The Scottish Parliament
Pàrlamaid na h-Alba

Jeane Freeman MSP
Cabinet Secretary for Health and Sport

Via email only

Health and Sport Committee
T3.60
The Scottish Parliament
Edinburgh
EH99 1SP
Tel: 0131 348 5210
Calls via RNID Typetalk: 18001 0131 348 5224
Email: healthandsport@parliament.scot

13 December 2019

Dear Cabinet Secretary

Access to Medicines

The Health and Sport Committee will be conducting an inquiry into the Supply and Demand for Medicines early in 2020.

Ahead of the start of this inquiry, the Committee has several areas on which it would appreciate an update.

Review of Access to New Medicines – Independent Review by Dr Brian Montgomery

The independent report of the Review of Access to New Medicines (Montgomery Review) was published in December 2016 and made several recommendations.

Datasets

Previously, it was "possible to look at the impact the new approach has had in terms of the number of medicines accepted by SMC but not in relation to patients treated or their outcomes"[1].

The Committee was pleased to receive an update[2] from your predecessor in November 2017 which included updates on progress in developing new datasets.

[1] Scottish Government (2016). Review of Access to New Medicines
[2] Letter from the Cabinet Secretary for Health and Sport, 16 November 2017

The Committee requests:

- **An update on work to:**
  - **"develop, agree and implement national datasets and data definitions for end-of-life, orphan and ultra-orphan medicines and for IPTR/PACS processes"[3];**
  - **"Develop, agree and implement a national chemotherapy dataset and equivalent datasets for medicines used to treat rare conditions;**
  - **Develop, agree and implement sets of outcome measures for classes of medicines or, in the case of very rare conditions, specific medicines;**
  - **Ensure that national systems being developed for electronic prescribing and electronic patient records are prioritised and support the above requirements.[4]"**
- **Information on progress towards implementing recommendations in the action plan contained in the Data Scoping Taskforce report published[5] in September 2018. The Committee notes the actions were "being considered as part of a range of ongoing policy initiatives including our Digital Health and Care Strategy, the Chief Medical Officer's Realistic Medicine approach and the ongoing development and implementation of a Hospital Electronic Prescribing and Medicines Administration (HEPMA) system"[6];**
- **An update on the output from the 3-year work to develop datasets for recording and measuring patient outcomes in relation to cancer medicines[7] including:**
  - **The outcomes of the Cancer Medicines Outcomes Programme (CMOP) [8];**
  - **Confirmation of whether this work is likely to continue and if so whether additional funding will be required; and**
  - **Detail on work has been undertaken to develop datasets relating to other conditions.**
- **Details of the internal content management system[9] to be developed by the Scottish Medicines Consortium (SMC), including progress to date (the Committee notes the SMC was in the final stages of testing this in May 2018[10]);**
- **Information on how data sets have been refined to "enable meaningful year-by-year comparisons and the monitoring of emergent trends" [11]**

---

[3] Scottish Government (2016). Review of Access to New Medicines
[4] Scottish Government (2016). Review of Access to New Medicines
[5] Scottish Government (2018). MEDICINES USE AND DIGITAL CAPABILITIES Building capability to assess real-world benefits, risks and value of medicines: Towards a Scottish Medicines Intelligence Unit - Report from the Data Scoping Taskforce September 2018
[6] Letter from the Cabinet Secretary for Health and Sport, 17 May 2018
[7] Letter from the Cabinet Secretary for Health and Sport, 16 November 2017
[8] Letter from the Cabinet Secretary for Health and Sport, 17 May 2018
[9] Letter from the Cabinet Secretary for Health and Sport, 16 November 2017
[10] Letter from the Cabinet Secretary for Health and Sport, 17 May 2018
[11] Scottish Government (2016). Review of Access to New Medicines

(Recommendation 12) with regard to acceptance rates for end-of-life, orphan and ultra-orphan medicines;

