RESPONSE TO THE HEALTH AND SPORT COMMITTEE INQUIRY INTO ACCESS TO NEW MEDICINES

Overview

The Scottish Government welcomes the systematic, rigorous and consensual approach of the Health and Sport Committee in their inquiry into access to new medicines. We believe that in responding to the issues raised through the Committee, and through the independent expert reviews by Professors Routledge and Swainson, that there is an opportunity to build on the Committee’s consensus and to shape our access to new medicines for the future.

Our shared ambition with the Committee is to improve access, within the NHS in Scotland, to newly licensed medicines that represent the best in therapeutic value and outcomes, allowing patients to achieve improved health gain and lead enriched lives.

Scottish Government Consultation and Stakeholder Engagement

The Scottish Government sought feedback on the Health and Sport Committee’s recommendations from those who provided evidence to the Committee and from other stakeholders who have expressed an interest in this area. Feedback was obtained through written responses; face to face meetings; and a stakeholder event involving industry, patient representative organisations and the Scottish Medicines Consortium (SMC). The face to face meetings included a meeting with clinicians and separate meetings with families who have had recent experience of the IPTR process.

Whilst the timescale for the consultation was challenging, the Scottish Government received good engagement and a willingness to contribute constructively.

Themes Emerging from the Consultation

We identified the following key themes that stakeholders agreed they would wish to see running through the response to your Committee:

- transparency to aid understanding;
- equity of approach across Scotland;
- person-centred approach;
- additional tools for SMC to look at issues such as burden of illness and wider assessment of value;
- sustainability;
- timeliness;
- a clear clinical focus in IPTRs with appropriate patient support and communication.
The Scottish Government’s response to the Health and Sport Committee’s report reflects the feedback received. The Health and Sport Committee’s comments on recommendations from Professors Routledge and Swainson have been grouped together under the following broad headings:

- Value-Based Assessment
- Getting Different Outcomes from the SMC through a Broader Assessment of Value
- Transparency and Public Engagement
- Implementation of SMC “Accepted” Advice – NHS Board ADTCs and Formulary Management
- Special Circumstances where a National Approach May be needed
- Local NHS Board Consideration of SMC “Not Recommended” Advice for Individual Patients or Cohorts of Patients (Replacement of the Individual Patient Treatment Request Process)
- Research Opportunities within the NHS in Scotland

**Value-Based Assessment**

**Context**

The UK Government published “The Coalition: our programme for Government”\(^1\) on 20 May 2010 which set out the UK Government’s intention to reform arrangements of the pricing of branded medicines and to introduce a new system of value-based pricing when the current Pharmaceutical Price Regulation Scheme (PPRS) expires at the end of 2013. Medicines’ pricing is a matter currently reserved to the UK Government.

The Department of Health’s published Impact Assessment for VBP at consultation stage\(^2\) describes the impact of change in price-negotiation roles as follows:

> “Under the current system, companies propose a price for their products and the government – through the authority devolved to commissioners – decides whether to accept or reject this offer. In VBP, the government will arrive at a “fair” price for a product, based on its value to patients, and it will be for companies to decide whether to accept this (and price at or below this level) or to decline to supply the product…”

The UK Government’s publication “The Coalition: our programme for Government” also set out their proposals to introduce a Cancer Drugs Fund which was positioned as a “bridge” to VBP.

**Health and Sport Committee Recommendations**

The Committee heard evidence from the UK Government’s Department of Health lead official on Value Based Pricing (VBP), who alluded that VBP had been reshaped and would no longer relate to medicines’ pricing, but would instead be a reshaping of the Health Technology Assessment (HTA) model employed by the National Institute for Health and Clinical Excellence (NICE) in its appraisal of new medicines.


While medicines pricing is reserved, medicines assessment is devolved. In the space of one short evidence session, it appeared that the common understanding of VBP had changed, and it now may be within the competence of the Scottish Government. The Committee consequently called for urgent clarity on the matter (Paragraph 100 of the Report).

The Health and Sport Committee were of the view that, subject to confirmation that Scotland can undertake value-based assessments, Professor Routledge’s recommendation (Recommendation 8) that NHSScotland explore the ways in which the expertise available within the SMC could be used to support the process of value based pricing presented an unique opportunity to develop a Scottish solution which could provide greater flexibility than the current arrangements (Paragraph 104 of the Report).

