of the evidence.

There are specific issues when it comes to assessing a medicine for a rare condition such as the smaller patient populations leads to smaller sized trials which often means greater uncertainty in the treatment effect. Studies may be more likely to use surrogate outcomes which means more clinically relevant and longer-term data may not be available.

Often the company makes assumptions especially when there is a lack of evidence. For example, if there is no direct evidence comparing the new medicine with the comparator medicine the company may assume a treatment effect, for example based on real world data, expert opinion or an indirect treatment comparison.

In terms of clinical need the key question here is does the medicine under review fill any unmet need such as is it intended to be used in a therapeutic area where there is currently no satisfactory treatment? We look at guidelines and previous SMC advice for the intended use of the new medicine to try and address this. Clinical experts also provide information on whether they consider the medicine to be a therapeutic advancement.

1.14 Inside the mind of the SMC Health Economist



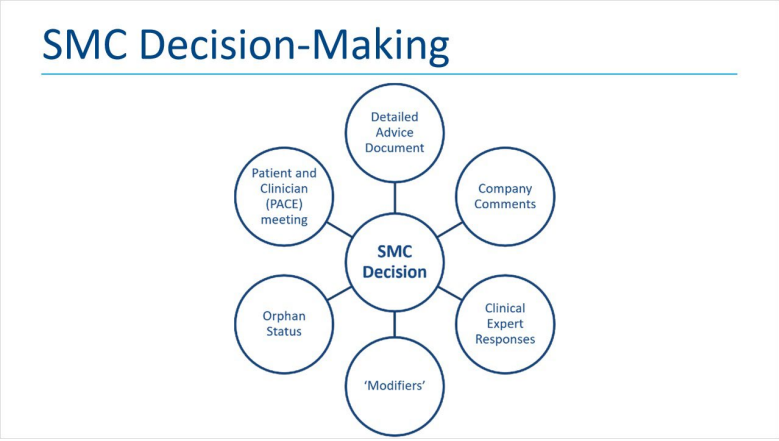
Notes:

The health economist will also consider the points raised in the clinical case and focus on the technical review of the estimates of cost-effectiveness that the company has provided. I have listed some of the more general questions that the HE will be faced with.

So when we talk about value for money or cost effectiveness, this does not just mean how much a medicine costs to buy, but the wider costs and benefits associated with it being regularly used to treat those with a particular condition, for example:

- what benefits the medicine offers compared to other currently available treatments
- the quality of life and amount of extra life that may be gained by patients using the new medicine
- how the medicine is administered (for example, does it require a visit to a clinic or can it be taken by the patient at home?)
- will it save money downstream, for example if the patient will have fewer hospital admissions due to complications from their condition, and
- if there are any additional GP/other healthcare professional visits required.

1.15 SMC Decision-Making

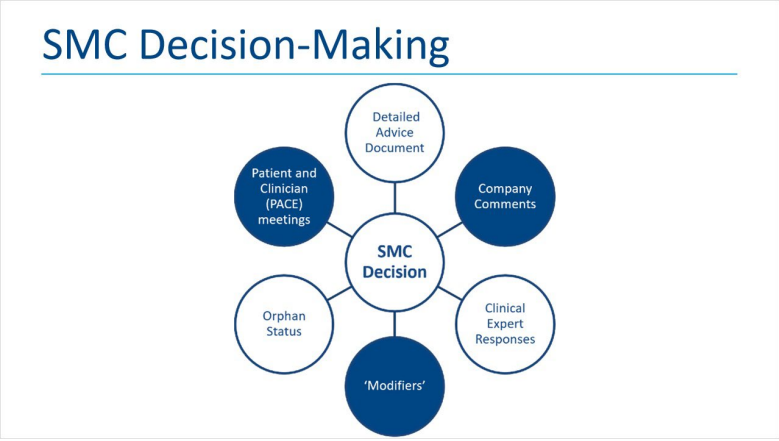


Notes:

So along with the issues posed in the draft detailed advice document the SMC committee has a number of other decision-making factors to consider some of which are on the slide. As you can see this takes a broader perspective.

Summary of figure: this consists of 6 circles that represent some of the factors that are central to SMC decision-making which are as follows; New Drug Committee Detailed Advice Document; company comments; clinical expert responses, modifers, orphan status and patient group submission.

1.16 SMC Decision-Making



Notes:

I am just going to talk just a through a few of these, as highlighted on the slide.

In relation to the company comments - the company has the opportunity to review the draft detailed advice document and make comments on it. The company may disagree with the SMC assessors about issues that they have raised during the assessment period and this gives the opportunity for the company to respond.

