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A REVIEW OF ACCESS PATHWAYS FOR MEDICINES WITHIN HEALTH AND SOCIAL CARE, NORTHERN IRELAND

1 Executive Summary

Medicines are the most common medical intervention within Health and Social Care (HSC), with an annual expenditure of circa £875m per annum. Given that this is the second largest HSC spend after salaries, it is worthy of a concerted focus to ensure equality and efficiency in the various medicines access processes.

This review aims to articulate existing arrangements for access to medicines in Northern Ireland (NI), consider arrangements in place across the UK, identify the case for change following assessment of the current and future medicines access landscape, and develop recommendations for change aimed at ensuring continued timely, equitable access to clinically and cost-effective medicines for the NI population on a sustainable basis.

The method used included interviews with over forty stakeholders involved in the various medicines access processes in NI, where the pro and cons of the current systems were discussed. A short on-line survey was also used to capture the views and experiences of patients and public, particularly amongst those with rare diseases in NI. Once the key issues with the current processes had been identified, examples of best practice from elsewhere in the UK were considered and then used to develop recommendations for change going forward.

The main findings of the review included confirmation that patients were getting access to treatment without undue delay in the majority of cases and that HSC Trust teams really appreciated the support they received from the Department of Health Strategic Planning and Performance Group (SPPG) team members. Frustrations with the current processes included inconsistency in commissioning timelines, use of cost-per-case commissioning, communication issues, gaps in policy coverage, and a lack of robust data throughout NI medicines access processes.

Based on the review findings, ten recommendations were developed. They include creating a team approach to medicines access, a redesign of the medicines access workflow, creating an industry forum, developing new service infrastructure impact assessment processes, redevelopment of the medicines access/managed entry website, embedding patient/public involvement in processes and strengthening the use of clinical and financial data to enable replacement of the cost-per-case system.

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2 Background

Medicines are the most common medical intervention within Health and Social Care (HSC), with an annual expenditure of circa £875m per annum[1] an all-time high and the second largest HSC spend after salaries. Across the UK, medicines access policy aims to balance the competing priorities of ensuring prompt access to new, innovative medicines, while incentivizing the pharmaceutical industry to develop new products, and ensuring that expenditure on medicines is affordable for the HSC. With growth in spend on medicines largely outstripping growth in available funding, this trilemma is becoming increasingly difficult to resolve, as is meeting public expectations in relation to the range of medicines available.

Globally, the use of medicines is increasing in response to demographic shifts, rising rates of multi-morbidity, developments in medical practice, and the rapid pace at which innovative treatments are becoming available. New medicines have the potential to be life-changing, with treatments becoming available for rare conditions that previously had no or little treatment options. The advent of personalised medicine is also impacting on clinical decisions and treatment options in some specialist areas. Often these high-cost medicines require specialist administration and/or reconfiguration of clinical pathways, thus creating additional affordability challenges for health providers.

The population of Northern Ireland (NI) has risen to over 1.9 million[2] and issues including age, deprivation, cultural challenges, impact of conflict-related trauma, have led to the highest per

[1] **Primary Care**: Health and Social Care Business Services Organisation (2024) *General Pharmaceutical Services Statistics for Northern Ireland 2023 – 2024*. Available at: https://bso.hscni.net/wp-content/uploads/2024/06/General-Pharmaceutical-Service-Statistics-for-NI-2023-24-Report.pdf. **Secondary care:** Strategic Planning and Performance Group of the Department of Health (NI) (2024). *Secondary Care Pharmacy Spend 2017/18 - 2023/24.* [Figures internally sourced]. Secondary care pharmacy spend extracted from Trusts JAC systems and includes all issues from pharmacy (medicines, medical gases, vaccines, dressings, medical and surgical items and sundries) but does not include rebates and large credits outside of JAC pharmacy system.

[2] **Northern Ireland Statistics and Research Agency**, Estimates of the population of Northern Ireland as of 30 June each year by age and sex (Mid Year Population Estimates | Northern Ireland Statistics and Research Agency)

person medicines use and spend in the UK[3]. A significant driver of increased costs in recent years has been a rise in HSC spend on commissioned high-cost medicines, with spend increasing by 85.6% since 2017/18 to almost £250m in 2023/24[4]. Furthermore, the cost of making a new medicine available is not just the cost of the medicine, and also includes infrastructure such as staffing. With the increasing complexity of novel treatments, there is a need to embed medical and digital technologies into clinical pathways to support diagnosis, screening and after care.

In this context, the Department of Health (DoH) decided to undertake a review of existing medicines access policy and processes to ensure that the population of NI can continue to benefit from advances in medicine and science on an equitable and sustainable basis compared to those elsewhere in the UK.

3 Aim of the review

The aim of this review is to articulate existing arrangements for access to medicines in Northern Ireland (NI), consider arrangements in place across the UK, identify the case for change following assessment of the current and future medicines access landscape, and develop recommendations for change aimed at ensuring continued timely, equitable access to clinically and cost-effective medicines for the NI population on a sustainable basis.

4 Method

Stakeholder engagement is arguably the most important ingredient for a successful project, therefore it was central to this review and followed an amended version of Cochrane's Six Step

[3] Valuing Medicines - A Strategy for the Sustainable Use of Medicines in Northern Ireland (Consultation on Valuing Medicines - A Strategy for the Sustainable Use of Medicines in Northern Ireland | Department of Health)

[4] Strategic Planning and Performance Group of the Department of Health (NI) (2024). Secondary Care Pharmacy Spend 2017/18 - 2023/24. [Figures internally sourced].

Stakeholder Engagement Framework, commonly used in health projects involving the public, clinicians, commissioners and policy makers.

The stakeholders identified for inclusion in this phase were:

- Service users, carers and public advocates
- HSC Trusts - representatives from consultants, senior pharmacists and finance teams
- Department of Health Strategic Planning and Performance Group (SPPG) - representatives from pharmacy and the specialist commissioning teams
- Individual Funding Request Scrutiny Panel – chair of the Regional Scrutiny Panel
- Department of Health – representatives from Pharmacy and Secondary Care Directorates
- National Institute of Health and Care Excellence (NICE) - Northern Ireland implementation facilitator
- Regional Pharmaceutical Procurement Service (RPhPS) pharmacists
- Association of British Pharmaceutical Industry (ABPI) – Northern Ireland representatives

A full list of the individuals invited to participate can be found in Appendix 1.

Meeting invitations were sent to the health sector stakeholders identified. The subsequent review meetings organised were a mixture of individual and group discussions, dependant on availability and the preferences of the stakeholders involved. A number of organisations decided to invite a range of staff members from the different professions involved in the medicines access process, to a single event, whilst others preferred a series of individual meetings. The meetings were either held in person or via MS Teams, as chosen by the attendees. At each meeting the facilitator used a list of key topics to prompt discussion about the various aspects of the current medicines access processes. Stakeholders were encouraged to share their views and experiences in relation to what was working well, the challenges and their frustrations with the current systems.

To ensure meaningful personal and public involvement (PPI) a Public Health Agency (PHA) PPI involvement plan was completed for the review. This led to the identification of a number of specialist patient/carer groups who were invited to contribute to the review as stakeholders, namely:

- Northern Ireland Rare Disease Partnership (NIRDP) - an umbrella group working to raise awareness, connect, educate and innovate on behalf of the entire rare disease community
- Versus Arthritis Northern Ireland - an organisation that supports people with arthritis and ensures their needs are a priority with policymakers.
- Cancer Focus NI – a leading local cancer charity, supporting cancer patients and their families, funding research and campaigning for better health policy.

In March 2025 representatives of the review attended two engagement events organised by the NIRDP and in April 2025 an on-line survey was developed and shared via social media, to collect patient and carer stakeholder feedback.

On completion of the stakeholder engagement phase, the key points from each meeting were sorted into common themes and used to guide the next phase of the review.

In the second phase information was gathered about the medicines access systems and processes used elsewhere in the UK. Key areas of interest were identified, and contacts were made within the relevant UK teams. Meetings were then arranged with the contacts to gather in-depth information and explore both the positive aspects and the challenges they experienced during and following implementation.

The following organisations/groups were considered and/or contacted during this phase of the review:

- All Wales Therapeutics and Toxicology Centre (AWTTC)
- All Wales Medicines Strategy Group (AWMSG)
- One Wales Medicines Assessment Group (OWMAG)
- Association of British Pharmaceutical Industry (ABPI) – Wales
- Welsh Pharmaceutical industry forum
- Blueteq Ltd

- Blueteq implementation team – NHS Wales
- Pharmacy, University College London Hospitals NHS Foundation Trust
- HSC Trust pharmacy EPIC leads
- Scottish Medicines Consortium (SMC)
- NHS England - Medicines (NHSE)

The final phase of the review involved the development of recommendations and preparation of the final review report.

5 Findings

5.1 Patient access to treatment

Despite some stakeholders from the pharmaceutical industry expressing concerns about potential delays to patient treatment, the review found little evidence of negative outcomes or patients coming to harm arising from delays in accessing treatment. The HSC Trust and Strategic Planning and Performance Group (SPPG) teams involved in the HSC Managed Entry processes are very experienced and navigate the various options quickly, such as individual funding requests (IFRs), including its 'urgent request' option, or early access to medicines/compassionate use schemes, to obtain treatment decisions on behalf of patients. HSC Trust consultants are able to use the cost-per-case method to obtain the medicine in advance of publication of the final NICE guidance, for patients who meet the criteria set by NICE in their technology appraisal (TA), as soon as the NICE TA final draft guidance (FDG) is published, which is sooner than happens elsewhere in the UK.

In the very rare instances where a delay may happen, it can be due to:

- lack of specialist service provision required to facilitate treatment, such as genetic testing, capacity in small specialist clinical teams and/or,
- the requirement for new infrastructure to be established to secure sufficient capacity, in either secondary or primary care to deliver the medicine. If new infrastructure is required it often takes time to establish, creating delays in access, a problem common across the UK. The example below in relation to GLP-1 receptor agonists, a class of

medicines used to treat type 2 diabetes and for weight management, clearly highlights this issue.

- An approved individual funding request (IFR) that exceeds £150k. For IFR medicines below £150k p.a. the IFR Regional Scrutiny Panel may give approval to proceed with treatment directly to the requesting consultant, whilst for medicines above £150k p.a., the panel must inform and involve SPPG.

Semaglutide is a GLP-1 medicine which NICE has recommended as an option for weight management, including weight loss and weight maintenance, alongside a reduced-calorie diet and increased physical activity for two years in adults. However, it is recommended that it should only be used within a specialist weight management service providing multidisciplinary management of overweight or obesity (including but not limited to tiers 3 and 4). The NICE TA was published in March 2023 and updated in September 2023 (TA875), yet it is not listed on the HSC Managed Entry website, as NI did not have a tier 3 or 4 specialist weight management service at that point in time, rather it refers to NICE NG28 from 2019.

5.2 Existing medicines access pathways

5.2.1 NICE TAs - from endorsement to implementation

The National Institute of Health and Care Excellence (NICE) is an executive non-departmental public body, in England, of the Department of Health and Social Care (DHSC), tasked with producing national guidance on the promotion of good health and the prevention and treatment of ill health. It publishes guidelines in four areas:

1. The use of health technologies within England's NHS and NHS Wales (such as the use of new and existing medicines, treatments and procedures)
2. Guidance on the appropriate treatment and care of people with specific diseases and conditions.
3. Guidance on health promotion and ill-health avoidance

4. Guidance for social care services and users.

NICE undertakes Health Technology Assessment (HTA), encompassing cost-effectiveness analysis, as the primary method used to ensure that the NHS in England pays prices for medicines that are commensurate with their benefits, hence offer value for money. Scotland and Wales adopt a similar approach to HTA assessment.

In addition, NICE also undertake Highly Specialist Technologies (HSTs) evaluations which are recommendations for the use of new and existing highly specialised medicines and treatments within the NHS in England. The HST process assesses medicines for very rare conditions following a process of topic identification by the National Institute for Health and Care Research (NIHR) Innovation Observatory. HSTs tend to be priced much higher than other medicines NICE consider through Technology Appraisals, reflecting the rarity of the condition and consequent small numbers of patients who will benefit, limiting the opportunity for manufacturers to make a return on their research, development and marketing costs.

