REF NO. HS/S5/19/MED/

HEALTH AND SPORT COMMITTEE

THE SUPPLY AND DEMAND FOR MEDICINES

SUBMISSION FROM CANCER RESEARCH UK

Submission key messages:

- Scotland has effective funding mechanisms in place to support patient access to clinically effective cancer medicines. Recent progress has been driven by process changes introduced since 2014, and the increase in the number of medicines appraised by the Scottish Medicines Consortium (SMC) in recent years. Further investment is required however to develop the technical and resource capacity to monitor variation in the uptake of cancer medicines recommended for routine funding across Health Boards.
- Scotland has led the UK in its provision of genomic testing to guide cancer patients' treatment. The Scottish Government should scope how to build on this existing infrastructure to support the introduction of a wider range of genomic tests in future, so that patients can continue to receive new targeted medicines as they become available. This will help ensure patients are receiving the most appropriate medicines for their condition and help make the most effective use of the medicines budget.
- Scotland has an opportunity to become a world leader in real-world patient data. This will support informed decision-making by patients and clinicians, and enable the use of innovative commissioning approaches like outcome-based payment to facilitate patient access to new medicines. Again, this will help ensure patients are receiving the most appropriate medicines for their condition and help make the most effective use of the medicines budget. Further investment in data collection on medicine use and outcomes within NHS Scotland, building on Programmes like the Cancer Medicines Outcomes Programme (CMOP), will be needed to achieve this.

Do patients receive the most clinically and cost-effective treatments?

Every person diagnosed with cancer in Scotland should have equitable access to the most effective, evidence-based treatments for their condition. This relies on the right processes being in place to ensure clinically and cost-effective medicines are approved for funding, then ensuring these medicines reach patients once funding has been recommended.

The number of new cancer medicines on which the SMC has produced advice has increased in recent years, allowing routine funding for an increasing number of clinically and cost-effective treatment options.[1] Significant progress has also been made in implementing process changes in the routes to approval and funding for new medicines, especially for rare or very rare diseases judged clinically effective by the SMC.

These changes include implementation of many of the recommendations of the 2016 Montgomery Review of Access to New Medicines, consolidating the positive impact of changes introduced by the SMC in 2014. We also welcome the introduction of the PACS Tier 2 process to promote a consistent approach to patient access to medicines not routinely funded in Scotland.

These successes mean we are confident that appropriate routes are in place to secure funding for patient access to clinically and cost-effective cancer medicines in Scotland.

However, further improvements in funding and approval mechanisms could be made in the short to medium term. In particular, the Scottish Government should continue to work with the SMC to ensure the SMC's processes are responsive to current and future trends which will make the clinical and cost effectiveness of future medicines more uncertain. This uncertainty poses challenges to sustainable patient access to future innovations within an evidence-based system. These trends include:

- the increasing cost and innovative nature of many new treatment options;
- increasing awareness of the demographic and outcomes gap between clinical trial and NHS patient populations; and
- the licensing of new medicines based on less mature or less complete clinical trial data (often from fewer trial patients than in the past).[2]

Scottish Government and the SMC should clarify whether any changes have been made or are planned in SMC processes, in response to the evaluation of health technology assessment best practice in other countries recommended in the Montgomery Review.[3]

In particular, the use of "managed access" or conditional acceptance is an important response to this uncertainty. This would allow the SMC to recommend a drug for NHS funding while further evidence is gathered about its effectiveness (from both ongoing clinical trials, but also "real world" NHS populations). This mechanism was recommended in the Montgomery Review,[4] and the SMC has introduced it for medicines which receive conditional marketing authorisation from the European Medicines Agency.[5]

An example of the advantage this provides in terms of patient access can be seen in the case of pembrolizumab for untreated urothelial cancer. The Cancer Drugs Fund in England has allowed managed access to this drug for some patients since April 2018, because of its "plausible potential" to be cost-effective.[6] But SMC were unable to recommend its use for patients in Scotland when it was last reviewed in September 2018, as the company could not provide a sufficiently definitive "justification of the treatment's cost in relation to its health benefits".[7]

We urge the Scottish Government to extend the option to use managed access mechanisms to all newly-licensed cancer medicines. Scottish Government and the SMC should clarify how use of the current approach will be evaluated, as well as how and on what timelines any future decision on whether to expand its scope will be taken.