- **Work to "Standardise data collection at Board level in relation to systems and process for requests to access non-formulary medicines." [12] (Recommendation 15);**
- **Progress to "Review the data set and definitions for data relating to IPTRs collected by Boards with the aim of achieving consistency and comparability and also extending the dataset to include data on outcomes." [13] (Recommendation 17 in the Review); and**
- **The Scottish Government's work with "academic and industry partners to investigate the potential to pilot the development and testing of outcome measures for orphan, ultra-orphan and interim acceptance medicines, using real world evidence, including that reported by patients."[14]**

Definition of end-of-life, orphan and ultra-orphan medicines

The review notes "concern was expressed that Scotland has taken a different path from the rest of Europe and the United Kingdom and in particular the National Institute for Health and Care Excellence (NICE) in England with regard to the definitions of end-of-life, orphan and ultra-orphan medicines". **The Committee requests details of whether the diverging definitions have been raised as an issue since their adoption and examples of where this has had an impact on decisions.**

The Committee notes the Scottish Medicines Consortium reviewed the definitions of end-of-life, orphan and ultra-orphan medicines, and that a new pathway was developed for ultra-orphan medicines as a result. **The Committee seeks an update on the outcome of the review of the definition of end-of-life and orphan medicines.**

The Committee further requests an update on:

- **Whether any examples have arisen to justify concern about the "future utility"[15] of the definitions "particularly as they apply to ultra-orphan medicines"; and**
- **Progress on the proposed adoption of a definition of a "true ultra-orphan medicine"[16].**

Patient and Clinician Engagement Process

The Committee notes the introduction of the Patient and Clinician Engagement (PACE) process was welcomed but that "many feel that it has not been clear how PACE has impacted on SMC decision making and that further development is required"[17].

---

[12] Scottish Government (2016). Review of Access to New Medicines
[13] Scottish Government (2016). Review of Access to New Medicines
[14] Letter from the Cabinet Secretary for Health and Sport, 17 May 2018
[15] Scottish Government (2016). Review of Access to New Medicines
[16] Letter from the Cabinet Secretary for Health and Sport, 19 June 2018
[17] Scottish Government (2016). Review of Access to New Medicines

The Committee seeks details of the progress on recommendations in this area, namely:

- **"Review communications of SMC's decisions to patients, patient groups and the pharmaceutical industry with a view to achieving greater transparency" [18] (Recommendation 8), including an update on the development of "public friendly summaries of their decisions" [19] by the SMC;**
- **Review and clarify the role of the SMC Public Partner"[20] (Recommendation 9), including the further work the Scottish Government noted would be required to "consider clinician engagement in the SMC decision making process" [21] and any further detail on the decision not to process with this option[22]; and**
- **"Consider key participants at PACE meetings being actively involved in the relevant parts of SMC meetings to enhance the quality of discussion and decision making."[23] (Recommendation 10).**

New ultra-orphan pathway

The Review proposed "An alternative assessment pathway should be developed for ultra-orphan medicines that preserves the integrity of SMC and its processes yet achieves the intended level of access to these medicines."[24] The Committee notes a new pathway has been developed and was introduced in October 2018[25]. **The Committee seeks an update on the first year of operation (including comparative figures with the previous year) and whether this has led to the "intended" increased availability recommended by the review. The Committee would also welcome an update on the development of the new pathway, including engagement and consultation activities.**

The Montgomery Review also noted the limits of the previous assessment for ultra-orphan medicines in accommodating assessment of true ultra-orphan medicines and that the "route for patients with these very rare conditions seeking access to medicines has become via IPTR and PACS."[26]

The Committee seeks an update on the development of a new assessment and approval pathway for true ultra-orphan medicines, particularly in light of the introduction of the Peer Approved Clinical System Tier 2.