NICE follows a standard approach to developing and publishing a TA for a medicine. The steps are summarised in the flowchart shown below (Figure 1).

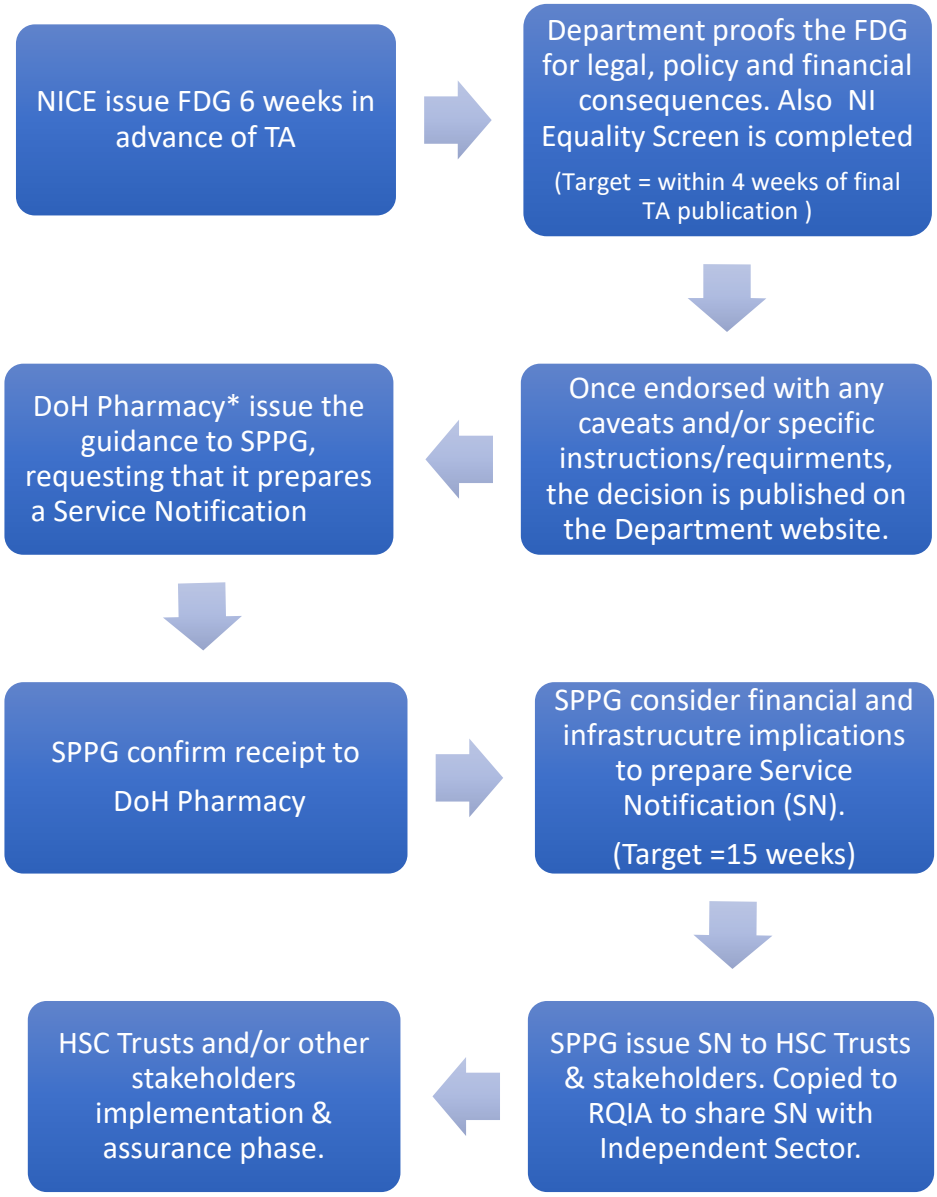
Figure 1: The NICE TA Development Process

The Department of Health (DoH) established formal links with NICE on 1 July 2006 whereby Technology Appraisal guidance published by NICE from that date would be locally reviewed by DoH for applicability to NI and, where appropriate, endorsed for implementation in the HSC. This link has ensured that NI has access to up-to-date, independent, professional, evidence-based guidance on the value of health care interventions. In practice this means that treatments that have been recommended by NICE for routine use in the NHS in England are also routinely available in NI.

The current Northern Ireland process for the endorsement of NICE TAs is set out in detail in a circular, issued by the Chief Medical Officer in April 2022: *Circular HSC (SQSD) 12/22 - NICE Technology Appraisals - Process for Endorsement, Implementation, Monitoring and Assurance in Northern Ireland. (*Circular HSC (SQSD) 12/22: NICE Technology Appraisals - Process for Endorsement, Implementation, Monitoring and Assurance in Northern Ireland.)

A summary of the endorsement process steps is set out in figure 2 below.

Figure 2: Current Northern Ireland NICE TA endorsement process



* In June 2022 DoH pharmacy took over this responsibility from QRIB (Quality, regulation and improvement branch) of Chief Medical Officer's Group.

As can be seen in figure 2, NICE publishes final draft guidance (FDG) for each TA approximately six weeks prior to the final guidance being issued. On receipt of a FDG from NICE, the DoH initiates the TA process for NI with a review of legal and policy consequences related to implementation of the guidance within the province. It does not repeat NICE's clinical or cost-effectiveness assessments. As a result, the guidance may be endorsed with caveats to advise local HSC organisations of any equivalent legislation/policy or any specific instructions/requirements.

In practice, DoH is not currently undertaking a financial/affordability assessment for NICE TAs as outlined in Circular HSC (SCSD) 12/22. Stakeholders reported that the loss of this intelligence could be linked to the changes in the commissioning arrangements from 2020 onwards (see section 5.2.2), as DoH affordability assessments were previously based on the intelligence gained from the specialist services commission team MDT function. The DoH Secondary Care policy observer on the Team (see section 5.2.2) was able to not only flag costs to DoH but was able to explain their make-up and the need for level of funding identified, very early in the process.

As part of the equality screening process and in compliance with Section 75, Northern Ireland Act 1998, DoH will complete an equality screening template, in addition to NICE's equality screening process and as soon as the local review is complete, endorsement decisions are published on the DoH website, with links to appropriate caveats where these apply. (NICE - Endorsed Technology Appraisals 2024/2025 | Department of Health). If a piece of NICE guidance is not applicable to NI, then this will be highlighted to Primary Care and/or HSC Trusts, along with an explanation. Overall, this process is expected to be completed within four weeks of the date of publication of the final TA guidance by NICE, approximately ten weeks after publication of the FDG.

A number of Trust and ABPI stakeholders questioned why NI endorse NICE TAs in this manner, given that other UK countries approach them differently. For example, England have an automatic funding mandate of 90 days, as set out in the NHS Constitution, whilst in Wales they automatically make treatment available without the need to endorse each TA individually. The Scottish Medicines Consortium (SMC) is the key body in Scotland that makes decisions about medicines, often in consultation with NICE. Once the SMC makes a decision, the Scottish NHS boards are then expected to make this medicine, or an equivalent, available to patients. Those stakeholders also questioned the need for individual equality screening of each NICE TA, given that it had already been through a rigorous equality screen during the NICE development process.

Following endorsement from DoH, HSC organisations are required, under the statutory duty of quality as specified in Article 34 of the HPSS (Quality, Improvement and Regulation) (NI) Order 2003, to put in place the necessary systems for implementing the NICE TA guidance.

While not formally endorsed by in the same matter as NICE TAs, DoH also request that the SPPG take the steps necessary to provide access to medicines recommended by NICE under a Highly Specialist Technologies (HST) evaluation within the parameters set by NICE, where NICE has recommended this as a cost-effective use of HSC resources.

Medicines which have been subject to a TA evaluation and are not approved by NICE are not routinely commissioned by the HSC, and so new treatment should not be routinely initiated. Where a patient has been receiving treatment under HSC arrangements with a drug which NICE has appraised and subsequently not recommended, patients have the option of continuing their therapy until they and their clinicians consider it appropriate to stop.

Following endorsement of a TA by NICE, the DoH Medicine Access Branch (MAB) will issue the guidance to SPPG and request preparation of a Service Notification (SN). SPPG will confirm receipt to MAB and within 15 weeks from the date of DoH endorsement, will issue a SN to the HSC Trusts and other relevant providers and stakeholders setting out the expectations for implementation. The SN will be copied to the RQIA for dissemination to the independent sector as appropriate.

To bring the point of initial access forward, the HSC Managed Entry process allows Trusts to request use of a medicine on a cost-per-case basis at the point NICE publish the FDG for the TA, rather than patients having to wait until the SN is issued. Therefore, depending on the date of FDG publication, the medicine may potentially already be in use for up to 25 or more weeks in advance of SN issue. In real terms, this may enable access to new medicines ahead of other UK nations including England and Wales, although this access is contingent on the

ability of the HSC Trust provider to comply with the requirements of the NICE FDG and any necessary infrastructure requirements for treatment.

HSC Trust stakeholders interviewed were very positive and complementary about the support provided by both the SPPG and Regional Pharmacy Procurement Service (RPPS) teams. Their knowledge and experience of the processes were said to be invaluable in assisting clinicians navigate through the medicines access processes for their patients. A frustration raised by all stakeholder groups, but particularly ABPI representatives and the Trusts, was inconsistency in the time between NICE TA completion and the issue of the SN in NI, resulting in inconsistent timescales for medicines becoming available via routine commissioning. However, it should be born in mind that the HSC Managed Entry process does contain provisions for Trusts to begin to use medicines on an interim commissioning or 'cost-per-case' basis as soon as the NICE FDG was published, subject to the ability of the provider to comply with the requirements of the NICE FDG, which is sooner than happens elsewhere in the UK as outlined above. Therefore, NI patients can potentially commence treatment up to 132 days in advance of those in England and 102 days in Wales, as long as the HSC Trust involved does not need any additional infrastructure support for implementation, as interim 'cost per case' commissioning does not allow for provision of additional infrastructure needs, arrangements for which are set out in the subsequent SN describing arrangements for routine commissioning. It should however be noted that the above timescales for access in England and Wales relate to routine commissioning arrangements, while in NI routine commissioning arrangements are confirmed only when the SN is issued by SPPG.

Another frustration raised by all stakeholder groups, but particularly ABPI representatives and the HSC Trusts, was inconsistent delivery against NICE TA managed entry timescales. SNs for NICE TAs are at times being issued in batches as backlogs form, within the endorsement to routine commissioning process, due to lack of available staffing resources in SPPG. Although the medicines are available from the NICE FDG stage using the cost-per-case option, as outlined above, the frustration from the service here seems to come from the lack of information as to whether any additional funding will be made available that will support the

TAs' implementation during this period, for example infrastructure funding. The impact of cost per case commissioning is explored in more detail in section 5.3.

To illustrate this issue the review considered the SNs issued to HSC Trusts on 13th December 2024, which included sixteen medication related NICE TAS. In many cases HSC Trusts clinical teams had started using these medicines, on an interim cost-per-case basis, from the date of their NICE FDG publication and all sixteen of the guidance decisions had been previously added to the HSC Managed Entry website, ranging from 2 to 98 days following NICE's final publication date. In contrast, the SN setting out arrangements for routine commissioning were being issued between 79 and 359 days after publication of the final NICE TA guidance as the SN process runs separate to and often behind the HSC Managed Entry process. As a result, some Trust stakeholders questioned whether there was any real merit in the SN process going forward, given the disconnect between the timelines for SN issue and the actual ability of patients and clinicians to access new treatments.

The other common frustration mentioned by stakeholders was the use of the cost-per-case option as a commissioning tool and this is covered in more detail later in the report.