The Committee also indicated that a value-based assessment model could facilitate NHSScotland to gain access to innovative medicines at a more favourable cost than is currently the case and also secure related clinical trial and post-licensing data benefit (Paragraph 106 of the Report).

**Scottish Government’s Response**

The Devolved Administrations asked for observer status at the Pharmaceutical Price Regulation Scheme (PPRS) negotiations between the UK Government and the Association of the British Pharmaceutical Industry (ABPI). This request was rejected by the UK Government and the Devolved Administrations were therefore put at a disadvantage.

Scotland will, in response to the Committee’s recommendations, develop a value-based approach to SMC’s assessment, incorporating issues such as burden of illness and wider societal impact.

This will be incorporated into the revised way of working by the SMC and, in response to the Committee’s recommendations elsewhere in the report the “pause” in the SMC process will be used where further discussion with the pharmaceutical company is needed on cost-effectiveness.

Although the PPRS negotiations are ongoing, value based pricing will not be delivered, and we are firmly of the view that value-based assessment is wholly within the powers of the Scottish Government and the Scottish Parliament.

We will now work to develop a Scottish model of value, and we will discuss with stakeholders how this new model of assessment will be evidenced and devised.

**Getting Different Outcomes from the SMC through a Broader Assessment of Value**

**Use of QALYs in SMC Appraisal - Context**

To conduct a comparison of health gains across a range of medicines and treatments, it is necessary to measure and quantify benefits from the new treatment relative to existing treatments. Many HTA systems, like the SMC, employ a model which centres on the establishment of a common unit of health benefits. The most prevalent unit of health benefit is the Quality Adjusted Life Year (QALY).
In SMC, QALYs provide the basis for discussion about individual medicines by the Committee; the QALY alone does not determine the decision reached. A cost per QALY of under £20,000 is generally considered acceptable value. For a medicine with a cost per QALY between £20,000 and £30,000 SMC might accept this if the medicine gives significant benefits over existing treatments. In addition, SMC has a number of factors that can be applied to medicines with a cost per QALY above £30,000 to allow their approval in some cases. SMC calls these Modifiers.

The Scottish Government introduced a £20 million Rare Conditions Medicines Fund (RCMF) for 2013/14 from 1 March 2013 on the basis of an interim recommendation from Professor Swainson.

**Health and Sport Committee Recommendations**

The Health and Sport Committee called on the SMC and the Scottish Government to review, as a matter of priority, how modifiers and thresholds are applied to take better account of orphan; ultra-orphan conditions; end of life and innovation; and to bring a higher degree of transparency (Paragraph 71 of the Report).

Whilst there were no recommendations from Professor Routledge or Professor Swainson regarding cancer medicines, the Health and Sport Committee notes that its evidence found little support for the establishment of a Cancer Drugs Fund in Scotland. The Committee also notes that criticism of the Cancer Drugs Fund was to an extent its focus on one particular disease category, bypassing the cost effectiveness and regular NICE procedures (Paragraph 85 of the Report).

The Health and Sport Committee welcomed Professor Routledge’s recommendation (Recommendation 5) for the SMC to develop a policy specifically related to ultra-orphan medicines to guide a process to consider all available evidence relevant to its advice on such medicines. The Committee recommended that the Scottish Government urgently address this with particular effort to review and consolidate the system of modifiers to take account of the factors specific to orphan and ultra-orphan medicines and to increase transparency and clarity in relation to their use (Paragraph 75 of the Report).

The Committee welcomed the decision to establish a £20 million Rare Conditions Medicines Fund (RCMF) which provides increased access for some patients suffering from orphan and ultra-orphan conditions, to medicines not accepted for use by the SMC (Paragraph 77 of the Report). This was based on Professor Swainson’s interim recommendation and further recommendation (Recommendation 12) that the Rare Conditions Medicines Fund should focus on access to medicines for ultra-orphan diseases and that access should be supported where the SMC had published “not recommended” advice after a full submission and after a successful IPTR or GPTR had been agreed.

The Committee further noted the time limited nature of the Fund for 13 months, and called on the Cabinet Secretary to update the Committee on how the Fund arrangements are expected to mesh with the development of Value-Based Pricing (Paragraph 80 of the Report).
Scottish Government’s Response

The Committee recognised that existing cost-effectiveness thresholds are not always appropriate for end of life medicine or for medicines to treat very rare diseases. The Cabinet Secretary has therefore directed the SMC to apply different approaches in the evaluation of these medicines, including a rapid review of the wider aspects of value and QALYs in order to increase access to patients to these medicines. The SMC has already begun this work and will report their finding to the Cabinet Secretary before Christmas.