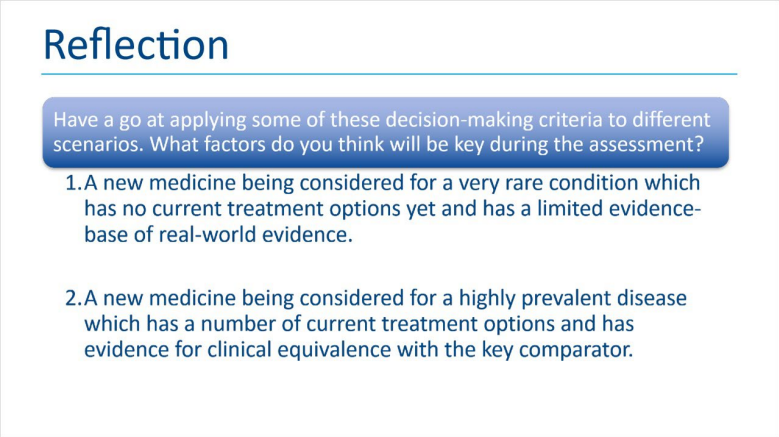
In relation to modifiers in some specific situations SMC may exercise greater flexibility in its decision making to allow consideration of additional factors. These may allow SMC to accept more uncertainty in the health economic case. Theses modifiers include evidence of a substantial improvement in life expectancy or an absence of other therapeutic options.

Patient and Clinician Engagement (referred to as PACE) is a step in the SMC assessment process for medicines for end of life or very rare conditions (called orphan or ultra-orphan medicines). It gives patient groups and clinicians a stronger voice in SMC decision making when these kinds of medicines are being considered.

More information on the modifiers and the PACE meetings are available on the SMC website.

Summary of figure: this consists of 6 circles that represent some of the factors that are central to SMC decision-making which are as follows; New Drug Committee Detailed Advice Document; company comments; clinical expert responses, modifers, orphan status and patient group submission.

1.17 Reflection



Notes:

Pause for a minute or two to consider the issues that may be raised when assessing these two scenarios listed on the slide -

1. A new medicine being considered for a very rare condition which has no current treatment options yet and has a limited evidence-base of real-world evidence
2. A new medicine being considered for a highly prevalent disease which has a number of current treatment options and has evidence for clinical equivalence with the key comparator

The key issues and factors for consideration are listed in the notes section of

the slide.

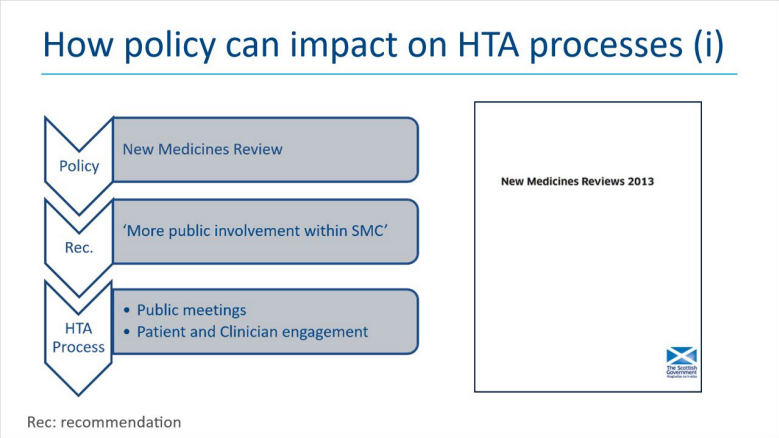
1. Some factors that you may like to consider are –

- The unmet need for this condition
- Consider the pf uncertainties the real world evidence within the context of limited information and lack of comparative data
- Patient and clinical opinion: more focus on the “added” benefit of a medicine from the patient and clinician perspectives that may not be captured within the usual clinical and economic assessment

2. Some factors that you may like to consider are –

- The strength of the evidence base to support clinical equivalence
- Does the medicine have a similar or lower cost than the comparator medicine?
- Clinical preference to uptake this medicine over the current medicine

1.18 How policy can impact on HTA processes (i)

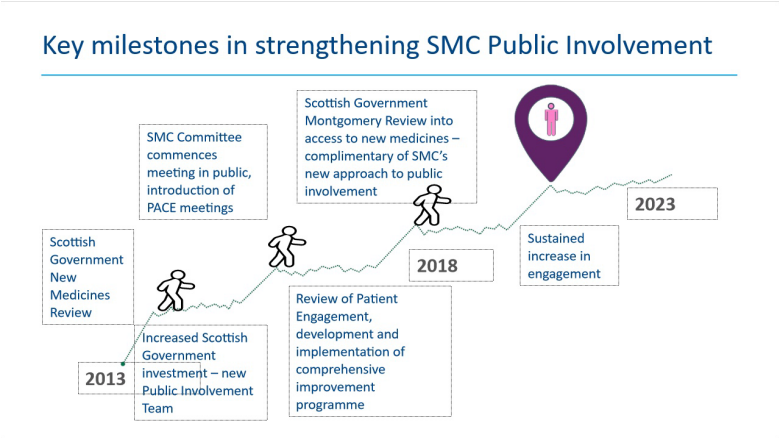


Notes:

Now just moving on to how healthcare policy can influence the way in which HTA is conducted.

In 2013 the new medicines review by the Scottish Government was published and one of the key recommendations was for more public involvement within SMC. At the time public involvement was very much part time and out sourced so the Scottish Government increased investment and the Public Involvement team within SMC was created.