5.2.2 Silo working

The various medicines access processes appear to be managed by people working in different sections of the service and often by the secondary care sections of both DoH and SPPG, with a lack of central coordination. This appears to be leading to fragmentation, process delays, communication issues and a reliance on single individuals with expertise in the system. For example, despite SPPG now being part of DoH, the various steps required to endorse a NICE TA in NI are still being carried out in sequence, as illustrated in figure 2 when potentially a number could be completed in parallel, reducing the time taken. Potentially as a consequence of most NICE TAs being for specialist medicines, the review also found that the majority of these teams are from the Secondary care side of the service and that Primary Care is not really

involved. Stakeholders reported concerns about the potential for significant problems and/or delays when a NICE TA adjudication requires a medicine to be delivered by primary care alone.

Within SPPG, the medicines access workload is split between two different teams and further challenged by a significantly reduced staffing resource available to cover an ever-increasing work load, as evidenced by the increased number of NICE approved medicines in recent years. Between 2010 and 2020 specialist medicines commissioning was undertaken via a specialist services commissioning team (SSCT) which operated as an MDT within input from up to 20 officers from PHA (consultants, nursing and AHP) alongside planning, finance, pharmacy colleagues from the former HSC Board, now SPPG. It also included a DoH Secondary Care policy observer.

This approach also supported a number of medicine sub groups and a horizon scanning function which informed short and medium term planning and commissioning of medicines. Detailed monitoring returns for non-cancer drugs were provided monthly allowing for follow up actions on variations and contributed to the estimate building for resources particularly in relation to rates of growth by Trust. At the same time cancer drugs were monitored on the same basis, through a specific report on activity across all five Trusts. The process, augmented by the horizon scanning and tracking work, provided projections to DoH on likely costs for new medicines, growth in existing regimes and emerging technologies.

SNs developed for new medicines during this period included estimates of uptake, informed by the NICE TA costing estimates and adjusted as needed in conjunction with clinicians involved in sub groups. The cost-per-case process was then monitored against the expected estimates of uptake allow in year, thus allowing any variations to be identified and queried with the local services. The combination of these processes provided a high degree of assurance with regards expenditure supporting budgeting and informing financial allocations and in year adjustments as necessary. During this period, the commissioning of specialist medicines was audited by Internal Audit and resulting in a satisfactory rating, the highest standard possible.

In 2020 SSCT ceased to operate due to the redesignation of officers to COVID-19 response roles and the HSC Board commissioning directorate teams were restructured. This resulted in a significant reduction of planning capacity for commissioning of medicines/specialist services and also a complete loss of the professional input into the medicines commissioning purposes, with the exception of pharmacy and the Individual Funding Request (IFR) process. The IFR Regional Scrutiny Committee (RSC) process was originally set up with input from eleven hospital consultants, one PHA consultant, one HSC Trust pharmacy representative and one HSC Board pharmacy representative to support the delivery of the policy. At this time, there is input to the process from seven hospital consultants. Finance and information support is available on request now, rather than being actively involved in the processes.

Stakeholders from SPPG, previously the HSC Board, reported that, as a result of their 2020 reorganisation, there was a loss of connection between their 'commissioning' function and DoH processes around affordability (and subsequent allocations) sourced from horizon scanning, estimates of uptakes for new medicines and financial tracking of all specialist drug monies and this was a contributory factor in the emergence of a significant cost pressure in January 2024. Funding was able to be secured to meet this pressure, however in 2024/25 two HSC Trusts handed back a very large amount of their medicine allocations, unspent. At this time neither the HSC Trust or SPPG, with its pared down specialist medicines commissioning capacity, are able to identify why this happened, although there is thought to be a connection with the roll out of Encompass and recording.

5.2.3 Individual Funding Requests

The Individual Funding Request (IFR) policy document (Version 1.2 – 11 June 2020) outlines the conditions and criteria under which hospital consultants, on behalf of their patients, can make an "individual funding request" to the Regional Scrutiny Committee (RSC) for treatment that is not normally commissioned. Requests are made under a set of defined conditions, namely:

- The request does not apply to a cohort of patients;

AND

- The patient is suffering from a medical condition for which the patient's particular clinical circumstances fall outside the criteria set out in an existing commissioning policy for funding the requested treatment;

OR

- The request is for a new intervention or, for an intervention for a new indication out with the licensed indication, where no commissioning arrangements exist;

OR

- The patient has a rare clinical circumstance for whom the hospital consultant wishes to use an existing treatment out with the licensed clinical indication, with the explicit consent of the patient.

Stakeholders were consistently positive in their views of the IFR process and whilst they were not always happy with request outcomes, they respected the process. They liked the transparency of the process, in that there is a policy document publicly available that clearly outlines the conditions and criteria used in making IFR decisions. A supporting standard operating procedures document also sets out the processes for progression and consideration of IFR applications along with agreed decision timelines. Stakeholders feel that the process is fair and delivered consistently in line with the policy and the agreed decision timelines. It was also reported that the number of IFR applications were reducing year on year, from 2021/22. In 2021/22 the IFR Scrutiny panel accepted 76 requests, approving 24, whilst in 2023/24 they accepted 52 of which 12 were repeat submissions, approving 19.

The only challenge reported by stakeholders was the lack of guidance available for situations where a small cohort of patients was identified by the IFR process, i.e. where more than three IFRs for the same condition/treatment have been presented within a rolling 12 month period, as explained in more detail in section 5.2.4.

5.2.4 Management of small cohorts

As mentioned in section 5.2.3 the IFR process can lead to the identification of a small cohort of patients who require medicine(s) that are not normally commissioned.

The current IFR policy (2020) indicates that an IFR application should be deemed a service development if there is a cohort of similar patients of more than three per 12 month period. It states that such requests should be forwarded to the commissioner who will make a timely decision on commissioning. However, under the current HSC Managed Entry process there is no basis for a medicine to be commissioned if it has not been previously approved by a UK health technology appraisal body. Where there is no available HSC Managed Entry decision, the SPPG typically cannot make these treatments available without specific DoH policy cover or Ministerial intervention.

HSC Trust and SPPG stakeholders reported that the lack of cover for this situation leads to a number of risks:

- potential for treatment delay,
- frustration amongst hospital consultants and pharmacists as they know the treatment is available to patients elsewhere in the UK,
- risk of postcode prescribing as individual Trusts have to make their own decision as whether to proceed with treatment on a case by case basis.
- potential for higher than necessary expenditure.

One recent example of this issue considered during the review process clearly illustrates these consequences. Adult Onset Stills Disease (AOSD) is a relatively rare multisystem autoinflammatory disorder of unknown cause. As well as high spiking fever, arthritis in multiple joints, enlarged lymph nodes, rashes, sore throat, an elevated white blood cell count and raised blood markers for inflammation, patients can have several other clinical symptoms including hepatosplenomegaly, weight loss, myalgia and pericarditis.

In patients that fail to achieve remission after use of methotrexate or disease modifying anti-rheumatic drugs (DMARDS), the use of anakinra, a medicine that blocks receptors for interleukin-1, or the monoclonal antibody tocilizumab have been suggested as alternative treatments. However, neither anakinra nor tocilizumab are licenced for use in AOSD. In 2021 NHS England (NHSE) reviewed the evidence for the use of anakinra and tocilizumab in the treatment of AOSD that does not respond to initial treatments and decided to make them available for these patients via issue of a clinical commissioning policy.

Epidemiology predicts that one to two people will receive an AOSD diagnosis per million of the UK population each year. Hence every year in Northern Ireland approximately three or four people will be newly diagnosed with AOSD and a number of patients living with the condition will progress to second or third line treatments. In early 2025 a NI consultant rheumatologist, aware of the 2021 NHS England guidance, began the process of requesting tocilizumab for an AOSD patient via the IFR route. However, the request could not proceed as it breached the IFR small cohort rule.

In several online discussions the consultant expressed their frustration as they knew this issue had been raised previously, requesting a NI commissioned position in line with that of England and Wales and they assumed it had been resolved in the interim. As the tocilizumab was not easily available to them, the consultant decided to request canakinumab (Ilaris®) for their patient instead, a product licensed to treat AOSD (specialist use only) and which is associated with a significantly higher cost per patient per year than tocilizumab. Canakinumab is not recommended in England and Wales as both anakinra and tocilizumab are commissioned as third line options.

In Northern Ireland SPPG cannot commission tocilizumab nor anakinra for AOSD as there is currently no provision within the HSC Managed Entry process to consider treatment requests in line with NHS England guidance, as NHS England is not a recognised UK technology appraisal body. In these situations, NHSE consider the evidence as to whether an intervention is

effective and will then make clinically effective treatments available if it is considered affordable. They do not undertake a health technology assessment as NICE do, although they undertake an impact assessment as part of process and will prioritise investment according to the criteria in their Specialised Commissioning Service Development Policy (2021).

It should be borne in mind that broadening access to medicines commissioned via the HSC Managed Entry process beyond the list of recognised UK technology appraisal bodies may potentially lead to greater financial implications in some circumstances, however in some instances, medicines recommended via NHSE commissioning policies may be cost neutral or even cost saving.

5.2.5 Paediatric medicines

The inequity of access to medicines for children was raised by a number of stakeholders and also in a response to the DoH Valuing Medicines Strategy consultation.

In England, NICE no longer appraise paediatric licence extensions for medicines already approved for adults. Instead they refer to their Commissioning Medicines for Children Policy (Commissioning Medicines for Children in Specialised Services). Similarly, Scotland and Wales no longer review such license extensions and do not issue written guidance to the service. Currently in NI paediatric licenses extensions for medicines, already approved by NICE or SMC for adults, are not considered in the same manner as the other UK countries as there no NI policy cover that would allow SPPG to commission licensed medicines for children or paediatric license extensions that will not be assessed by NICE.

Both these issues are leading to a level of inequity of access to medicines for NI children and SPPG stakeholders felt that this issue requires urgent policy consideration. Children represent 20 per cent of our population and are more at risk of disability and/or poorer outcomes which will be potentially lifelong.

5.2.6 Changes in best practice and/or license extensions

Similarly to the scenarios outlined in section 5.2.4 and 5.2.5, there is currently no provision within the HSC Managed Entry process that allows SPPG to commission a product license extension or a new accepted national/international best practice using a medicine unless it has been reviewed by NICE, or another UK HTA body in the absence of NICE recommendations.. While there may be occasions, particularly in specialist areas of clinical practice, where medicines are used as best practice or recommended in specialist literature or guidelines in line with the available evidence, in practice this evidence may not be sufficient to support a licence variation, and consequently NICE will not issue recommendations for use on the NHS outwith the existing product licence. There are provisions in place elsewhere in the UK to commission medicines in such situations, for example the One Wales process, however decisions from such groups are not reflected in the current NI policy or access arrangements.

This issue has been raised by a number of stakeholders during the review and is well illustrated by a recent Northern Ireland Cancer Network (NICaN) proposal in relation to the use of neo-adjuvant-adjuvant pembrolizumab for stage III melanoma. Currently patients with stage III melanoma are offered adjuvant systemic therapy after resection as studies have shown that the use of adjuvant therapy in this context reduces the risk of recurrence by 15-20% in absolute terms. There is however ongoing risk of recurrence despite adjuvant therapy, with up to 50% of treated patients still developing melanoma relapse over the following 3 years

A number of recent studies have shown that using the checkpoint inhibitor (CPI) pembrolizumab up to nine weeks before surgery substantially reduces the risk of recurrence further, and is much more effective than the current adjuvant approach. As a result of this data, pre-operative CPI use has been written into international guidelines, however there is no plan to change the license of these drugs to include pre-operative use, as the clinical trials were academic studies not registration trials, and without a license change, NICE and SMC/AWMSG are unable to review and make a technology appraisal recommendation.

Therefore, individual jurisdictions must consider the data and this has already led to national routine use in countries including Italy, the Netherlands and Germany

In the UK there is consensus from melanoma experts that the data is robust and should be incorporated into guidelines to maximise benefit. NHS England has developed a pathway, which is also being followed by NHS Wales. In Scotland the National Cancer Medicines Advisory Group are reviewing the data similar to England, with a view to issuing advice to NHS Scotland on the use of this product.