[18] Scottish Government (2016). Review of Access to New Medicines
[19] Letter from the Cabinet Secretary for Health and Sport, 16 November 2017
[20] Scottish Government (2016). Review of Access to New Medicines
[21] Letter from the Cabinet Secretary for Health and Sport, 16 November 2017
[22] Letter from the Cabinet Secretary for Health and Sport, 17 May 2018
[23] Scottish Government (2016). Review of Access to New Medicines
[24] Scottish Government (2016). Review of Access to New Medicines
[25] Scottish Government (2019). Ultra-orphan medicines pathway: guidance
[26] Scottish Government (2016). Review of Access to New Medicines

Implementation of the SMC decisions under the new approach, including funding and the New Medicines Fund

The Review noted the cost of giving access to end-of-life, orphan and ultra-orphan medicines had been met through the New Medicines Fund. Uncertainty as to the future funding arrangements for provision of such medicine was expressed.

The Committee requests clarification on the future funding arrangements for end-of-life, orphan and ultra-orphan medicines.

A 'Once for Scotland' Approach

The Review recommended the Scottish Government should "Standardise NHSScotland's approach to formulary development and use" at recommendation 19. Your predecessor helpfully provided an update in November 2017 to say this recommendation was "reliant on the alignment of a number of other recommendations or linked to other policy timelines. Work is in hand to take all of these forward and I plan to provide the Committee with a further update on progress in Spring 2018"[27]. A further update provided to the Committee in May 2018[28] did not mention progress towards a national formulary.

The Committee requests an update on the development of a national standardised approach to development and use of formulary, including work to date, and timescales for future work and delivery.

Scottish Medicines Consortium Process and Commercial Negotiation

Dr. Montgomery made several recommendations[29] relating to how the Scottish Medicines Consortium process should be adapted to include commercial negotiation with the aim of ensuring best value for the NHS and getting to a pharmaceutical company's best offer on price earlier.

Your predecessor's update[30] to the Committee in November 2017 highlighted work "underway to enable the SMC to have an additional decision option of "recommend for use subject to ongoing evaluation and future assessment"" and in May 2018, the Committee was told work on this was "at an advanced stage" [31].

The November 2017[32] update also noted ongoing work between NHS National Procurement and the SMC on conditional acceptance options and Managed Access Schemes (MAS). Further correspondence to the Committee in May 2018 noted the latter was due for implementation last year and that "NHS National Procurement (NP) has given consideration to the changes needed to the current Patient Access Scheme (PAS) arrangements to support interim acceptance through a form of a managed access agreement. This will support arrangements to provide a medicine at a discounted price whilst further clinical data is collected over an agreed time

[27] Letter from the Cabinet Secretary for Health and Sport, 16 November 2017
[28] Letter from the Cabinet Secretary for Health and Sport, 17 May 2018
[29] Scottish Government (2016). Review of Access to New Medicines
[30] Letter from the Cabinet Secretary for Health and Sport, 16 November 2017
[31] Letter from the Cabinet Secretary for Health and Sport, 17 May 2018
[32] Letter from the Cabinet Secretary for Health and Sport, 16 November 2017

period. NP are at an advanced stage of discussions with the Association of the British Pharmaceutical Industry on revising PAS guidance" [33].

The Committee would welcome an update on implementation and evaluation of the new decision option of "subject to ongoing evaluation and future assessment".

The Committee also requests further information on progress on recommendation 21, 22, 24 and 25 of the Montgomery review:

"21 Explore MAS with a view to early adoption in NHSScotland. These should build on the experience of complex PAS within NHSScotland and payment by-results schemes in operation in other health systems.

22 Review the proposal to introduce a "pause" in light of some of the wider changes and actions recommended in this report.