In addition to appropriate funding routes for new medicines being in place, these medicines must go on to reach patients once funding has been recommended. Although Health Boards usually provide new treatments as recommended by the SMC, we have heard anecdotal concerns of variation in the speed and/or comprehensiveness of provision of individual medicines across Health Board geographies. This may mean not all patients who could benefit from clinically and cost-effective medicines are receiving them.

Professor Andrew Morris' 2018 data scoping taskforce recommended NHS Scotland build further capacity to "capture medicines use for patients in all clinical settings".[8] Scotland's UK-leading use of e-prescribing, through data sources like the Chemotherapy Electronic Prescribing and Administration System (CEPAS), offers a strong foundation for this.

To realise the ambitions set out by the taskforce, further investment is needed to build on this foundation and develop a stronger NHS data infrastructure within Scotland. This should include a focus on monitoring prescribed treatment regimens, tracking uptake of new treatments, and examining the extent and drivers of any variation. This would be a key step in delivering on this recommendation and support a 'once for Scotland' approach.

The Scottish Government should review the extent and drivers of any variation in the speed or comprehensiveness of medicines uptake as a priority. In addition, and as part of the Scottish Government's ongoing work to improve data collection on medicine use and outcomes, we would welcome additional investment in the technical and resource capacity to monitor variation within NHS Scotland in the uptake of cancer medicines recommended for routine funding.

Does NHS Scotland achieve the most value from the money spent on medicines?

Based on anecdotal evidence, it is our understanding that discrepancies exist in the prices of new medicines across the UK nations. We welcome the commitment in the Voluntary Scheme on Branded Medicines Pricing and Access (VPAS) to confidentially share details of commercial agreements between national purchasing authorities, to help achieve "comparable arrangements" across the UK.[9] This should help NHS Scotland drive value for money in future commercial negotiations with medicines manufacturers.

Alongside a focus on the price of new medicines, it is vital that NHS Scotland ensures optimal use of medicines in routine clinical use, to get the best value from prescription of these medicines. For comparison, NHS England has established a medicines optimisation workstream, delivered through its Medicines Value Programme.[10]

One key element of that workstream is improving the uptake of biosimilar medicines, since figures suggest biosimilars are around 45% less expensive than originator biological medicines.[11] Appropriate use of biosimilars within NHS Scotland would help to drive value for money from the money spent on medicines already routinely prescribed, as well as freeing up financial headroom to fund the introduction of new innovative medicines.

NHS Scotland should consider producing for Scotland an equivalent to NHS England's Commissioning Framework for Biological Medicines,[12] to promote the uptake of biosimilars.

To drive best value from medicines spend, patients must be receiving the most appropriate medicine for their condition. Informed and co-operative decision making by clinicians and people affected by cancer is a crucial element of this, and we welcome the proactive steps being taken by NHS in Scotland to encourage this through their Realistic Medicine work.[13]

This can be complemented by Scotland's pioneering work into collecting real-world data on NHS patient treatment outcomes via the Cancer Medicines Outcomes Programme (CMOP). We welcome the Scottish Government's support for this initiative, based within NHS Greater Glasgow and Clyde, which has the potential to provide valuable information to patients and clinicians on medicines' benefits and side-effects (including patient-reported outcome measures, PROMs), beyond the evidence that can be gathered in clinical trials.

By giving a better understanding of the impacts of specific medicines on patient populations in NHS Scotland, this data can support more informed patient and clinician decisions about beginning or continuing treatment with a specific medicine. This could potentially help reduce the number of patients not completing treatment and ensure patients are prescribed the medicines most likely to be effective for them, improving value for money.