NICaN has submitted a proposal to initially implement a minor adjustment to the local treatment pathway for patients who are v-raf murine sarcoma viral oncogene homolog B1 (BRAF) negative and suitable for immunotherapy, as this is the most straightforward aspect of the emergent data. This would be to facilitate the option of giving 9 weeks CPI pre-operatively, and the remaining treatment post-surgery (total duration of one year as per current practice). This has clear clinical benefit and is cost-neutral at worst. BRAF+ stage III patients would continue to receive post-surgery adjuvant treatment as per currently, pending broader evaluation for this group.

Where there is no available UK HTA recommendation upon which to base a HSC Managed Entry decision, SPPG typically does not make such treatments available without specific DoH policy cover or Ministerial intervention. Therefore, as there is no established equivalent pathway to evaluate and commission such a change in NI, NiCaN have not yet received agreement to proceed with their proposal.

Additionally, NICE do not assess medicines which subsequently becomes cheaper than at the time of their appraisal, for example Kuvan® (sapropterin dihydrochloride) in the treatment of phenylketonuria. SPPG stakeholders explained that the subsequent availability of generic sapropterin at a lower price allowed NHSE to expand their eligibility criteria while maintaining cost-effective provision of treatment, with very significant clinical benefit for women of childbearing age. This required a specific Departmental direction that treatment should be made available to eligible patients in NI on an equitable basis to NHS England. Similarly, SPPG had to create a workaround for the treatment of alkaptonuria with nitisinone.

The SPPG Hospital Care Directorate team feel that consideration needs to be given as to how best to provide commissioning decisions for medicines that fall out with the identified managed entry process, to ensure equality of access for NI patients who would benefit as a result. Some of these decisions may also be cost saving in the long run.

5.2.7 Managed Entry decisions involving antimicrobials

Similarly, to the paediatric and best practice issues outlined above, current NI policy also does not permit the SPPG to commission treatments for highly infectious diseases unless they have been assessed by a recognised UK HTA body. If action cannot be taken in a timely way, it may have wider public health implications. The treatment of highly infectious multi-drug resistant tuberculosis (MDR-TB) illustrates this issue well.

In 2022 the World Health Organisation (WHO) recommended the use of bedaquiline, pretomanid, and linezolid for the treatment of multi-drug resistant tuberculosis (MDR-TB) (Rapid communication: key changes to the treatment of drug-resistant tuberculosis).

Bedaquiline is approved for use within the HSC under the Managed Entry process, however the combination of medicines recommended by the WHO is not. As WHO is not recognised as a UK HTA body within the HSC Managed Entry process, SPPG is unable to commission their use. There are several antimicrobial agents recommended for use on the HSC Managed Entry website that have been superseded in NICE clinical guidance and again this creates issues for Trusts. For example, the Managed Entry decision for Ceftazidime + avibactam (Zavicefta®) dates back to 2018 and states that the product is not accepted for use in NI, in line with the SMC decision from that time. However in 2022 NICE published a Health Technology Evaluation HTE1 (Overview | Ceftazidime with avibactam for treating severe drug-resistant gram-negative bacterial infections | Guidance | NICE) which contradicts the ME website entry in that the HTE states that 'ceftazidime–avibactam is recommended, within its marketing authorisation, as an option for treating severe drug-resistant infections caused by gram-negative bacteria. This includes, but is not limited to, infections caused by OXA-48 carbapenemase-producing enterobacterales. Clinicians should follow advice from specialists in microbiology or infectious

disease and offer ceftazidime–avibactam only if there are no suitable alternative treatment options'.

5.2.8 Early Access to Medicines Scheme

The Early Access to Medicines Scheme (EAMS) aims to give people with life threatening or seriously debilitating conditions early access to new medicines that do not yet have a marketing authorisation but where there is a clear unmet medical need. By promoting early engagement between companies, and key partners including the Medicines and Healthcare products Regulatory Agency (MHRA), NICE and NHS England, EAMS also helps to create a smoother route to market for new treatments and allows important drugs to be used in clinical practice during the later stages of the regulatory process.

If medicines have a positive scientific opinion, they could be made available to patients around 12 to 18 months before formal marketing authorisation. During the period when a medicine is an EAMS product it will be provided to the HSC free of charge by the company, and consequently EAMS medicines should only be used by the HSC in line with the information provided by the MHRA in its scientific opinion. When a marketing authorisation is granted, existing patients will continue to receive supplies of medicine free of charge until a NICE TA of HSTA is completed. However, the HSC will be charged for any new patients commenced on the medicine and given the specialist nature of these medicines, funding is identified via the HSC Managed Entry process. If no marketing authorisation is granted, the company is required to agree a clear exit strategy with relevant bodies.

The review found that the EAMS process was well understood and the only challenge stakeholders reported was in relation to infrastructure pressures in certain circumstances, as outlined in more detail in section 5.2.10.

5.2.9 Zero and nominal cost medicine schemes

In addition to the early access to medicines schemes (EAMS) as set out in section 5.2.8, there are an increasing number of zero or nominal cost medicine schemes being offered by the pharmaceutical industry within the UK, for both unlicensed and licensed medicines. The schemes to date have included medicines used in clinical specialties such as cystic fibrosis, epilepsy, haematology, inflammatory bowel disease, oncology, dermatology and rheumatoid arthritis.

As there is no regional approach to such schemes, HSC Trusts manage this issue in different ways. Two HSC Trusts have developed and implemented formal policies to ensure appropriate clinical and financial governance frameworks for the acceptance or rejection of zero cost medicine schemes, whilst another has taken the decision not to accept any such offers from the pharmaceutical industry due to concerns about their effect on the commissioning pathway and potential for future financial risk. The other two assess each offer individually, dependant on the resources required for implementation. As a result, there is potential for inequality of access to these medicines for patients.

5.2.10 Service infrastructure to support medicines access delivery

SPPG are required to oversee the implementation of NICE TAs and other new endorsed guidance and this means that they will take all reasonable actions to ensure the availability of treatment within three months of endorsement. Therefore, they are always ready to engage with the service on what can be done when circumstances are challenging.

Funding to support additional staffing resource can be requested and will be supported by SPPG if the HSC Trust demonstrates the requirement for an interim level of support pending agreement or establishment of the full infrastructure. For example, SPPG offered additional in year funding to support the use of sapropterin in advance of the consolidated service model but unfortunately the HSC Trust were unable to deliver the capacity on this basis due to other factors.

Stakeholders involved in commissioning expressed frustration at when they provided infrastructure funding, such as in the example above, some HSC providers were not able to recruit the necessary staff within the timeframe available and on occasion had to return the funds to SPPG. However, often Trusts are not able to recruit the necessary staff within the timeframe available or to temporary posts, as necessitated by the 'in-year' type of funding.

An additional challenge here is that communication between commissioner and clinician in this respect does not appear to be consistently effective, as set out in section 5.3.

In oncology and haematology service impact assessments (SIA) are currently part of the NICaN agreed commissioning process for managed entry decisions. Although the SIA process lags behind the introduction of the medicine, it provides the necessary infrastructure resources to safely deliver those medicines. However, during the review HSC Trust stakeholders reported that the SIA template, that they developed previously, now needs to be updated. Their current method of assessment focusses on the clinical team time required (medical, nursing and pharmacy), however many new specialist treatments in oncology/haematology require additional resources from other areas/specialties, i.e. cardiology assessments, overnight observation stays, genetic testing, complex supportive therapies, etc.

SPPG stakeholder also expressed dissatisfaction with this HSC Trust developed mechanism to inform infrastructure costs. While some principles of the approach are recognised, i.e. multiple small additional infrastructure 'slices' adding up to create staffing pressures, the methodology produces very large investment proposals, which do not compare well with similar delivery models in non-cancer areas in SPPGs experience. Also, the tracking of cancer medicines and associated activity information is not currently possible at the moment and this seems to create a further difficulty in understanding and agreeing infrastructure needs. Stakeholders reported that the Encompass project should address this problem going forward. SPPG stakeholders reported that they are open to any revised approach to supporting infrastructure as the current process is a cause of friction.

Apart from in oncology/haematology, SIA templates are not used as part of the Trusts' response to the managed entry commissioning process and this was a frustration mentioned often by Trust pharmacy teams during the review, as they feel they are consistently being asked to take on more work without additional staffing resource to support it.

An example given by a pharmacy stakeholder to illustrate this frustration was the use of fampridine in multiple sclerosis (MS). In June 2022 NICE rejected fampridine as they did not consider it a cost-effective treatment at the price offered by the manufacturer. Then in May 2023, based on a SMC decision (SM2253) it was approved on the managed entry website with the proviso of '*Where infrastructure is in place and the Service has capacity, interim commissioning of this drug is accepted on a cost-per-case basis*'. The Trusts' pharmacies did not have the necessary service capacity but came under huge pressure from patients, clinicians and interest groups to provide the product. A very significant number of MS patients were eligible for a treatment which was an additional medicine, rather than a replacement for an existing product already being managed and supplied by the Trust pharmacies.

HSC Trust stakeholders also reported that challenges with implementation of managed entry decisions in the primary care sector also adds to their infrastructure pressures, for example the decisions taken around the introduction of Inclisiran®. In October 2021 NICE supported the use of Inclisiran® in a primary care delivered model (TA 733). However, the NI primary care sector was not in a position to deliver this, therefore in September 2022 it was added to the ME website in accordance with the August 2021 SMC guidance (SMC2358), where it is listed as 'specialist use' only. As a result, the Trusts had to take on what was a primary care service in some other parts of the UK, with Trust pharmacies having to procure, store and dispense the medicine supplies directly to those patients. Patients were also potentially inconvenienced, as they had to collect their medicines from a hospital, rather than being able to collect from their usual community pharmacy. This example also serves to illustrate the lack or primary care input into the medicines access process, mentioned elsewhere in this report.

As illustrated in both examples above, the commissioning of new medicines can put particular pressure on Trust pharmacy services. When a new medicine is being introduced often medical and nursing can set up a series of short life clinics for example, funded by overtime payments, to see potential patients and moving onto the new specialist therapy. The patients are then reviewed as normal via the existing outpatient clinic process. However, this approach creates a continuous 'tail' of work for the hospital pharmacy team which cannot be covered by the same overtime method, i.e. monthly activities such as procurement, storage, cold chain maintenance, pre-dispensing clinical checks, dispensing, delivery or homecare governance, etc.

The pharmacy work force appears to be insufficient to allow any element of 'flex' when a new medicine is being introduced and this view was supported by SPPG stakeholders interviewed during the review. The Trust Pharmacy Infrastructure Project (TPIP) work, carried out previously by SPPG, evidenced that the pharmacy infrastructure in Trusts is set too low and as a result it cannot flex in the way that other staffing groups can, when asked to respond to a new request. Unfortunately the TPIP work has since been stood down.

5.3 Themes common to all stakeholder groups

During the stakeholders meetings participants were asked about their frustrations with the current medicines access processes and a number of strong themes emerged from their feedback. It was striking that the themes were common amongst the different stakeholder groups regardless of their role in the current processes.

Although these points could be read as criticisms of the teams involved, they are definitely not. The stakeholders interviewed were clear that they knew these issues had emerged as a result of the resources available not keeping pace with the ever increasing workload and that everyone was doing their utmost to ensure patients received treatment.

The themes were:

- **Communication**

  Communication issues were reported by every stakeholder and used to illustrate the consequences of resources not keeping pace with an increasing workload, particularly in relation to the large number of NICE TAs being published compared to a decade ago. Examples provided included clinicians continuously checking the Managed Entry (ME) website, as they had been 'caught out' previously when an update was made to an entry and they first heard about it from a pharmaceutical company representative. Some teams reported keeping screenshots from the website on file as there is no facility to view an entry's history i.e. dates of updates, superseded decisions, what changed when, etc. They reported needing this information to answer questions about implementation, why patients were on certain treatment plans, complete audits and tracking expenditure. Some Trust staff reported that they were not aware that Service Notifications (SNs) were still being issued. They had stopped looking for them as they often came a long time after NICE final publication / ME website entry and they had started using the medicine as soon as the NICE FDG was published, despite the Service Notification being their source of information about additional support available to support the implementation of the TA, such as infrastructure funding.