This is the first step in a wider process to determine Scotland’s requirement to a Value-Based Approach to Assessment. The question of how innovation should, or could, be considered in the new medicines assessment system in Scotland will be taken forward in the Scottish Model of Value.

Pending the introduction of Value-Based Assessment, the Scottish Government Will continue the Rare Conditions Medicines Fund to assist NHS Boards meet the high costs of the specified medicines until at least April 2016. This action will ensure the interim system (of medicines appraisal) is given time to establish itself and for the Scottish Model of Value to be developed.

Transparency and Public Engagement

Transparency

The Health and Sport Committee accepted the recommendation from Professor Routledge (Recommendation 1) that the SMC should meet in public (Paragraph 55 of the Report). Whilst the Health and Sport Committee, did not directly comment on recommendations 2 and 3 from Professor Routledge:

- to invite the manufacturer of a new medicine to give evidence at the main SMC meeting (Recommendation 2); and

- that the SMC should be able to appraise any new medicine which the NHS in Scotland considers potentially of major importance but for which the manufacturer has chosen not to submit clinical and cost-effectiveness evidence within 12 weeks of the medicine’s launch in the UK (Recommendation 3).

The Committee generally welcomed proposals to improve transparency but acknowledged that these would do little to change decision-making and identified the need to ensure the SMC process in the first instance better assesses the cost-effectiveness of medicines as a key challenge (Paragraph 56 of the Report).

Scottish Government’s Response

The Scottish Government supports an approach whereby the SMC holds its meetings in public and will instruct the SMC to work on a transition to allow the first public meeting to take place in May 2014.
The Scottish Government supports an approach whereby a representative from the manufacturer of a medicine being appraised, may attend the SMC meeting to answer any questions the Committee may have on the evidence submitted.

The Scottish Government is also supportive of the SMC (working with ABPI) to meet with manufacturers prior to a submission for a newly licensed medicine. This would provide an opportunity to secure a high quality submission first time around.

The Scottish Government expects pharmaceutical companies who wish to have their medicines prescribed within the NHS in Scotland to comply with the submission arrangements as set out by the Scottish Medicines Consortium.

However, if a submission is not received by the SMC for a medicine that they judge to be potentially of clinical importance to the NHS in Scotland, the Scottish Government is supportive of the SMC commissioning an independent evaluation of publicly available information about the medicine in question to use as a basis for an SMC appraisal.

The significant increase in scope for the SMC will be underpinned by a further investment of £1 million per annum.

### Engagement with Patients and the Public

The Health and Sport Committee broadly accepted Professor Routledge’s recommendation (Recommendation 6) to establish a “Citizen’s Council” or “Citizen’s Jury” to explore views around societal issues of importance to the people of Scotland but noted the caveats mentioned by witnesses and recommended that this be approached cautiously (Paragraph 66 of the Report).

The Committee called on the Scottish Government to consider plans for Citizen’s Juries and provide more detail on how it expects them to work in practice to ensure that they improve the process (Paragraph 67 of the Report).

The Health and Sport Committee noted Professor Routledge’s recommendation (Recommendation 7) to explore other opportunities for the SMC to increase patient/public awareness of its role and the need for clear and concise documentation. The Committee’s view was that this recommendation was about relatively minor enhancements intended to improve transparency rather than radical changes to the systems themselves and therefore would do very little to improve access to new medicines in any meaningful way (Paragraph 45 of the Report). Nevertheless, the Committee welcomed the review proposal and identified the need to ensure the SMC process in the first instance better assesses cost-effectiveness of medicines as a key challenge (Paragraphs 55 and 56 of the Report).

### Scottish Government’s Response

During the Scottish Government’s consultation, it became clear that the proposed function of the “Citizen’s Councils” could be met by expanding and supporting the role of the SMC’s Patient and Public Involvement Group (PAPIG) to engage proactively with patient representative organisations and the public on SMC’s work generally rather than limiting this to the SMC.
As part of the PAPIG’s extended role, they will assist in the development of “Plain English” Guides to describe the work of the SMC and NHS Board Area Drug and Therapeutics Committees.