1.19 Key milestones in strengthening SMC Public Involvement



Notes:

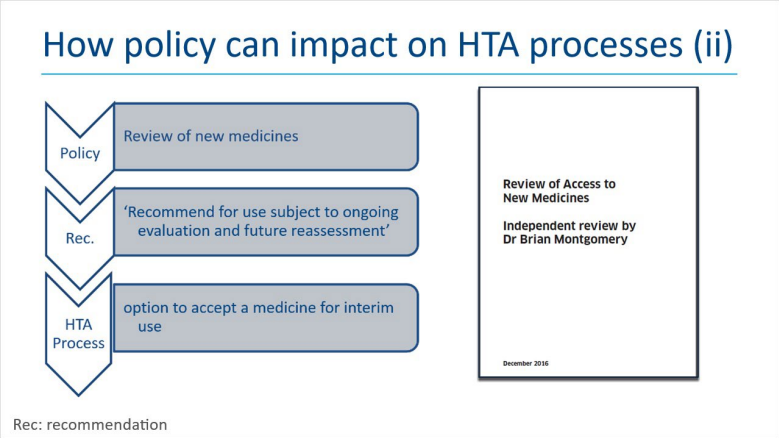
In response to this, SMC made changes to involve the public and patients in the HTA process which are laid out on the slide.

In 2014 SMC committee meetings were held in public for the first time and added transparency in decision-making. There was also the introduction of Patient and Clinician Engagement meetings, the PACE meetings which I have mentioned previously. If a medicine for a rare condition or end of life condition is not recommended at NDC committee then the company can request a PACE meeting. The PACE meeting is an additional step in the assessment process and just to recap gives patient groups and clinician treating patients with the disease a stronger voice at SMC decision-making.

In 2016 further Scottish Government review was highly complimentary of 'new' approach to public involvement and asked SMC to look at other areas, such as ultra orphan medicines, which I am going to talk about shortly. Ongoing sustained increase in patient engagement and public involvement and processes are being noticed and recognised internationally by the HTA community.

Summary of image: a drawing of a person climbing up a mountain. There are captions which describe each of the milestones as the person progresses up the mountain.

1.20 How policy can impact on HTA processes (ii)

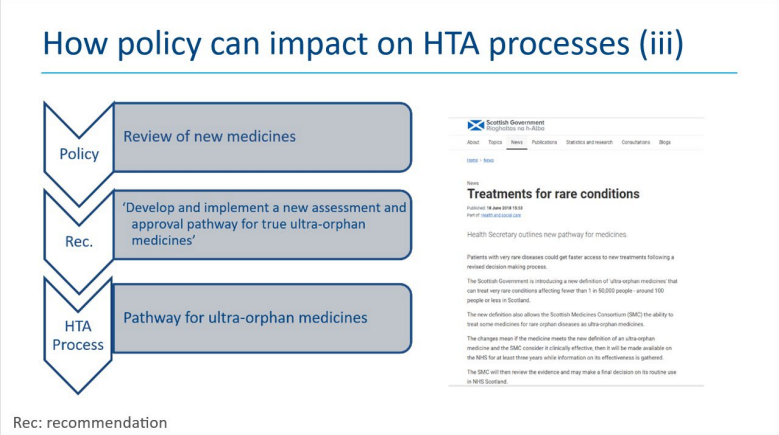


Notes:

In 2016 a subsequent review of access to new medicines recommended that SMC should have the option to accept a medicine for interim use subject to ongoing evaluation and future reassessment. The policy direction was to increase access to promising new medicines but with the reassurance that further data would be evaluated to ensure the medicine was a good use of resource. SMC introduced this decision option in 2018 with a focus on medicines with conditional marketing authorisation as these were the medicines that were most likely to have further evidence available that could resolve the uncertainties identified as part of the HTA process.

We have granted interim acceptance to over 12 medicines in the last few years, most are cancer medicines. The medicines have been licensed for use where the current treatment is unsatisfactory and has a poor evidence base so considered by the regulator that they address an important unmet need. Generally, the clinical evidence is uncontrolled studies with response rates as the primary outcome which acts as a proxy for overall survival. Although some of the response rates are impressive, this evidence base is notoriously difficult from an HTA point of view and often require some assumptions to fill in the data gaps. These are the type of medicines that committee would have struggled to approve due to the uncertainty so the decision option of permitting use on an interim basis is attractive. Interim acceptance signals to the health boards, clinicians and patients that the committee consider these promising new medicines but with important clinical uncertainties.

1.21 How policy can impact on HTA processes (iii)

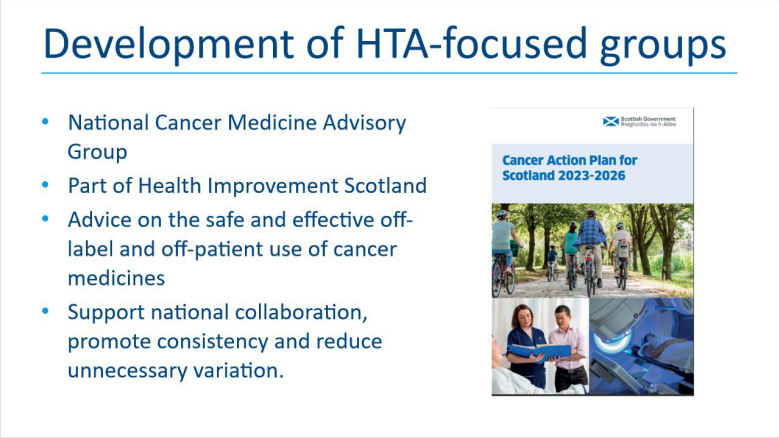


Notes:

Another recommendation from the review was to introduce a pathway for ultra-orphan medicines. An ultra-orphan is a medicine used to treat an extremely rare condition (the condition has a prevalence of 1 in 50,000 or less in Scotland; fewer than 100 patients) that is chronic and disabling and requires highly specialised management. If SMC validates that a medicine meets the ultra-orphan criteria, the company submits the evidence and an initial assessment of clinical and cost-effectiveness is performed using a broader context within the ultra-orphan framework.

The SMC committee do not make a decision at this point but publishes an assessment report to describe the key clinical and economic uncertainties. The company commits to data collection arrangements as a condition of entering the pathway. The medicine is then available to prescribe in NHSScotland within the specialist services for a three-year period while the further data, which may include real-world data, is collected. After three years, the company will submit to SMC for reassessment. The expectation is that this will be an updated submission with further evidence. The decision-making will be in the context of the ultra-orphan framework which places more emphasis on the qualitative evidence, alongside the quantitative.

1.22 Development of HTA-focused groups



Notes:

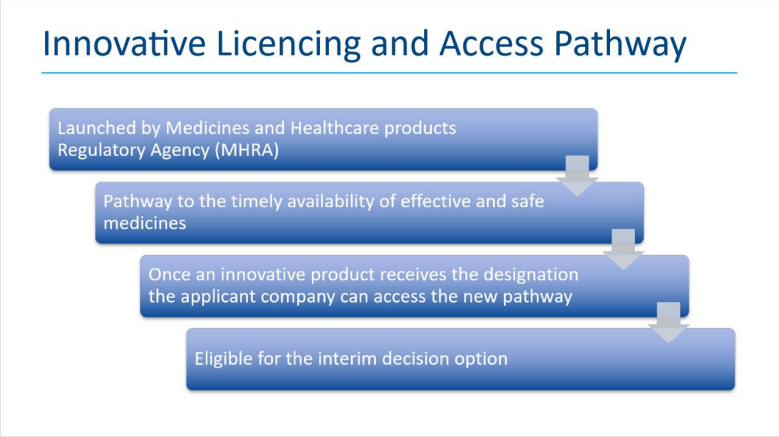
This final example illustrates how policy recommendations can be the driver to develop new HTA focused programmes of work within Health Improvement Scotland.

Aligned to a commitment in the Scottish National Cancer Plan, the National Cancer Medicine Advisory Group, referred to as NCMAG, was developed to provide advice to support access to safe and effective off-label uses of cancer medicines. The group's remit is different to SMCs in that it focuses on the off-label use of medicines, that is prescribing a medicine outside of the marketing authorisation. Unlike SMC this group accepts submissions from clinicians not pharmaceutical companies.

One of the challenges for this group is the limited evidence base for the off-label use of many of these cancer medicines, especially if it is rare cancer. There is also a dearth of economic data which means that deciding whether or not a medicine is cost-effective is difficult. Where there is no economic

evidence more weight often needs to be given to budget impact (calculated as the number of patients eligible for new medicine per year multiplied by medicine cost) and service impact which are factors not traditionally considered in HTA. This highlights that depending on the amount of evidence available a different approach to HTA is often required. This group is developing decision-making frameworks for these types of situations to ensure the process is fair and explicit.

1.23 Innovative Licencing and Access Pathway



Notes:

I am just going to introduce the Innovative Licencing and Access Pathway (ILAP) which is an example of how a more recent UK wide initiative has impacted on HTA conduct.

ILAP was launched by the Medicines and Healthcare Regulatory Agency in January 2021, as part of the new regulatory arrangements following the UK-EU Transition period. The objective of the new ILAP pathway is to create a more seamless pipeline to the timely availability of effective and safe medicines. It involves HTA and regulatory bodies working together to support the movement of promising medicines meeting unmet need more quickly through the processes of gaining approval and implementation.

The interim decision option I mentioned earlier is now also available for

medicines that have been granted an Innovation Passport from this pathway. This decision option allows earlier patient access to new medicines for an important unmet medical need and also provides reassurance that a final decision will be made once further data on clinical outcomes are available to address the key uncertainties identified in the original evaluation.

1.24 Scottish Health Technology Group (SHTG)

Notes:

I am now going to talk briefly about the other national HTA agency within Health Improvement Scotland – the Scottish Health Technology Group. I am not going to go into the same depth as I did with SMC as some of the principles in terms of HTA assessment and process are transferable to this group too.

SHTG provides advice on health technologies to support informed decision making that improves the health and care for the people of Scotland. Health technologies considered by SHTG include tests, devices, procedures, talking therapies, digital healthcare, programmes or systems.