  Another example of communication issues came from SPPG stakeholders and related to difficulties in information exchange between themselves and HSC Trust clinicians in relation to medicines access challenges. To illustrate this the review was told about a situation where difficulties arose in arranging a particular genetic test to determine eligibility for a new TA. A lot of concern was generated internally in the HSC Trust concerned before the matter reached SPPG colleagues, via a cancer steering group meeting. It had not been raised with SPPG by the Trust's management team, which would have been the fastest route to resolving the issue for the patients concerned.

  The stakeholders reported that there is a need for such queries to be raised with SPPG via HSC Trust management teams as soon as possible to allow for early resolution, rather than assuming the worst and generating unnecessary anxiety for staff and potentially patients, if the concern is shared with them.

Stakeholders from the Regional Pharmacy Procurement Service (RPhPS) also reported an example of communication breakdown between themselves and SPPG in relation to patients referred to provider in another UK nation for specialist tertiary treatment with a NICE TA medicine. Such tertiary providers may invoice SPPG directly rather than involving the NI HSC Trust and in this situation there does not appear to be a regional process for agreeing a commercial access agreement for the medicine. As a result an unnecessarily high price may be charged by the provider. Strong communication channels between the two groups would ensure the patient access scheme price was applied correctly from the start of the process, saving money and time.

ABPI representatives reported that their members felt unable to contribute information on newly released products, in line with their code of conduct, as their only route was an anonymous email address that did not or rarely acknowledged their input, again due to resourcing challenges. If they tried any other method of communication they are referred to the email address. They felt there was no opportunity to discuss or assist with the forecasting and preparation process for a new medicine nearing launch, as they know happens elsewhere in the UK.

- **The use of Cost per Case in commissioning**

The cost-per-case (CPC) commissioning method was a significant issue for every stakeholder interviewed during the review. It does not seem to be delivering for any group apart from the important exception, patients. For patients the use of CPC has allowed early use of certain medicines and on publication of NICE FDGs, which should not be forgotten or lost.

For SPPG teams, the CPC forms provide a level of assurance regarding clinical and financial governance in the ME process, using then to estimate the potential cost of a ME decisions. However, there is acceptance that this is a very inaccurate tool, as the CPC forms give no information about the amount of that treatment the patient went on to receive or even whether it was started at all. A patient may not receive any treatment or may stop prematurely without SPPG knowing that information.

ABPI representatives see the prolonged use of CPC as an interim commissioning tool as challenging and at odds with the rest of the UK, where defined timelines exist for routine commissioning of newly approved medicines. They understand why and when it is was used in the past as an interim commissioning tool, but not when it remains for some medicines on the ME website entry for multiple years.

Meanwhile HSC Trusts are unhappy with CPC for a number of reasons:

- prolonged use for some medicines rather than agreeing recurrent funding in HSC Trust budgets.
- It does not allow for infrastructure/resource discussions (see section 5.2.10)
- HSC Trust Consultants were particularly frustrated with being asked to complete forms for treatments for prolonged periods of time, particularly once a final NICE TA was published and some admitted that they stopped or refused to complete them once a medicine had been accepted into practice.
- Seen as an unnecessary administration task by clinical teams.

- **Lack of accurate data**

  A common theme that emerged during the review discussions was the lack of accurate and timely data on the various medicines access routes. Using previous software systems in place, HSC Trusts are/were unable to easily provide reports that link patient, medicine, diagnosis and expenditure. As a result, many have developed their own 'work-arounds' involving manually kept spreadsheets, so that they can track patient related spend, answer questions from their own finance teams and/or SPPG. DoH stakeholders report not receiving concrete data led assurance of NICE TA implementation whilst SPPG have to rely on complete CPC forms to estimate likely spend, despite the forms having no link to the patients' actual use of the medicine concerned.

- **Postcode prescribing risks**

  For medicines which are not routinely commissioned, stakeholders reported numerous concerns about the risks of postcode prescribing, hence inequity of provision within NI and potentially the rest of the UK. Postcode prescribing arises from the decisions of commissioners or HSC Trusts on whether they can afford to supply a specific non-commissioned medicine for a particular condition or patient. Access to a medicine can thus depend on where you live.

  As outlined in previous sections, situations that lead to this risk include:

  - Free stock offered in advance of a NICE TA decision
  - Products that NICE have decided not to review
  - Requests to use a medicine outside NICE recommendations for defined clinical criteria, to follow emerging recognised best practice
  - Requests for paediatric use of a licensed specialist medicine
  - Requests for an off-label use of a licensed medicine in accordance with emerging best practice across the UK
  - A request for an antimicrobial agent not reviewed by NICE
  - Treatment of small cohorts of patient where the is no NICE or SMC guidance.

5.4 Patient and Public Involvement

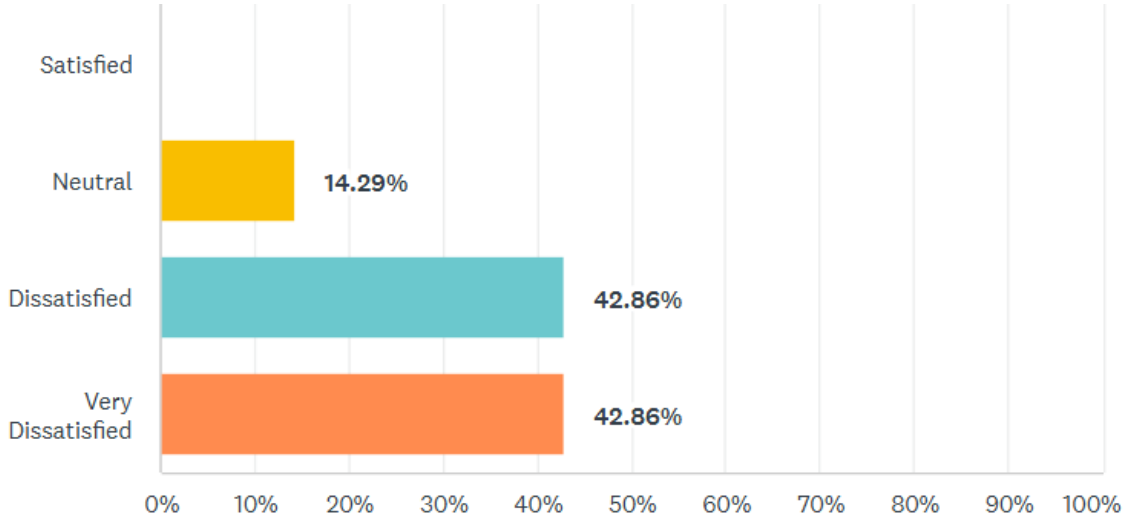
As part of the review colleagues attended two NIRDP engagement events where it was reiterated that, in January 2021, the UK Rare Diseases Framework was jointly published by all four UK Health Ministers, with the priorities listed as helping patients get a final diagnosis faster, increasing awareness of RD among HC professionals, better coordination of care and improving access to specialist care, treatments and medicines.

In addition to attendance at the engagement events, an on-line survey was developed and then shared via the NIRDP social media accounts, with the aim of gathering the views and experiences of patients and carers about the medicines access processes in NI. Unfortunately, only seven people responded to the survey during the time available, however the insight

they gave to their experiences was excellent and consistent with the views of many other stakeholders who contributed to the review. Of those who responded 15 per cent were patients, 57 per cent carers, 14 per cent were both patient and carer and 14 per cent preferred not to say.

When asked 'How would you rate the process that makes medicines available in NI', 43 percent of respondents selected 'very poor', 14 per cent 'poor', 29 per cent 'average' and 14 per cent selected 'good'. In response to the question 'How satisfied are you with the ease of obtaining information about the availability of medicines for rare diseases in NI' the respondents indicated overall dissatisfaction, as shown in figure 3.

Figure 3: Satisfaction with ease of obtaining information re availability of medicines for rare diseases in NI



Similarly, when asked to rate their satisfaction with the overall availability of medicines for rare diseases in NI, 42 percent selected 'very dissatisfied', 14 per cent 'dissatisfied' and 14 per cent selected a 'neutral' level of satisfaction.

When asked about specific problems encountered, comments included:

- Problems with consultants not seeming to understand how to access a medicine for the patient's particular condition.
- Having to enlist the help of relevant charities to secure access to an orphan drug on compassionate use as clinician was not aware of the process, as above.
- Views that the whole system is not working well and needs a complete overhaul.
- Issues around having to lobby for a year for a medicine to be made available in NI.
- That cost is taking precedence over access in lifesaving medication decisions.
- Views that there is inequity in comparison to other regions of the UK, using that there are pathways available to provide medicines in Scotland that are not available in NI.

Whilst in the 'what works well' section of the survey, comments included:

- Once the medicine is available, the system works well
- Having a dedicated nursing team is an advantage

Suggestions for areas of improvement to the process included:

- Improved understanding/involvement of primary care so that patients are given consistent information about access and availability of their medicines, particularly for children
- Faster access to these medicines
- Transparency of the process involved
- International alignment of the process
- Clear information
- Benchmarking with other UK countries
- Regular reports/information about medicine availability
- Improved compassionate use of medicines
- Support for the LifeArc centres and registry.

6 Recommendations

Following the detailed end-to-end review of the medicines access systems, the following recommendations have been developed.

6.1 Medicines Access policy coverage

As set out in sections 5.2.4 to 5.2.7, there are several situations where there is a lack of provision in current NI medicines access policy, including paediatric license extensions, antimicrobials recommended by WHO, and where small cohorts may benefit from medicines that are off label but are recommended in best practice guidance. This is leading to difficulties and delays in the provision of service, alongside the potential for unnecessary expenditure and inequity of provision across NI and the rest of the UK. In January 2024 the SPPG managed entry team rightly recognised that our differing approach to commissioning such treatments could present the potential for challenge in terms of equality and human rights legislation.

This issue could either be addressed by extending policy coverage or perhaps, as has happened elsewhere in the UK, by the use of position statements for NI. For example, in 2022 the All Wales Medicines Strategy Group (AWMSG) decided to suspend the appraisal of new antimicrobials. Instead they issued a position statement recognising the importance of antimicrobial stewardship and, that for individual patients, the prescribing of antimicrobials not previously appraised or recommended (by AWMSG or NICE) should be done in consultation with a microbiologist, based on the best available evidence. In additional their position statement made it clear in emergency clinical circumstances, following microbiologist advice, access to an antimicrobial should not be denied or delayed. Likewise, the AWMSG has issued a position statement for paediatric minor licence extensions where treatment has already been made available for the adult population, with the aim of improving access to medicines for children, ensuring they can be made available as soon as is practically possible and in alignment with NHS England and NHS Scotland.

Recommendation 1: Address inequitable access for NI patients by provision of policy direction for identified areas including paediatric medicines, antimicrobials and small cohorts.

6.2 Use data to provide clinical and financial governance in commissioning

As set out in section 5.3, the review found that there is a distinct lack of robust data throughout NI medicines access processes. SPPG, for example, use completed cost-per-case (CPC) forms to assist with prediction of potential in-year expenditure for various specialist medicines, however there is no link between the CPC forms and the Trusts' actual expenditure for each patient. If a patient were to pass away before commencing treatment, as can happen, that prediction would be totally inaccurate. There is also a lack of metrics about timeliness of access to medicines that would facilitate benchmarking against policy targets and other UK countries.

At the same time, the Trusts' JAC pharmacy system, the main source of medicines use data prior to the Encompass programme roll out, could not produce a report that links patient demographic to medication, diagnosis and expenditure, as part of that data was held on predominantly 'paper based' prescribing and patient notes systems.

Going forward the medicines access processes need to be based on robust data, that provides assurance to policy makers as well as clinical and financial governance for both commissioners and providers alike.

As a potential solution to this concern, the review considered the pros and cons of introducing specialist medicines software into the medicines access process, particularly as several stakeholders (SPPG, DoH, Trusts & RPPS) reported having considered such software systems previously and with a particular focus on the Blueteq High Cost Drugs (HCD) system already in use in England and Wales. The review investigated the potential positives and negatives of such systems by discussions with system users in England and Wales, in addition to a demonstration of the Blueteq HCD systems provided by its company representatives.