24 Make greater use of National Procurement in NSS to lead negotiations on behalf of NHSScotland on the cost of new medicines

25 Undertake a comparative review of the arrangements in place in the healthcare systems of other countries for the introduction of new medicines and specifically end-of-life, orphan and ultra-orphans, seeking to learn from their experiences." [34]

New medicines and developing regulatory framework

At recommendation 27, the review calls for NHSScotland, through wide stakeholder engagement, to consider the best way to "take advantage of the opportunities afforded by anticipated developments in the way that new medicines will be introduced in the future. This is likely to be through the establishment of a multi-agency taskforce or equivalent group." In correspondence[35] to the Committee in November 2017, notice of a commissioned comparative review of international health technology processes, the output of which would contribute to the delivery of recommendation 27.

The Committee would welcome an update on the range of actions being taken to deliver recommendation 27 as well as on the outcomes of work on international health technology processes.

A Scottish Model of Value

The Committee notes the recommendation on the development of a new Scottish Model of Value. In correspondence in November 2017, it was noted this was reliant on other recommendations and policies.

---

[33] Letter from the Cabinet Secretary for Health and Sport, 17 May 2018
[34] Scottish Government (2016). Review of Access to New Medicines
[35] Letter from the Cabinet Secretary for Health and Sport, 16 November 2017

The Committee seeks an update on the development of a new Scottish Model of Value.

Best Value
In the May 2018 update to the Committee, it was noted that National Procurement "is in advanced stages of discussions with ABPI about a voluntary price alignment arrangement which will enable companies to adjust the price of a PAS in Scotland to ensure equitable pricing arrangements across the UK – seeking to end the possibility of the NHS in Scotland being charged more than the NHS in England for the same medicine." [36]

The Committee seeks an update on the outcome of these discussions and whether a voluntary price alignment has been achieved.

Process for medicines not routinely accepted for use in NHS Scotland

Your predecessor appraised the Committee of developments towards the replacement of IPTR with PACS Tier 2 in November 2017[37], February 2018, May 2018 and June 2018. In May 2018[38], the Committee was told of:

- A review of the initial operation of PACS Tier 2;
- A National Review Panel (NRP) for the PACS Tier 2 would be established; and
- A review of PACS Tier 1.

The Committee would welcome an update on these reviews and the work of the National Review Panel.

Area Drug and Therapeutic Committees

The Committee would appreciate an update on current thinking regarding the structure of Area Drug and Therapeutic Committees (ADTCs) in Scotland.

In its report into Access to New Medicines, the previous Health and Sport Committee concluded:

"The Committee notes Professor Swainson's findings in relations to ADTCs and heard arguments put forward for the retention of all 14 ADTCs in their current form. However, there may well also be arguments that have not, so far, been fully explored, in favour of a smaller number, or even a single national body, particularly in relation to patient treatment requests."[39]

The Scottish Government's response stated:

"The Scottish Government currently supports the retention of 14 NHS Board Area Drug and Therapeutics Committees (ADTCs) to maintain clinical engagement and education and training for clinicians to ensure safe and effective prescribing practices. Continued retention of the 14 ADTCs is, however, contingent on their

[36] Letter from the Cabinet Secretary for Health and Sport, 17 May 2018
[37] Letter from the Cabinet Secretary for Health and Sport, 16 November 2017
[38] Letter from the Cabinet Secretary for Health and Sport, 17 May 2018
[39] Health and Sport Committee. 8th Report, 2013 (Session 4). *Access to New Medicines*

demonstration that the new processes are working well to ensure clinical outcomes are optimised. The Scottish Government will introduce rigorous monitoring arrangements over the next three years in this regard."[40]

The Committee notes the establishment of the Area Drug and Therapeutics Committee Collaborative in 2014 and **requests an update on the development, implementation and outcome of monitoring arrangements of the operation of 14 ADTCs to 2016, as well as developments since this time and the Scottish Government's current position on these matters.**

The Committee requests a response to this letter by **14 January 2020**. I look forward to hearing from you.

Yours sincerely

Lewis Macdonald

Convener, Health and Sport Committee

[40] Scottish Government (2013) *Response to the Health and Sport Committee, 8th Report 2013, (Session 4) Access to New Medicines*