I thought it would be interesting for you to hear about a few of the drivers behind this group. Firstly, as I am sure you are aware the rapid pace of technology innovation, including the integration of digital technology and data into everyday life is a key driving force behind this group. So from

devices to artificial intelligence and genomics, it is crucial that Scotland has a HTA process capable of informing the use of innovative technologies in a timely manner across Scotland. Another driver is the need to make efficient use of resources. The economic challenges intensified by the COVID-19 pandemic has lead to greater pressure on the health and social care budget in Scotland. HTA can help decide the maximal value of our resources, through the evaluation of effectiveness and cost effectiveness of health technologies.

Summary of images: this consists of pictures of four devices as examples of technologies that may be assessed by the Scottish Health Technology Group. This includes a picture of a tube-like device called a cystoscope, a picture of a small oral shaped device which is a novel-imaging device for use as anon-invasive alternative to colonoscopy, a picture of a black hand-held device that offers a glucose monitoring system and a picture of a phlebotomy kit in use on a patient's arm.

1.25 Question 3

Question 3

There is **another key driver for SHTG** that has been mentioned previously, can you think what this could be?

Hint: it is a strategy that aims to minimise the risk of variation in access to new technologies

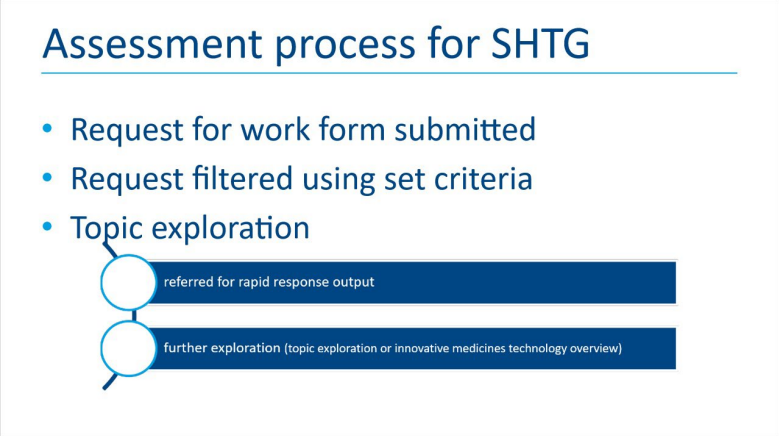
Answer: 'Once for Scotland' decision-making strategy

Notes:

There is another key driver for SHTG that has been mentioned previously for SMC, can you think what this could be?

The answer is to support the **once for Scotland** decision-making strategy by advising on the use of health technologies to be applied consistently and fairly across Scotland, addressing (or minimising) the risk of variation in access and outcomes.

1.26 Assessment process for SHTG



Notes:

I am now going to provide some points about the assessment process for SHTG. So starting with the request form, anyone can ask for SHTG advice to help answer questions about health technologies so this is different from SMC which relies on submissions from pharmaceutical companies only.

The second stage is the initial filter where the request is assessed against set criteria such as potential impact on health and care provision; the level of uncertainty relating to evidence base and how it aligns with national or organisational priorities. The request may be referred for rapid response outcome or further exploration.

If the topic is allocated for further exploration it is worked up using the PICO framework into a research question that is aimed at being impactful.

1.27 SHTG output - recommendations

Notes:

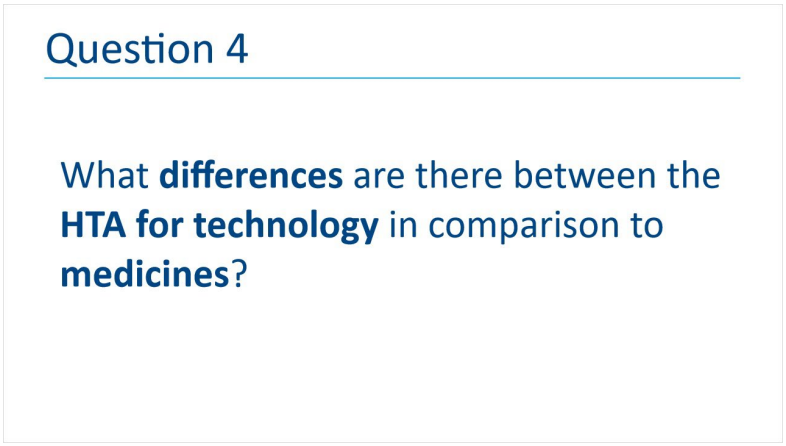
I am going to focus on the development process for just one of SHTGs products - recommendations. Evidence-based SHTG recommendations are developed by a national committee in consultation with stakeholders. Clinical effectiveness, safety, and cost effectiveness evidence will be considered; alongside patient and public views, professional expert views, and social and organisational implications. SHTG recommendations may also include an adaptation of an HTA conducted elsewhere in the UK or internationally, which would include consultation with experts in Scotland.

At the beginning of this presentation, I mentioned "evidence to decision making" frameworks earlier to make the process more objective and transparent. SHTG are in the final stages of developing one. This considers four core domains to guide decision-makers to consider consistently - the technology and its value; safety, acceptability and credibility; demonstrating the performance of the technology and capturing the cost and value for money of the technology.