The benefits of specialist medicines software system appear to include:

- Offers a standardised process with opportunity to record multiple datasets (such as baseline demographics, clinical outcomes, patient characteristics) whilst reducing variance.
- Web based portal allows multiple users access and there is software to install and maintain locally.
- Multifactorial authentication for users can be enabled for enhanced security
- Has functionality for SMS and/or emails to flag request actions needed
- Letter templates are available and can be dynamically populated for the patient and/or their GP, which can be auto sent, following medication approval for example.
- User-friendly tick box forms, which provide instant approval for clinicians and should take less time than completion of a CPC form.
- The system checks the completed forms for the requesting clinician during completion, thus reducing both the pharmacy and nursing input at that point.
- System users have access to their own relevant data within the system, which offers support for clinical audits and planning.
- Reports can be created easily and run quickly to assist with financial reporting and clinical governance of prescribing.
- The software can provide a full range of reports to clinical services to help with service development and workforce planning.
- Medicines forms created elsewhere in UK can be imported and adopt for use in NI, saving implementation time.
- Improves governance by evidencing compliance with commissioned NICE and other guidance.
- Systems can be set to require 'reviews' to be logged at agreed time internals for treatment to continue, if required.
- The clinical data available can help inform on service requirements in forecasting, planning and implementation activity for new medicines approved by NICE and would assist RPhPS team with CDF and other rebates.

The potential negatives reported by users and stakeholders included:

- One UK based team warned that use of a specialist medicines software system had slowed specialist drug approvals in their region, sometimes by several weeks, as the auto approve function had not been enabled. As a result, the commissioning team running the system had to review and approve each request individually, leading to decision backlogs and delays in patient treatment commencing. It would be important to learn from this and potentially only disable the auto approval function in pre-agreed situations, for extreme high-cost medicines requiring additional approvals before commencing treatment.
- If such software was implemented in NI the current processes around earlier access following NICE FDG in NI may be affected.
- The systems need resourced properly to manage administration tasks in a timely way and to create reports.

Alongside the possibilities of such software, the Encompass project roll out phase culminated on the 7th May 2025, when the remaining two Trusts went live on the Epic system, thus creating a single digital care record for every citizen in Northern Ireland for the first time. Therefore, in the future HSC Trusts will be able to use the system to produce reports that link patient, medicine, diagnosis and expenditure, however an interim solution will potentially be required, to allow full optimisation of the reporting functionality in Epic.

Although some of the advantages listed for the specialist medicines software may, in time, be available through the reporting functions of Epic, both Epic and a specialist medicines software system could be used together to address the lack of data in the medicines access process going forward, for example:

- Instead of using CPC forms, SPPG could ask HSC Trust clinical teams to complete a regular monitoring return for NICE TAs. The report template could be provided as part of the initial commissioning documentation (see section 6.3). This could then move to a standard regional Epic report in the future, as that system allows. This reporting template would be a similar approach to data collection already in use for biologics

medicines monitoring in rheumatology, gastroenterology and dermatology. Initially the returns could be monthly, to give assurance of implementation, then moving to quarterly and even annually as required. In future this could be developed further to include ideas such as 'medicine group' monitoring returns for those regimes which are well established, rather than requiring a return for each individual medicine involved.

- At the same time SPPG could use the chosen specialist medicines software to produce a report of patients approved for the medicine/indication for the same time period as the Epic report.
- As set out in figure 4, both reports could be exported into a program such as MS Excel and, using the common data set of patients' H&CNs, merged to create a single report. That report would identify patients being treated without specialist medicines approval, which could be followed up directly with the relevant HSC Trust clinical team.

As part of the review the pharmacist working for Epic was contacted, in relation to the future reporting capability of the system, however unfortunately it was not possible to obtain that information within the timeframe available for the project. At some point in the future, as Epic's functionality develops and embeds, it may be possible to phase out the specialist medicines software.

The introduction of such software would not be a quick process, with the current estimate software company lead in times running at approximately 12 months and it would also require a working group of clinical and technology experts from DoH, SPPG and HSC Trusts. However, there is a lot of useful learning and information available from both English and Welsh implementation teams that could smooth the process for NI.

Figure 4: Suggested process for Clinical and Financial Governance Oversight

Although other specialist medicines software providers are available, there would appear to be merit in selecting the Blueteq HCD system. The Blueteq HCD system is already widely used in England and Wales and is being considered as a potential option for Scotland. Therefore, if it was also in use in NI, UK wide benchmarking would be an option in the future. Also, there would be advantages in implementation, for example for their most recent expansion of the

system, Wales was able to import approximately 200 completed Blueteq medication forms from colleagues in England, significantly reducing their workload, as well as a system for import existing patients on each medicine so they will already be in the system when they next come for review.

The Encompass programme has completed the roll out of the Epic system to the five HSC Trusts in NI, and Blueteq is currently working on integration of their HCD system with Epic in Trusts elsewhere in UK. If this was made available in NI it would significantly improve the clinical team's experience of the HCD system, with auto population of additional fields in the medicine form, reducing completion and approval times. The integration could also identify Blueteq approval on the Epic patient record. Blueteq also offer an Individual Funding Request (IFR) software add on which could be used to reduce the administration associated with the current NI IFR Scrutiny Panel process in the future.

Although this review is focussed on medicines access, Blueteq HCD software could also be employed in the management of other products that have clearly defined patient eligibility criteria in NI, for example immunoglobulins.

Recommendation 2: Strengthen clinical and financial governance of medicines access through improved use of data that would enable replacement of interim cost-per-case arrangements.

6.3 Addressing the challenges of medicines access workforce pressures and fragmentation

As set out in section 5.2.2 the various medicines access processes are being managed by people in teams from different sections of the service, which are predominantly from the secondary care and specialist commissioning sections of both DoH and SPPG. This is understandably leading to a level of fragmentation, process delays, communication issues and a reliance on single individuals with particular expertise in their piece of the system. Within

SPPG, the medicines access workload is further challenged by a significantly reduced staffing resource split across two teams, that are facing an ever increasing work load.

Northern Ireland spends circa £875m per annum on medicines for primary and secondary care sectors with an 85.6% increase in spend on commissioned high-cost medicines between 2017/18 and 2023/24. It is the second largest HSC spend after salaries, therefore it deserves a dedicated, fully resourced team to manage and monitor that expenditure.

The first step to addressing this issue would be to create a single programme, that brings together all the existing staff resource working on medicines access, across the various employing organisations. For the purposes of this report and its recommendation, that new programme will be referred to as the Regional Medicines Access Programme (RMAP). The programme members would still be employed by SPPG, DoH and RPhPS but they would have their role identified as a protected resource for RMAP work. The programme members could have weekly progress update meetings and an identified programme lead to agree their work plans, hold members to account, etc.

Their suggested remit would include activities such as:

- Making use of NI's existing and important links with NICE by becoming more involved in TA assessment process, thus allowing the RMAP to:
    - calculate the NI population impact data in advance of the NI TA's FDG stage
    - advance Equality Screening in compliance with section 75
    - have early discussion of any NI issues regarding implementation
- Use of NI's links to other recognised UK technology appraisal bodies to gather medicines access intelligence and undertake horizon scanning.
- Receiving and utilising input from the pharmaceutical industry representatives, in line with their code of conduct.
- Identification of suitable guidance available elsewhere in UK for treatments that will not be assessed by NICE or other recognised body.

- Management of the managed entry/medicines access website to include activities such as:
    - Website redevelopment to create a single information source for all things medicines access in NI, similar to the One Wales website (One Wales Medicines process - All Wales Therapeutics and Toxicology Centre)
    - Upkeep of managed entry pages, to include an archive section for each entry
    - Timely communication re new entries and updates
    - Publication of agendas and meeting reports for RMAEG meetings (see below)
- Management of any specialist medicines software system
    - Creating and managing the templates for each medicine on the software system
    - Creating standard and bespoke reports
- Data analysis - making use of the information available from implementation monitoring returns from Trusts/Primary Care and the specialist medicines software system, to allow more accurate budget forecasting, assurance re clinical uptake, etc.
- Preparation of commissioning documents in advance so they can be issued to the service at the point of NICE TA publication, including:
    - service notification letter,
    - specialist medicines software template, and
    - monitoring return template and reporting schedule.

An important part of RMAP's work would be to use and further develop the existing links NI has with other healthcare bodies in the UK. This would allow NI to make maximum use of the resources already available elsewhere, rather than using our limited resources to develop new guidance documents.

It is important going forward to have sufficient resources to allow RMAP to develop wider levels of experience so that it is not reliant on the expertise of lone people, thus creating risk in its ability to consistently deliver the medicines access programme. The RMAP resource should also include representation from the medical profession. With this in mind a workforce

analysis would also be needed, to identify what additional resource the programme would require to consistently manage and deliver its objectives. This analysis should investigate what resource could be made available from within the system at present, bearing in mind the other responsibilities held by the people involved in medicines access currently and the manageability of their current workload within the time available.

Many of the SPPG stakeholders mentioned that activities such as ministerial correspondence, media briefings, Assembly/Minister briefings, policy consultations and responding to legal challenges are becoming increasingly part of the job, therefore this aspect needs to be included in the workforce analysis to ensure sufficient capacity is included, so that medicines access processes are not affected by these asks. This analysis should include what skill set is best placed to undertake each task required. For example, the programme may function optimally with a mix of clinical, management, data analyst, information technology and administration staff. The analysis could also include the current IFR scrutiny panel arrangements, given the process is well embedded and the numbers of applications have greatly reduced.

Funding from the VPAG scheme could potentially be used to recruit to the identified RMAP resource deficits, as currently happens in Wales. This would be in keeping with one of the aims of the VPAG agreement (see section 6.10), i.e. securing rapid patient access to new clinically and cost-effective medicines through efficient, responsive and joined up approval**.** This approach will require significant collaboration and discussion with finance colleagues.

Whilst the RMAP team would be responsible for 'day to day' medicines access processes , there also needs to be an overarching group to give strategic direction in relation to medicines access and oversee the work of RMAP. For the purposes of this report this group will be referred to as the Regional Medicines Access Executive Group (RMAEG). This group could work in a very similar way to the All Wales Medicines Strategy Group (AWMSG), with one major exception; it would not assess new products for NI itself, rather RMAEG would endorse guidance created elsewhere in the UK, as identified and proposed by RMAP.

Northern Ireland does not currently have the resources to carry out its own clinical assessments in relation to guidance and/or best practice, therefore it is essential that we make best use of such work carried out elsewhere in the UK. With that in mind and similar to the Welsh model in some respects, RMEG could:

- Meet ten times per year
- Include two lay members
- Include a representation from the NI pharmaceutical industry forum (see section 7.10)
- Include a representative from NICE
- Have publicly available agendas and minutes, published on the Medicines access/entry website, and
- Include senior clinical, finance and management representatives from:
    - DoH
    - SPPG
    - Trusts
    - RPPS
    - Primary Care

The core of RMAEG's remit would be to:

- Provide strategic direction to the work of the RMAP
- Endorse implementation plans for newly approved NICE medicines such as Service Notifications and associated documents as developed by RMAP, and,
- Endorse guidance proposed by RMAP, to allow commissioning for 'small cohorts' as identified by the IFR panel and/or in response to other emerging best practice identified by specialist clinician groups.

Some stakeholders reported that on occasions delays in the issue of Service Notification (SN) documents were in part related to understandable concerns about their affordability, within the medicines budget available for NI. One purpose of NICE is to make judgments on specialist treatments, which will then be prescribable or not. The Human Rights Act 1998 supports

individuals to challenge future decisions of commissioners and/or Trusts who refuse to fund medicines based on cost. (Postcode prescribing and the Human Rights Act 1998 - PMC). Therefore, if such a decision must be made in the future, they must be supported by a very robust and transparent decision making process and this could be developed in collaboration with RMAEG, in case it is required in the future.