This conclusion was echoed in the Scottish Parliament Cross Party Group on Cancer's November 2019 report into "Priorities for the Future of Cancer Services, Support and Research in Scotland". The report identified the use of NHS data, and data on PROMs in particular, as "a potential game-changer for patient outcomes, data-led service planning, and resource optimisation in Scotland".[14]

The Scottish Government should undertake and publish a review of CMOP's findings, and their implications for NHS Scotland clinical and administrative practice, as soon as possible after the Programme's existing funding expires at the end of 2019/20, ensuring this is incorporated into its wider ongoing work to improve data collection on medicine use and outcomes. It should also commit to providing funding for further Programmes of study to continue this work. Funding should be prioritised for projects that seek to expand the focus of the existing Programme's work to a national level, and which continue its work to define robust PROMs from treatment and integrate these into routine data reporting.

In what ways can the system be made more efficient?

A strong genomic testing infrastructure will be need in the future to ensure the right patients can quickly access the most appropriate medicines for their condition. Around 90% of new medicines emerging from the R&D pipeline are genetically targeted medicines.[15] These can be more effective and less toxic than existing treatment options, but they also require patients to undergo genomic testing to determine their eligibility for the treatment.

To date, Scotland has led the UK in its provision of genomic testing for patients, for the limited number of tests required to determine patient eligibility for existing standard of care medicines. Anecdotal evidence suggests local commissioning and clinical pathways for genomic tests have been well-embedded within broader patient care, with established molecular pathology centres at 4 sites – Edinburgh, Glasgow, Aberdeen and Dundee.

However, the emergence of new targeted therapies and associated genomic tests, targeting a wider range of genetic variations found in some patients' cancers, will place pressure on this system. These include for example new "tumour agnostic" medicines designed to target specific changes in cancer cells' DNA, regardless of where the cancer is growing in the body.[16]

Consistent and equitable access to beneficial genomic tests across the whole geography of Scotland is critical to ensure NHS Scotland can effectively identify patients who could benefit from these new targeted therapies, ensuring the system is efficiently directing patients towards targeted medicines recommended for routine funding.

NHS Scotland and the Scottish Government should work with Health Boards and the 4 regional molecular pathology centres, to scope how they can support the introduction of a wider range of genomic tests into existing local testing pathways. In particular, they should review whether they should take a stronger central role in the funding and commissioning arrangements for new tests, or in setting national-level expectations around the availability of specific tests (similar to the new National Genomic Testing Directory in England).[17]

How can the medicines budget be controlled while maintaining clinical and cost effectiveness?

As noted in response to the first question above ("Do patients receive the most clinically and cost-effective treatments?"), determination of the clinical and cost effectiveness of new medicines is becoming increasingly challenging. New commercial and commissioning approaches are required in response to this trend, to ensure effective management of the medicines budget.

More flexible medicines pricing mechanisms, such as outcome-based payment (OBP), offer an opportunity for NHS Scotland to target its medicines spending on those treatments which are most clinically effective. Under OBP, the price the NHS pays for a medicine is linked to the outcomes it achieves in practice for NHS patients. This ensures NHS Scotland would only be paying for medicines where there is evidence of clinical and/or quality of life benefit to patients, while assuring industry that genuine innovations and therapeutic breakthroughs will continue to be rewarded.

OBP will not be an appropriate commissioning approach for every new medicine, given the additional administrative burden associated with the design and operation of such arrangements. However, targeted use of OBP offers a way to ensure value for money from medicines spending, while continuing to encourage companies to bring new clinically and cost effective medicines to Scotland.

As noted above, schemes such as CMOP and good existing provision of e-prescribing infrastructure mean Scotland is already able to capture high quality data on NHS cancer patients' treatment and medicines prescriptions, and has an opportunity to become a world-leader in the systematic monitoring of patients' treatment outcomes.

There is therefore scope for Scotland to pioneer the use of these kind of flexible pricing mechanisms within the UK and internationally. This is especially so given CMOP's work to establish robust ways of capturing data on patient-reported treatment outcomes (including quality of life indicators), alongside more traditional 'clinical' outcomes. Cancer Research UK's research into the use of OBP schemes within the NHS has found that these outcomes are crucial in understanding the treatment effects cancer patients care about most.[18]

The Scottish Government should work with Health Boards, as well as patient groups and industry, to develop a joint approach to building the capacity of NHS Scotland to design and operate outcome-based payment schemes for new cancer medicines.