The SHTG Council is responsible for the endorsement of the evidence presented and for making recommendations to NHSScotland. The council consists of Board Chief Executives, Medical, Planning and Public Health Directors, Public Partners and Industry representatives.

Please visit the SHTG website to see more SHTG products -Our Advice (shtg.scot) https://shtg.scot/our-advice/

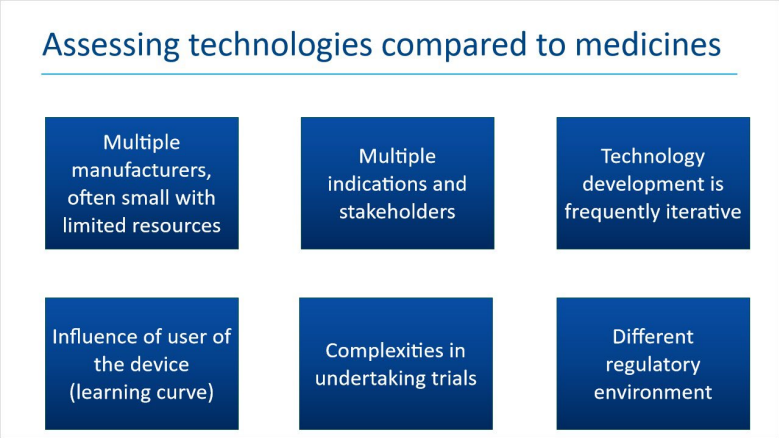
1.28 Question 4



Notes:

Pause and make note of any differences that you can think of between the HTA for a technology in comparison to the HTA for medicines? For example, consider the issues that may arise from assessing a type of glucose monitoring system to measure glucose levels in a patient with diabetes compared to the issues that may arise from assessing an immunotherapy medicine for a type of cancer. It may be useful to also think about the use of each of these in practice and work back.

1.29 Assessing technologies compared to medicines



Notes:

So lets look at some of these differences now.

Firstly, unlike the pharmaceutical companies that we see producing new medicines, technologies are often development by small companies or academic spin off groups without the resources, knowledge and experience of getting products to market.

Technologies find application in different areas within healthcare provision, not just treatment; one technology may have multiple indications – think of the thermometer; given all this, there can be multiple stakeholders and in terms of making decisions based upon evidence-based advice and also no defined audience to direct guidance towards.

Unlike medicines which tend to go through a development period to the final product and then remain static, technology development is frequently iterative with many versions of the final product, and evidence may relate to previous versions.

The influence of the person administering and using the technology tends to be far greater for a healthcare technology than for a medicine, as does the context in which it is used.

Undertaking trials, particularly trying to blind participants such as those conducting and experiencing a surgical procedure, can be extremely difficult and ethically challenging. Often technologies have a lower quality, more limited, evidence base than medicines. Also, there are often specific considerations for digital technologies that go beyond the standard evaluative framework. (SHTG uses the NHS England and Digital Technology Assessment Criteria (DTAC) to support decision making for digital technologies.)

Regulatory requirements have traditionally been much less rigorous than for medicines, particularly in Europe, although this is changing, and things are changing further in the UK following Brexit.

Using the NHS Digital Technology Assessment Criteria (DTAC) - AI regulation service - NHS (innovation.nhs.uk)

DTAC is an advisory assessment body and sets out baseline standards for clinical safety, data protection, technical security, interoperability and usability and accessibility.

1.30 How policy can impact on HTA processes

Notes:

As before I am going to provide an example of how policy can impact on the conduct of HTA, this time for the technology group. The example I am going to use is the policy agenda to drive greater innovation in healthcare design and delivery and the implications that this has had for SHTG.

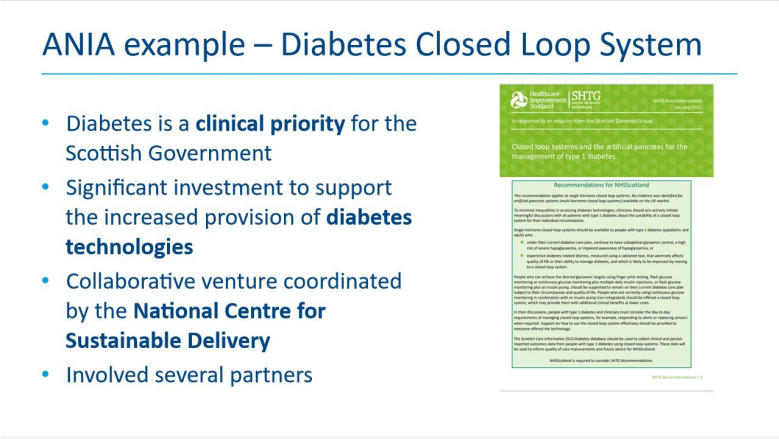
The Accelerated National Innovation Adoption Pathway (referred to as ANIA) is a new initiative focused on fast-tracking the adoption of proven technological innovations across NHS Scotland. ANIA aims to ensure the quick and safe rollout of technological innovations that will improve patient outcomes, reduce waiting times and improve patient and staff experience. The ANIA pathway has been developed to enable adoption of proven

technological innovations to be scaled at pace as part of the ‘Once for Scotland’ approach. Following submission of an ANIA referral form, high impact innovations that meet the ANIA criteria will progress along the pathway**.**

The ANIA pathway is also designed to:

- Ensure only the highest impact, evidence-based innovations that are aligned to Scottish Government priorities are adopted nationally.
- Enable joint planning with territorial NHS Boards for accelerated adoption and implementation of innovations and associated service change requirements.