Although this review focusses on medicines access processes, both RMAEG and RMAP could, with further discussion with SPPG, also have responsibility for delivering efficiencies/savings, monitoring expenditure performance and providing a challenge function via the interface with the service. The Medicines Optimisation Regional Efficiency (MORE) programme function could potentially be served by these groups with strategic objectives set each year. The groups could also lead on the development of new medicines related innovations in the future.

Recommendation 3: Undertake a workforce review to inform creation of a single Regional Medicines Access Programme to coordinate medicines access workstreams across the HSC.

Recommendation 4: Establish a new overarching Medicines Access Leadership Group to provide strategic direction and system leadership to the Regional Medicines Access Programme.

6.4 Redesign medicines access work flows

When the review considered the current process for the endorsement of NICE TAs in NI, as set out in figure 2, it noted that the various steps happen in series, with one team completing its task, before formally passing the information on to the next team to commence their allotted task. This is a very time consuming way of managing such an activity, particularly when each step does not significantly change, if at all, the guidance being considered. It also does not allow for teams or individuals to work closely together and discuss pertinent issues that arise in a timely way. The time taken to process a new NICE TA could be reduced if the tasks were completed in parallel, rather than in a series.

An example of how the workflow could be managed going forward is set out below in figure 5. Figure 5 also illustrates how a new approach to the NI health technology assessment endorsement process could be used to pull the various strands of medicines access in NI into one easily understandable and transparent system which also includes patient/carer and pharmaceutical industry input.

The proposed workflow would centre around the work of RMAP and RMAEG, as suggested in section 6.3, supported by the IFR Scrutiny Panel, existing clinical specialist interest groups, Interface Pharmacists Group for Specialist Medicines, etc. Whilst the proposed workflow is the ideal option, issues of affordability would need to be taken into consideration when developing it and a phased approach may be potentially required.

As mentioned in section 5.2.1 several stakeholders questioned why NI endorse NICE TAs in this way, given that other UK countries approach them differently. The review does think this question warrants further exploration between DoH and SPPG teams, while acknowledging current equality screening requirements. The possibility of changing the equality screening process completed by DoH should also be needs to be considered as part of this work.

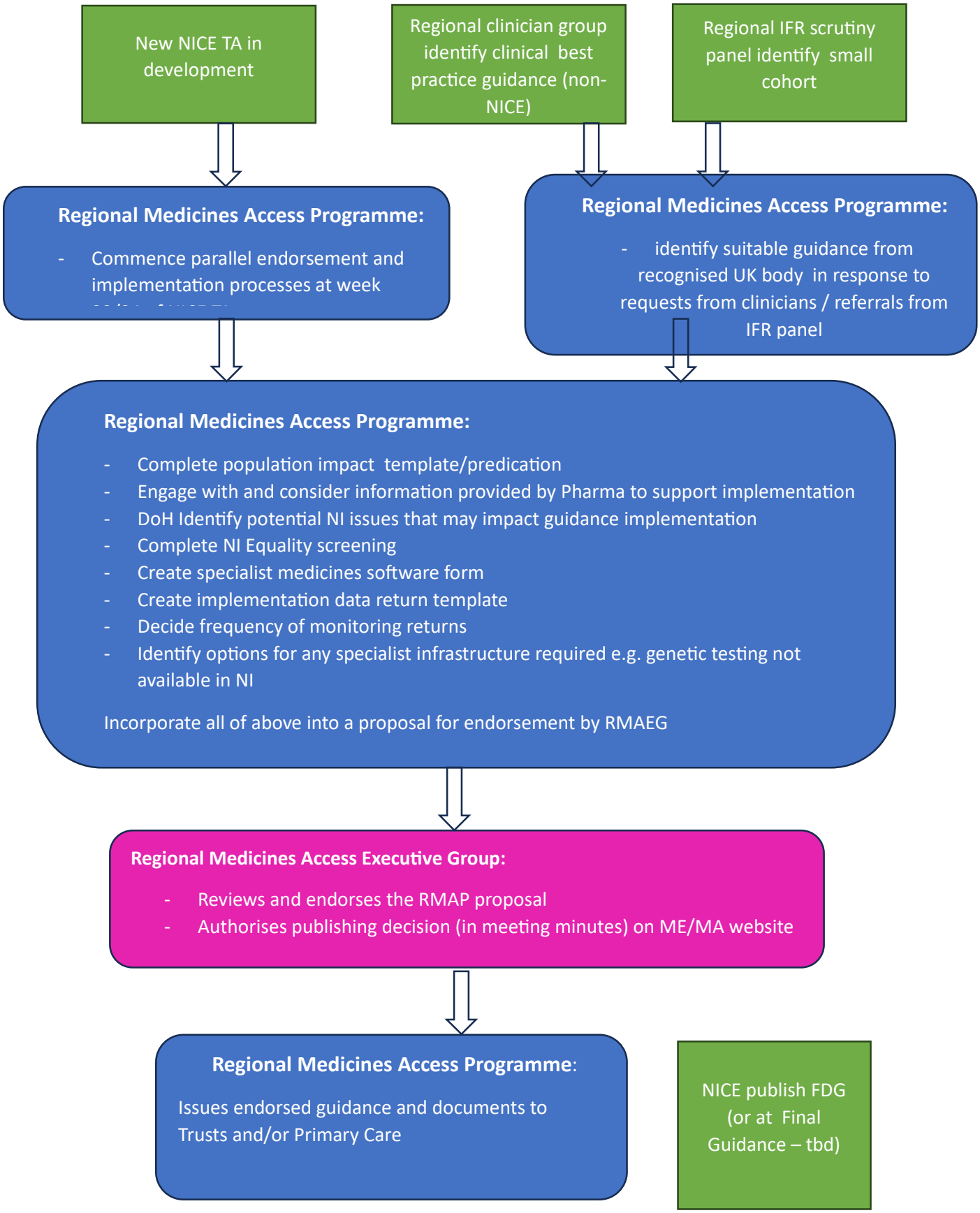
Equality screening, a process to assess the impact of policies on equality and good relations, differs in England and Northern Ireland due to distinct legislative frameworks. In England, the Public Sector Equality Duty (as defined in the Equality Act 2010) guides public bodies to consider equality in policy making, hence is used by NICE. In NI, Section 75 of the Northern Ireland Act 1998, according to the Equality Commission for Northern Ireland, focuses on both equality of opportunity and good relations, often with a more detailed screening and impact assessment for policies deemed highly relevant to equality. Given medicines are not something that can discriminate between communities in NI, consideration should be given to developing a new fast track approach to NICE TA equality screening in discussion with the Equality Commission for Northern Ireland, thus reducing the time and resource required for this step.

Although some stakeholders questioned whether there was any merit in SPPG continuing to issue SNs, the review considers that this process still has merit, as the SN sets out the infrastructure support available to the HSC to support commissioning of the medicine and the uptake monitoring/reporting methods to be used. However the review considers that timelines for issue of SN documentation need to be reviewed and if possible brought forward so that they better align with the medicine being made available to prescribe in NI, as set out in figure 5.

Recommendation 5: Develop new communication arrangements and HSC medicines access roadmap, with PPI embedded in all processes to improve transparency for patients, clinicians and industry.

Recommendation 6: Optimise alignment between Departmental NICE endorsement and HSC Managed Entry processes to minimise timelines to routine commissioning of new medicines.

Figure 5: Proposed new Managed Entry/Access process



6.5 Communication and transparency

Although there is nothing 'hidden' in the current NI medicines access and entry processes, stakeholders reported issues with consistency of communication, which appear to be leading to concerns around transparency surrounding how the various parts of the systems make their decisions about medicine availability for the HSC.

As set out in section 6.3, in Wales this has been addressed by their One Wales website , which acts as a single information source for all things medicines access, for both clinicians and public alike. The current HSC Managed Entry website could be redeveloped and relaunched to provide the same level of transparency and communication. This could include archive sections for each Managed Entry decision page and publication of RMAEG agendas and meeting reports.

In addition, there could be regular communication bulletins for the service providers, outlining any additions or changes made to the website.

The issue regarding poor communication between clinicians and commissioners mentioned in section 6.3 also needs to be addressed. The RMAEG meetings could be used to provide an interface directly between commissioners and clinicians. When a new medicine is being considered for endorsement in NI, a leading clinician in the area could represent their colleagues at the relevant meetings of RMAEG if required.

Recommendation 5: Develop new communication arrangements and HSC medicines access roadmap, with PPI embedded in all processes to improve transparency for patients, clinicians and industry.

6.6 Patient and public involvement

As set out in section 5.4, the PPI engagement activities undertaken during the review showed that issues of delays in the medicines access processes, clinician knowledge of how to access specialist medicines, communication and transparency regarding the process used/decisions made were all frustrations for patients and their carers.

These issues should be addressed by the recommendations made in this review, however it is important to check that patients and public are fully engaged with changes to medicines access processes going forward, particularly given the small number of respondents to the online survey.

Recommendation 5: Develop new communication arrangements and HSC medicines access roadmap, with PPI embedded in all processes to improve transparency for patients, clinicians and industry.

6.7 Service infrastructure and impact assessments

The review found several underlying issues related to service infrastructure.

Communication difficulties around infrastructure seems to cause friction between HSC Trusts and commissioners, which in some instances may be leading to delays and unnecessary concern in patients and staff groups. Suggestions to address this issue are set out in section 6.5.

The service impact assessment template, developed by HSC Trusts a number of years ago, does not cover all the inputs that may be required to deliver many new and complex medicines, such as those becoming available for oncology/haematology indications. SPPG also have some concerns around the template currently in use. Therefore, during the review both commissioners and providers have expressed dissatisfaction and frustration in respect of the

methodology used to inform infrastructure requirements associated with new specialist cancer medicines.

Stakeholders identified that existing levels of HSC Trust pharmacy infrastructure is insufficient to readily meet additional requirements that can be associated with rollout of new medicines. Where funding is identified to meet pharmacy infrastructure requirements, there can be difficulties in recruiting staff in a timely way for reasons including the perceived unattractiveness of temporary posts created from in year funding, and the lack of trained pharmacy technicians within the wider HSC pharmacy workforce.

Previously SPPG established the Trust Pharmacy Infrastructure Project (TPIP), to assess HSC Trust secondary care pharmacy infrastructure requirements for adults and children across the region. Its aim was to inform the phased commissioning of equitable, effective and efficient services provision consistent with extant policy and recognised quality, safety and efficiency standards. While TPIP was stood down in early 2025 the initial findings clearly demonstrated that many areas of HSC Trust pharmacy services, including aseptics, were already under significant pressure.

In early 2024 one of the areas being considered by TPIP was the investment associated with the implementation of NICE Technical Appraisals and the view that the funding provided in this area should be aimed at retrospectively addressing what the service has already been delivering against the existing TAs. The capacity plans viewed at that time showed that the service was overdelivering and functioning between 130 and 140 per cent of its capacity.

Pharmacy technicians are an excellent resource in healthcare and have great potential to enhance the skill mix of pharmacy teams in all settings, however if a HSC Trust receives infrastructure funding for such roles, it will often be at least two years before the posts are filled with qualified people due to the time taken to train pharmacy technician students. At present HSC Trusts undertake a significant proportion of pharmacy technician training in NI,

recruiting students into vacant technician posts, training and guiding them through the two-year programme, including day release to the further education colleges to complete the necessary qualifications. Ideally technicians in NI should be training in a similar fashion to pharmacists, i.e. through a course offered and run completely by the further education colleges, independent of the Trusts. As happens with undergraduate pharmacists, the courses would be supported by day release into Trusts and community pharmacies, supernumerary, for the practical aspects of their training. This would create a pool of trained technicians and also promote their role as an excellent STEM career opportunity for those not interested in progressing to university after leaving school. The review welcomes the ongoing work to progress the registration and regulation of pharmacy technicians in Northern Ireland, including detailed consideration of the education and training requirements for pharmacy technicians.