This will ensure patients are able to access improved information, particularly where a medicine which is not available for routine use is requested.

PAPIG will also input to the development of a revamped SMC Annual Report to clearly articulate their work to the public and patients.

Engagement with Pharmaceutical Industry

The Health and Sport Committee welcomed Professor Routledge’s recommendation (Recommendation 4) for the SMC to have a temporary “pause” in the appraisal process at any stage to permit further dialogue with the manufacturer on issues that could be central to subsequent decision-making. The Committee’s view was that it could create an opportunity for discussion on, for example, whether there was scope to develop a reimbursement rate which could take account of various factors such as supplying post-licensing data or assessed benefit post-approval (Paragraph 105 of the Report).

Scottish Government’s Response

The Scottish Government supports the recommendation to introduce a temporary “pause” in the appraisal process which would represent a beneficial step to be instigated by the SMC where the clinical effectiveness of a medicine has been accepted by the SMC but the cost-effectiveness poses a stumbling block to allowing acceptance of the medicine.

The “pause” would facilitate a confidential discussion with the manufacturer, through an external negotiator, about improving the medicine’s cost-effectiveness through a new or improved Patient Access Scheme.

Implementation of SMC “Accepted” Advice – NHS Board ADTCs and Formulary Management

Context

Feedback from stakeholders indicates a clear need for improved communication and transparency of local NHS Board consideration of SMC “accepted” advice and in particular, the need to communicate opportunities that exist for patient and public involvement.
Health and Sport Recommendations

The Health and Sport Committee noted Recommendations 3 and 5 from Professor Swainson:

- 14 NHS Board ADTCs should be retained to maintain alignment of patient and GP interests, safe prescribing and enable NHS Boards to manage their costs and that Regional Clinical Networks could have a role in agreeing equitable access to new medicines in relation to populations (Recommendation 5); and

- The Health and Sport Committee noted Professor Swainson’s recommendation that NHS Board ADTCs should demonstrate engagement with the Patient and Public Forum (PPF) in their work and preferably include at least one member drawn from the PPF on the ADTC (Recommendation 3).

The Health and Sport Committee supported Recommendation 1 from Professor Swainson that NHS Board Area Drug and Therapeutics Committees (ADTCs) should publish their local response on the Board’s website within 30 days of SMC’s published advice on accepted medicines. The recommendation indicated that where further work is required, this should be made clear and final arrangements published within 90 days.

The recommendation further indicated that formulary decisions should be easily accessed by the public and patients in “user friendly” language with established links to the Patients and Public Forum (Recommendation 1).

The Committee’s view was that this recommendation would help to promote consistency and transparency. However, it considered that there may be a further case to be argued that all ADTCs should put new SMC accepted medicines on their formulary within three months whether or not prescribing and clinical guidelines had been fully completed by that time. Clinicians could therefore use their professional judgement on whether to use medicines on a national formulary or to await guidance locally (Paragraph 59 of the Report).

The Health and Sport Committee supported Recommendations 2 and 11 from Professor Swainson that:

- NHS Board ADTCs should publish their formulary decisions and the reason for these in relation to SMC advice to comply with the national guidance set out under SGHD/CMO (2012)1. Professor Swainson recommended that this should be done in a systematic way linking the formulary decision to the published SMC advice and access to this information should be signposted from the Board’s home page on their website and the information kept accurate and up to date (Recommendation 2); and

- the Scottish Government and Boards should produce clear and concise documentation, available on national and local websites, that explains the role of ADTC and IPTR and how the public and patients can be involved, and provides links to ADTC and IPTR published information (Recommendation 11).

However in response to these, the Committee indicated that there may also be arguments not yet explored in favour of a smaller number of ADTCs or even a single national body (Paragraph 62 of the Report).
Special Circumstances where a National Approach May be Needed

Context

In certain circumstances, there may be a need to make decisions at a national level for implementation of SMC “accepted” medicines to reflect the key clinical importance of such medicines.