1.31 ANIA example – Diabetes Closed Loop System



Notes:

SHTG undertook a detailed HTA of Closed Loop System technology that led to a formal recommendation for its deployment to people living with Type 1 diabetes across Scotland. The technology is considered the most significant development in type 1 diabetes treatment in recent years and can transform lives, particularly for children and young people. Closed Loop Systems help people improve their glycaemic control and in turn reduce the likelihood of complications.

This contributed to the Scottish Government's decision to invest nearly 15million with past few years to improve patient access to a range of diabetes technologies, which were subsequently allocated to Boards for rapid deployment. The investment will see a dedicated team to support NHS health boards to rollout the technology faster and more efficiently across Scotland. The collaboration is led and coordinated by the Centre for Sustainable Delivery and involves several partners including NHS National Services Scotland, Healthcare Improvement Scotland, Public Health Scotland, Digital Health & Care Directorate and NHS Education for Scotland. The national rollout of diabetes Closed Loop Systems is one of the first innovations to be approved through the ANIA Pathway.

1.32 Further ANIA examples

Notes:

On the slide are three further ANIA examples. The Stroke clopidogrel Gene Test project is looking at adapting NICE guidance on whether personalised antiplatelet therapy based on genotype testing is more effective at reducing stroke recurrence than treating everyone with clopidogrel regardless of their genotype. So this is an example of a national approach to genetic testing relating to clopidogrel.

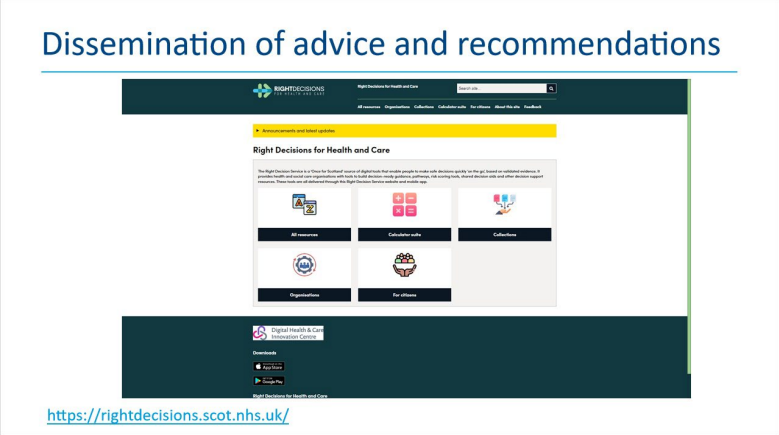
Digital dermatology is looking at the safe and effective transfer of a digital

image alongside a referral from primary to secondary care.

The type 2 digital diabetes remission programme uses digital technology to provide a 12 month remission programme to people recently diagnosed with Type 2 diabetes across Scotland.

Summary of image: a scientist using a pipette to put a substance into a test tube to represent the genetic testing relating to the clopidogrel ANIA example.

1.33 Further ANIA examples



Notes:

One of the last areas that I would like to cover is the publication and dissemination of the advice and recommendations arising from the HTA conducted within Health Improvement Scotland. Each group has their own website to publish their products.

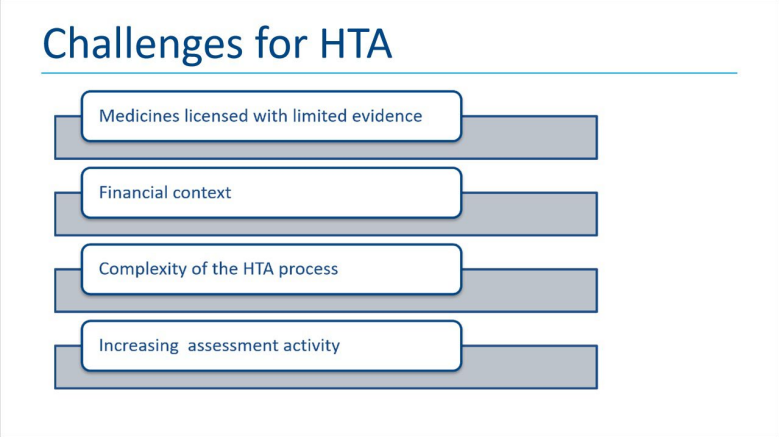
Currently, Health Improvement Scotland products are being integrated into a new platform called the Right Decision Service in the form of digital tools. The Right Decision Service is a 'Once for Scotland' source of digital tools that enable people to make safe decisions quickly ‘on the go’, based on validated evidence. It provides health and social care organisations with tools to build

decision-ready guidance, pathways, risk scoring tools, shared decision aids and other decision support resources. RDS is also an example of a key deliverable from high level health policy in Scotland, in particular, the Digital Health and Care Strategy and the Vision for delivering Value-based Health and Care.