Recommendation 7: *Develop new service infrastructure impact assessment processes that identify all requirements for introduction of new medicines including medical, nursing and pharmacy support.*

6.8 Engage with the Pharmaceutical Industry

As mentioned in the findings section, pharmaceutical industry stakeholders reported concerns about effective communication and also that they felt unable to contribute meaningfully to the medicines access processes in NI, in line with their code of conduct. When asked if there were any examples of good practice elsewhere in the UK they identified the AWTTC Industry Forum.

The AWTTC Industry Forum provides a forum for representatives from the pharmaceutical industry [Association of British Pharmaceutical Industry (ABPI), and the Ethical Medicines Industry Group (EMIG)] to meet with staff from the All-Wales Therapeutics and Toxicology Centre (AWTTC) to discuss issues relating to medicines access in Wales. The All-Wales

Medicines Procurement Specialist Pharmacist also attends meetings, which are held regularly on a bimonthly basis. The group was established to facilitate a two-way communication channel between industry and AWTTC to inform process or methodology improvements in Wales and to share experiences of industry engagement with other Health Technology Assessment (HTA) organisations.

Topics at the meetings include:

- Decision making methodology including review of submission forms and pharmaceutical industry information and future developments
- Communication channels with industry
- Communication with the NHS, patients and the broader public arena
- Information and methodology relating to medicines access
- Implementation of medicines approved by NICE and AWMSG
- Development of best practice prescribing guidance
- Development of prescribing audits and supporting information to prescribers

Recommendation 8: Strengthen partnership arrangements between the HSC and pharmaceutical industry through establishing a new HSC Industry forum, adopting best practice from GB.

6.9 Zero and nominal cost medicines

As set out in section 5.2.9 there is no regional approach to such schemes, the NI Trusts manage this issue in different ways. As a result, there is potential for inequality of access to these medicines for patients in NI. This has been addressed in other jurisdictions by the use of regional guidance; for example Wales has All Wales guidance for free of charge medicine supply which could easily be adapted, with permission, for use in NI.

Recommendation 9: Provide regional guidance on the management of zero and nominal cost medicines schemes to promote a consistent approach across the HSC.

6.10 Voluntary Scheme for Branded Medicines Pricing and Access (VPAG) funding

The VPAG scheme is formally negotiated on behalf of all nations of the UK between the Department of Health and Social Care (DHSC) and the Association of the British Pharmaceutical Industry (ABPI). The current agreed iteration of the scheme runs until December 2028 and includes an undertaking that all parties involved will use their best endeavours to ensure that the 2024 Voluntary Scheme is fully implemented and sustained throughout the NHS for its duration.

The scheme aims to promote better patient outcomes and a healthier population, by:

- Securing rapid patient access to new clinically and cost-effective medicines through efficient, responsive and joined up approval, commercial and funding arrangements, with appropriate rewards for innovation;
- Tackling unwarranted variation in the adoption of new medicines; and
- Encouraging development of innovative and cost-effective medicines of the future.

In addition, and for the first time in the history of the scheme, the 2024 VPAG includes a new industry-funded investment programme to channel around £400 million of investment into the UK's health and life sciences sector. As a result the HSC R&D Division in Northern Ireland have received funding of £12.6 million to be spent during the term of the agreement, to establish a Commercial Research Delivery Centre (NI CRDC) and bolster existing clinical research delivery infrastructure. The review learnt that other UK regions are also using a portion of their VPAG funding to provide staffing resources, to support various aspects of the medicines access process in their region.

To better understand the use of the Northern Ireland share of the VPAG rebate and how it satisfies the agreement with ABPI, the review tried to ascertain the exact value and how it is

currently used. Unfortunately, within the time available for the review project, it was not possible to get an exact value or ascertain detailed explanation of how it is being utilised in the health budget. At a very basic level, the review understands that the annual VPAG rebate goes into the general HSC funding 'pot', rather than being offset directly against the totality of the medicines spend and it is not currently being used in accordance with the spirit of the VPAG agreement to fund initiatives such as tackling unwarranted variation in the adoption of new medicines in the current NI access processes.

Although the VPAG funding is non-recurrent, the other UK regions appear to have taken a pragmatic approach and used it to fund new posts, in the expectation that there will be another agreement made after current VPAG finishes in 2028, so they are confident funding will be available going forward. In Wales for example a proportion of their rebate is ringfenced for projects and recruitment of new team members, with the aim of improving their medicines access processes.

In keeping with the aims of the scheme, in NI a proportion of VPAG funding should be used to support implementation of the recommendations set out in section 6.3, i.e.:

- Increase staff resource in the RMAP so that it does not depend on single handed expertise
- provide RMAP with sufficient capacity to consistently exploit the potential of the important NI agreement with NICE, thus allowing preparation for commissioning to begin well in advance of each TA FDG stage.
- Redevelopment of the medicines access/managed entry website.
- Fund staffing required to implement and manage the medicines access software system.
- Fund a data analysis resource for RMAP.

Recommendation 10 : Consider adopting regional policy for how VPAG rebate income can best be utilised to support continued access to medicines and ongoing quality improvement.

7 Conclusion

Medicines are the most common medical intervention within Health and Social Care, with an annual expenditure of circa £875m per annum. Given that this is the second largest HSC spend after salaries, it is worthy of a concerted focus to ensure equality and efficiency in the various medicines access processes.

This review set out to examine existing arrangements for access to new medicines in Northern Ireland, capture the HSC stakeholders and patients' views, both positive and negative, identify the key issues and examples of best practice from elsewhere in the UK. This led to the development of several recommendations for change to Northern Ireland's medicines access processes.

The recommendations are aimed at ensuring continued timely, equitable access to new clinically and cost-effective medicines for the NI population on a sustainable basis going forward. They include creating a team approach to medicines access, a redesigning of the medicines access workflow, creating an HSC / industry engagement forum, use of regular HSC Trust data returns to replace the cost-per-case system, redevelopment of the medicines access/managed entry website and full patient/public involvement in the process.

Although some elements of the recommendations may take time to progress, it is hoped that they will lead to fruitful discussions about how processes could be done differently, to increase efficiency and improve communication, thus improving the totality of the medicines access processes for NI.

8 Summary of recommendations

The review resulted in the following recommendations:

Policy and Guidelines

- Address inequitable access for NI patients by provision of policy direction for identified areas including paediatric medicines, antimicrobials and small cohorts.

- Provide regional guidance on the management of zero and nominal cost medicines schemes to promote a consistent approach across the HSC.

- Consider adopting regional policy for how VPAG rebate income can best be utilised to support continued access to medicines and ongoing quality improvement.

Leadership and governance

- Strengthen clinical and financial governance of medicines access through improved use of data that would enable replacement of interim cost-per-case arrangements.

- Undertake a workforce review to inform creation of a single Regional Medicines Access Programme to coordinate medicines access workstreams across the HSC.

- Establish a new overarching Medicines Access Leadership Group to provide strategic direction and system leadership to the Regional Medicines Access Programme.

- Strengthen partnership arrangements between the HSC and pharmaceutical industry through establishing a new HSC Industry forum, adopting best practice from GB.

Systems and processes

- Develop new communication arrangements and HSC medicines access roadmap, with PPI embedded in all processes to improve transparency for patients, clinicians and industry.

- Optimise alignment between Departmental NICE endorsement and HSC Managed Entry processes to minimise timelines to routine commissioning of new medicines.

- Develop new service infrastructure impact assessment processes that identify all requirements for introduction of new medicines including medical, nursing and pharmacy support.

9 Appendices

Appendix 1 – List of Stakeholders invited to contribute to the review

Ms Helen Adams, Lead Pharmacist (Blueteq Programme), All Wales Therapeutics and Toxicology Centre

Ms Rachel Allen, Commissioning Pharmacist, University College London Hospitals, London

Mr Andrew Barron, Chief Pharmacist, University College London Hospitals, London

Mr Joe Brogan, Pharmacy and Medicines Management Team, SPPG, Department of Health

Dr Kathryn Burnett, Pharmacist, Regional Pharmaceutical Procurement Service

Mrs Suzanne Cassells, Lead Pharmacist, Regional Pharmaceutical Procurement Service

Ms Joanne Castle, Head of External Affairs & Operations - Wales, ABPI

Mr Andrew Champion, Programme Director, All Wales Therapeutics and Toxicology Centre

Mrs Kerry Corey, Lead Accountant, BHSCT

Mr Paul Cunningham, Commissioning Lead, SPPG, Department of Health

Mrs Anita Doherty, Pharmacy Adviser, Specialist Medicines & Commissioning, SPPG, Department of Health

Dr Martin Eatock, Consultant Oncologist & Chair IFR Scrutiny Panel

Ms Lesley Edgar, NICE Implementation Consultant, Northern Ireland

Dr Ashley Elliott, Consultant Rheumatologist, BHSCT

Dr Anne Friel, Head of Pharmacy and Medicines Management, WHSCT

Mr Chris Garland, Senior Principal Pharmaceutical Officer, Department of Health

Mr James Gordon, Medicines Access Branch, Department of Health

Mrs Nicola Hampshire, Healthcare Business Manager, Abbvie

Mrs Bronagh Hegarty, Pharmacist Procurement Manager, WHSCT

Mr Jonathan Houston, Commissioning Lead, SPPG, Department of Health

Mr Declan Hutchings, National Sales Manager, Blueteq

Ms Victoria Jordan, Head of HTA and Market Access ABPI

Mrs Lynn Keenan, Pharmacy Coordinator (Specialist Medicines Commissioning), SPPG, Department of Health

Mrs Sandra Kilpatrick, Aseptic Services Manager/QA Pharmacist, SHSCT

Ms Ruth Lang, Senior Liaison Manager, All Wales Therapeutics and Toxicology Centre

Mrs Marion Laverty, Head of Public Affairs - Northern Ireland, ABPI

Mrs Janet Lawson, Pharmacist, Interface Pharmacist Specialist Network, SHSCT

Mrs Emma Lockhart, Integrated Healthcare Manager, BMS

Mr Emmett Lynch, Senior PPI Officer, Public Health Agency

Mrs Catherine Lynn, Medicines Access Branch, Department of Health

Ms Anne Lyttle, Pharmacy Adult Cancer & Aseptic Services Lead, BHSCT

Mrs Jill Macintyre, Head of Pharmacy and Medicines Management, SEHSCT

Mrs Teresa Magirr, Commissioning Lead, SPPG, Department of Health

Mrs Ann McCorry, Head of Pharmacy and Medicines Management, SHSCT

Mrs Eimear McCusker, Head of Pharmacy and Medicines Management, BHSCT

Mrs Finola McGrady, Head of Rare Diseases, Genomics, Imaging & Pathology Unit, Secondary Care Directorate, DoH NI

Ms Breda McKee, Immunology Healthcare Partnership Manager, AbbVie

Mrs Fiona McLaughlin, Co-Chair, Northern Ireland Rare Diseases Partnership

Ms Seaneen McLaughlin, Strategic Account Manager, Novartis

Mr Damien McMullan, Partnership Manager, Pfizer

Mrs Michelle McVerry, Biologics Pharmacist, SHSCT

Mr Eamon Mulaney, Professional Manager, Pharmacy Services, BHSCT

Mrs Deborah Neeson, Interim Regional Lead Cancer Services Pharmacist, BHSCT

Dr Connor O'Neill, Consultant Oncologist, WHSCT

Ms Jillian Redpath, Lead Encompass Pharmacist, SHSCT

Mr Graeme Rose, Public Affairs Lead Devolved Nations, Novartis

Dr Girish Shivashankar, Consultant Nephrologist, WHSCT

Mr James Taggart, Lead Pharmacist, Interface Pharmacist Specialist Network, BHSCT

Mrs Fiona Tarpey, Lead Pharmacist NICE Managed Access Agreements, Regional Pharmaceutical Procurement Service

Dr Sandya Tirupathi, Consultant Paediatric Neurologist, RBHSC

Mrs Julia Tolan, Head of Pharmacy and Medicines Management, NHSCT

Mrs Orla Traynor, Pharmacist, Interface Pharmacist Specialist Network, WHSCT

Mr Anthony Williams, Head of Medicines Access Team, All Wales Therapeutics and Toxicology Centre