References

[1] According to the SMC's website, and including abbreviated submissions, but not including non-submissions or medicines subsequently resubmitted, we estimate the SMC produced advice on 27 cancer medicines from January to October 2019, and 21 medicines in 2018. This compares to advice on 12 medicines in 2014 and 13 medicines in 2015. See https://www.scottishmedicines.org.uk/medicines-advice/

[2] Cole, A., Cubi-Molla, P., Pollard, J., Sim, D., Sullivan, R., Sussex, J. and Lorgelly, P. (2019). Making Outcome-Based Payment a Reality in the NHS. Cancer Research UK. Available at: https://www.cancerresearchuk.org/about-us/we-develop-policy/our-policy-on-access-to-cancer-treatments/outcome-based-payment-for-cancer-drugs

[3] Recommendations 18 and 25. See Montgomery B. (2019), *op. cit.*

[4] Recommendations 21 and 23. See Montgomery B. (2019) Review of Access to New Medicines. Scottish Government. Available at: https://www.gov.scot/publications/review-access-new-medicines/

[5] Scottish Medicines Consortium – Interim Acceptance Decision Option. See https://www.scottishmedicines.org.uk/how-we-decide/interim-acceptance-decision-option/

[6] NICE (2018). Pembrolizumab for untreated PD-L1-positive locally advanced or metastatic urothelial cancer when cisplatin is unsuitable. Available at: https://www.nice.org.uk/guidance/ta522

[7] SMC (2018). pembrolizumab (Keytruda). Available at: https://www.scottishmedicines.org.uk/medicines-advice/pembrolizumab-keytruda-fullsubmission-133918/

[8] Data Scoping Taskforce (2018). Medicines Use and Digital Capabilities: Building capability to assess real-world benefits, risks and value of medicines: Towards a Scottish Medicines Intelligence Unit. Scottish Government. Available at: https://www2.gov.scot/Resource/0054/00540468.pdf

[9] The 2019 Voluntary Scheme for Branded Medicines Pricing and Access (2018). Department of Health and Social Care and the Association of the British Pharmaceutical Industry. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/761834/voluntary-scheme-for-branded-medicines-pricing-and-access-chapters-and-glossary.pdf

[10] NHS England, Medicines Value Programme. See https://www.england.nhs.uk/medicines/value-programme/

[11] Proposed changes to the statutory scheme to control the costs of branded health service medicines (2018). Department of Health and Social Care. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/736023/Statutory_Scheme_Consultation_Document_corrected.pdf

[12] Commissioning framework for biological medicines (including biosimilar medicines) (2017). NHS England. Available at: https://www.england.nhs.uk/wp-content/uploads/2017/09/biosimilar-medicines-commissioning-framework.pdf

[13] Realistic Medicine. See https://realisticmedicine.scot/

[14] Scottish Parliament Cross Party Group on Cancer (November 2019). Priorities for the Future of Cancer Services, Support and Research in Scotland. Available at: http://anassarwar.co.uk/wp-content/uploads/2019/11/CPG-Cancer-Report.pdf

[15] Cancer Research UK policy statement: Patient Access to Molecular Diagnostics and Targeted Medicines in England (2018). Cancer Research UK. Available at: https://www.cancerresearchuk.org/sites/default/files/access_to_molecular_diagnostic_tests_and_targeted_medicines_in_england_0.pdf

[16] Cancer Research UK (2019). NHS to 'fast track' new personalised cancer medicines – but it's not ready quite yet. Available at: https://scienceblog.cancerresearchuk.org/2019/06/19/nhs-to-fast-track-new-personalised-cancer-medicines-but-its-not-ready-quite-yet/

[17] NHS England, National Genomic Test Directory. See https://www.england.nhs.uk/publication/national-genomic-test-directories/

[18] Cole, A. et al (2019). *Op. cit.*