The last policy document I mentioned there notes that 'we can improve the use of health and care resources by supporting all health and care colleagues to deliver value-based health and care through the use of approaches such as: .....**the Right Decision Service and knowledge services**. These are essential to making sure people are accessing the right care at the right time and help ensure only people who will benefit are waiting for a procedure, which will also improve equity of access."

Right Decisions | Right Decisions (scot.nhs.uk)

1.34 Challenges for HTA



Notes:

So as a way to round of I thought I would touch on some of the challenges that HTA agencies face that increase uncertainty when assessing new medicines and technologies.

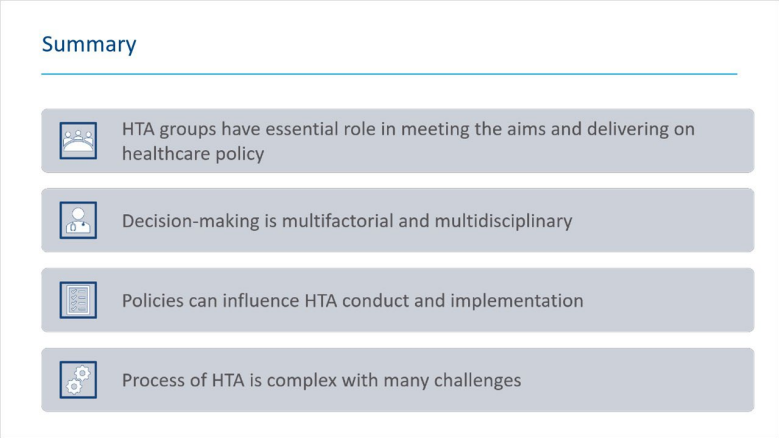
Firstly, there is a global push for earlier access to new medicines, which means that some medicines are licensed with a limited evidence base. This leaves companies with important gaps in the evidence in their HTA submissions making it more difficult for our decision-makers to be sure that the medicines represent a good use of NHS resources.

Next up is the financial context. SMC does not consider affordability; it provides a company budget impact template to health boards to assist with financial planning but it does not influence the decision. The current financial climate is challenging so we are very aware of the opportunity cost associated with approving high cost technology and medicines for use in NHSScotland. This is particularly important when there is a great deal of uncertainty in the benefits for a medicine.

Furthermore, there is increasing complexity in the HTA process in Scotland and there is a need to adapt to regulatory changes and policy recommendations that support earlier patient access. There is more use of indirect comparisons with complex methodology requiring specialist statistical input. Within HIS we are working to effectively incorporate patient related outcome measures and real world evidence into the life cycle of HTA.

Using SMC as an example there is often a struggle with capacity to manage the increasing assessment activity. One of the ways SMC have managed this is by introducing more streamlined processes for medicines where alternatives within the same therapeutic class have already been approved for use. These medicines are also likely to have a limited budget impact. This is referred to as the abbreviated therapeutic submission pathway. SMC have also streamlined the process for medicines that the company has clearly demonstrated are of good value. This has allowed resources to be prioritised to focus more on the first in class medicines and medicines that impact on treatment pathways.

1.35 Summary



Notes:

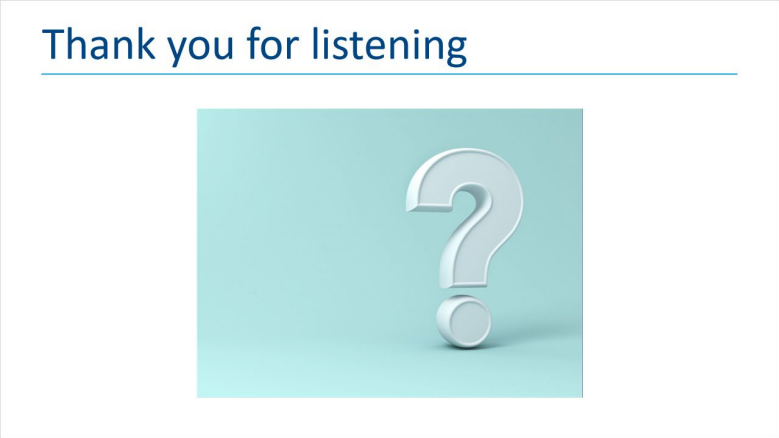
To conclude this session, I hope you have gained some perspective on the role of HTA in informing healthcare decision making and the provision of advice for the uptake of new medicines and technologies. This all has to align with the healthcare policy agenda set for NHSScotland.

As you see HTA is multifactorial and multidisciplinary and is not limited to clinical and cost-effectiveness and often needs to involve other factors depending on the medicine type and the amount and type of evidence available. We have worked through how the HTA for medicines differs from that of technology.

It is also important to consider how these healthcare policies might drive the topics which are referred and prioritised for HTA. I have also provided some examples of how policy recommendations can drive new assessment pathways or processes such as the ultra-orphan medicine pathway or the introduction of PACE meetings.

In summary, I hope you can see how the process of HTA is complex and there are many types of challenges posed to how this is conducted.

1.36 Thank you for listening



Notes:

Thank you for listening and I would like to encourage you to put any questions or comments in the discussion forum.