Health and Sport Committee Recommendations

The Health and Sport Committee noted Professor Swainson’s recommendation (Recommendation 4) that NHSScotland should consider a national meeting of all relevant specialists to explore and agree a national implementation for some new medicines accepted by the SMC that meet agreed criteria. These could include novel, first in class medicines where there is uncertainty of its place in therapy. Healthcare Improvement Scotland (HIS) should continue to audit access to new medicines compliance with national guidance set out under CEL 17 (2010) and SGHD/CMO(2012)1. However, the Committee indicated that there may also be arguments not yet explored in favour of a smaller number of ADTCs or even a single national body (Paragraph 62 of the Report).

Scottish Government’s Response

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 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.

The Scottish Government supports the recommendation that NHS Board ADTCs should demonstrate engagement with the Patient and Public Forum (PPF) in their work and, indeed, our recommendation goes further to say that each ADTC should have two members of the PPF involved.

The Scottish Government supports the NHS Board publication of their local response on the Board’s website within 30 days of SMC’s published advice where this is possible. Where further work is required, NHS Boards are expected to publish their response within 60 days of SMC’s published advice.

The Scottish Government supports the recommendation that NHS Board ADTCs should publish formulary decisions and the reason for these in relation to SMC advice in a systematic way, linking the formulary decision to the published SMC advice. The Scottish Government supports open and transparent access to this information for patients and the public via clear signposting from the Board’s home page on their website with the information kept accurate and up to date.
The Scottish Government supports the recommendation that clear and concise information about local NHS Board consideration of SMC advice should be made available to patients and the public, including opportunities for patient/public involvement in such decision-making and providing links to published information.

The Scottish Government supports decision-making at national level for the implementation of certain medicines of key clinical importance though discussion and agreement of the relevant specialists within NHSScotland to ensure clinical outcomes for patients in all parts of Scotland are optimised.

The Scottish Government supports the Healthcare Improvement Scotland audit of NHS Board ADTC compliance with national guidance.

Local NHS Board Consideration of SMC “Not Recommended” Advice for Individual Patients or Cohorts of Patients (Replacement of the Individual Patient Treatment Request Process)

Context

The Scottish Government is supportive of introducing robust auditing of NHS Board decision-making about SMC “not recommended” medicines for individual patients or groups of patients through Healthcare Improvement Scotland, and for the results to be published in an anonymised way in line with data protection requirements. This audit process will begin following decisions taken under the new arrangements set out below.

The Individual Patient Treatment Request (IPTR) process was established in April 2011 to recognise that not all patients will respond to medicines in the same way and to acknowledge that SMC “not recommended” advice, which was based on the results of a patient population, may not be appropriate for an individual patient because of their particular clinical circumstances.

The IPTR arrangements were never intended to be an alternative route to accessing such medicines on a regular basis; rather it was an attempt to articulate that the SMC “not recommended” advice did not mean an absolute and final block on medicines where clinicians believed there was clinical evidence to suggest an individual patient might achieve a clinically significant benefit.

Health and Sport Committee Recommendations

Whilst the Health and Sport Committee did not make any specific comments on Recommendations 9 and 10 from Professor Routledge and Recommendations 6, 7, 8, 9, and 10 from Professor Swainson, they generally welcomed review proposals regarding improving transparency (Paragraph 55 of the Report):

- Professor Swainson’s recommendation (*Recommendation 6*) that all NHS Boards should have the same IPTR paperwork and process based on examples by NHS Greater Glasgow & Clyde and NHS Lothian.

- Professor Swainson’s recommendation (*Recommendation 7*) that NHS Board IPTR arrangements should be audited by Healthcare Improvement Scotland (HIS) to
assess compliance with guidance and consistency of application and to publish the results.

- Professor Swainson’s recommendation (Recommendation 8) that NHS clinicians should be provided with basic training and guidance on the IPTR process locally. Clinicians who are uncertain or inexperienced should be able to access specialist advice and support.

- Professor Swainson’s recommendation (Recommendation 9) that all NHS Boards should consider whether IPTR panels should include a member of the public drawn from the Board’s Patient and Public Forum (PPF). Members would require training and support.

- Professor Swainson’s recommendation (Recommendation 10) that all doctors considering an IPTR must be able to access consistent, knowledgeable support for their patients. National Services Division should establish and maintain a register of approved specialists to support IPTR. One specialist may be sufficient for orphan and ultra-orphan diseases, but more than one specialist may need to be available for more common diseases or variants and on a regional basis. The model of cancer networks is an example.

- Professor Routledge’s recommendation (Recommendation 9) that a register of IPTR decisions should be established (suitably anonymising patient details) and supporting information on IPTRs to be shared between NHS Boards.

