MAP BioPharma summary of changes to Scottish access to medicines arrangements

Background
In January 2016, the Scottish Government asked Dr Brian Montgomery to take forward an independent review of the assessment of new medicines in Scotland. He was asked to consider the impact of changes to the Scottish Medicines Consortium (SMC) process for assessing medicines in 2014 and the wider system for patient access to newly licensed medicines.

The report was published on Wednesday 14th December 2016 and Shona Robison, Health Secretary, announced the Scottish Government’s intention to implement all its recommendations. Alongside the review, the Health Secretary also outlined plans to reform the process for non-routine access to medicines.

The decision by the Health Secretary to accept all the recommendations from the report and reform non-routine access arrangements demonstrates a welcome commitment on behalf of the Scottish Government in addressing access to medicines issues.

This briefing provides further detail on the proposed changes and their potential impact.

Review of access to medicines
The review sets out that access to end-of-life, orphan and ultra-orphan medicines has increased as a result of the 2014 system updates and the availability of funding via the New Medicines Fund. Stakeholder satisfaction with the SMC process is generally high. There were, however, some notable issues raised, particularly relating to the assessment of ultra-orphan medicines and the need for a sustainable system that takes affordability into account and is better aligned with the Chief Medical Officer’s “Realistic Medicine” proposition.

1. Ultra-orphan medicines
The rate of SMC approvals for ultra-orphan medicines is low but generally applications for these medicines through the new Peer Approved Clinical System (PACS) have been successful. The review notes that it is not good for there to be a reliance on an individual request system when there might be a central position agreed for these medicines. Analysis of SMC applications showed that even with the changes introduced in 2014, the process is still not fit for purpose for ultra-orphan medicines. The review recommends that an alternative system should be developed outside the SMC. It is expected that a revised process will be developed in the coming months.

MAP BioPharma welcomes this decision as it should support more predictability in terms of access for these treatments. Having a centralised system should also help to ensure equitable access across Scotland. This also sets Scotland apart from England where arrangements for ultra-orphan treatments fail to recognise the specific nature of these drugs.

2. Funding mechanism and affordability
The review notes that although the New Medicines Fund had provided additional resource and the NHS in Scotland has hitherto been able to fund the increased access as a result of the access reforms, the system needs to consider long term sustainability. It was also noted that “universal access to new medicines was not desirable” as it would not necessarily reflect that the NHS was getting the most for taxpayers’ money. Stakeholders expressed concern that the more permissive Individual Patient Treatment Request (IPTR) did not necessarily provide an incentive for the pharmaceutical industry to offer their best price to NHS Scotland.

The report recommends that an interim decision from the SMC be introduced that will recommend treatments for use “subject to ongoing evaluation and future reassessment”. This will help to ensure that
NHS money is spent on effective treatments. To reflect the complexities in assessing value for money for these treatments, the review recommends that a sophisticated approach to assessing outcomes is required that would extend beyond traditional metrics to include real world data, patient reported outcomes and wider societal benefit. The report recognises that the development of these metrics is no easy task, indeed, efforts to assess wider societal impact to assessments in England were abandoned.

Reference is also made in the review to the need for earlier consideration of affordability and it recommends that exploration of patient access schemes, managed access schemes should be undertaken. It also recommends that National Procurement has a bigger role to play in terms of negotiations on the cost of new medicines. Ongoing review of capacity and demand should also support NHS Scotland to address any potential issues in advance.

Given the current financial environment, the decision to make greater consideration of sustainability and affordability is to be expected. Criticism made of the cancer drugs fund process included a failure to fully evaluate how the funds were being spent and the arrangements for an interim recommendation are similar to those being taken forward in England. MAP BioPharma would recommend that any changes in approach towards pricing and affordability should be closely monitored – although it is important that the NHS secures value for money, these recommendations should not open the door to arbitrary restrictions as have been seen south of the border.

3. Other recommendations

Aside from these major focus areas, a number of other issues were raised in the report. These include:

- Recognition of overarching challenges relating to data, with no comprehensive system in place to monitor use of or assess the impact of treatments funded via the Individual Patient Treatment Requests (IPTR) or PACS in particular. A number of recommendations consider the need for better data and monitoring through use of electronic prescribing for example. A multi-agency taskforce will be established to take forward these issues
- Concerns about how the SMC uses the welcome Patient and Clinical Engagement (PACE) process to inform its final decisions. The report recommended that the SMC reviews its communications processes to support greater transparency in its decision-making process
- The need to look ahead to developments such as personalised and genomic medicine to ensure that the definitions and approaches used in Scotland are fit for purpose

Efforts to improve data, transparency and horizon scanning are welcomed by MAP BioPharma. Steps to increase stakeholder understanding and participation in these processes will help to support a robust system and should ensure timely and appropriate access to medicines

Non-routine access arrangements

Although significant detail is not provided, the Scottish Government’s press release states that the PACS for ultra-orphan medicines has been successfully rolled out and will be maintained across Scotland.

Alongside this, a second tier PACS will be introduced to replace the Individual Patient Treatment Request (IPTR) system for all other medicines. A new national appeals process will be introduced as part of this, which “will include equity of access with other parts of the UK as a material part of its decision-making process”. The new process will not consider cost-effectiveness.

It is difficult to assess the full impact of these proposals before full policy is made available but MAP BioPharma’s initial comments are that:
• The focus on clinical expertise for all non-routine applications for funding is welcome, along with
the decision that the tier two PACS process will not consider cost-effectiveness – this should support
a flexible system
• Reference to using access mechanisms across the UK as a reference point could be good in some
areas but potentially restrictive in others. For example, if the NHS in England is choosing to delay
or restrict access on the basis of affordability, the NHS in Scotland might decide to follow a similar
path. On the positive side, a positive NICE appraisal for a particular treatment would make it
difficult for the system in Scotland to decline a particular application
• We hope that by replacing the IPTR system with the PACS, the Scottish Government will take steps
to ensure that there is equal access to treatments between NHS Boards in Scotland

Next steps
There are a number of recommendations that will be taken forward by the Scottish Government to
implement these changes and MAP BioPharma will be monitoring as further details become available. Given
that a number of taskforce groups are mentioned, there may be a possibility for active engagement in the
development of these policies.