- Professor Routledge’s recommendation (Recommendation 10) that there should be regular sharing of expertise between IPTR panels across NHSScotland with opportunities to meet at least annually for induction; feedback and training.

The Committee remained concerned about the requirement that IPTRs for orphan and ultra-orphan conditions was proving the exceptionality of patients’ circumstances which is difficult in such small patient numbers. They indicated that this is believed to be a barrier for access to medicines that clinicians believe their patients need. The Committee called on the Scottish Government to outline the steps it plans to take to improve the process (Paragraph 57 of the Report).

The Committee further recommended that the Scottish Government should review and analyse previous IPTR decisions and look to improve monitoring of applications and consistency of future decisions. The number of applications, negative and positive decisions, among other relevant details should be published regularly (Paragraph 58 of the report).

The Committee noted that there may be arguments that have not, so far, been fully explored - particularly in relation to IPTRs such as a national treatment request body to ensure a both consistent application of IPTR and GPTR criteria as well as consistency in decision-making. This is particularly important in relation to IPTRs for orphan or ultra-orphan conditions where the clinical expertise of these is not available within particular localities or perhaps not in Scotland at all (Paragraph 62 of the Report).

However, the Committee remained concerned about the criteria to be applied when considering IPTRs and believes that urgent consideration should be given to encouraging greater flexibility in the IPTR process to approve drugs where there is clear, clinical evidence
that a particular patient would derive material benefit from such a drug even if the existing IPTR criteria had not been met fully (Paragraph 89 of the Report).

**Scottish Government’s Response**

The Scottish Government believes that the introduction of value-based assessments of new medicines and the new interim arrangements (to be applied in the assessment of cost-effectiveness for newly licensed medicines to treat end of life situations and orphan/ultra-orphan medicines licensed to treat very rare conditions) will significantly reduce the current dependence on Individual Patient Treatment Requests (IPTRs).

The Scottish Government believes that the procedure for accessing drugs in exceptional prescribing circumstances, when all other treatments have been exhausted, should be clearly linked to clinical opinion. Therefore the Scottish Government is replacing the IPTR/GPTR system with a new system of “Peer Approved Clinical System” (PACS).

The new PACS guidance will be issued shortly and will clarify that there is a single, national system to be applied locally, and this will be clinically led. Variation in approach to such decision-making will be minimised through strict auditing arrangements.

The Scottish Government has listened to the concerns raised about the criteria associated with the IPTR process. In recognition of these, the new PACS system facilitates a peer review approach to access SMC “Not Recommended” medicines for individual patients based on the anticipated clinical outcome for an individual patient.

The new guidance will introduce, as a requirement, standardised application forms for NHSScotland.

It will set out clear parameters for expected deadlines for decisions in relation to requests.

The Scottish Government is supportive of establishing a centralised patient support team to act as adviser; support and advocate for patients and families involved in requests for SMC “not recommended” medicines, or those not yet appraised.

The Scottish Government supports the establishment of a robust central collection of NHS Board data related to decisions about applications to prescribe SMC “not recommended” medicines. This will provide aggregated information only on an annual basis to ensure that patient confidentiality is maintained.

The Scottish Government is supportive of introducing robust auditing of NHS Board decision-making about SMC “not recommended” medicines under the new PACS system for individual patients or groups of patients through Healthcare Improvement Scotland and the results to be published in an anonymised way.

The Scottish Government supports the development of training materials for NHS clinicians and the introduction of training and guidance on the new “Peer Review” approach to local NHS Board consideration of SMC “not recommended” medicines.
for individual patients or groups of patients.

Improved information will be developed for patients, their families and carers in order that they know what to expect at each stage of the PACS. This will receive input from PAPIG and will replace the existing guidance available through the Health Rights Information Scotland website.

The Scottish Government supports the availability of specialist clinical advice via a register of clinical specialists to assist local NHS Boards in consideration of SMC “not recommended” medicines for individual patients or groups of patients.

The Scottish Government supports the regular sharing of expertise between NHS Boards across Scotland with opportunities to meet at least annually for induction; feedback and training. This will be facilitated by Healthcare Improvement Scotland as part of their Audit role.

Research Opportunities within NHSScotland

Whilst there were no recommendations from Professor Routledge or Professor Swainson regarding the availability of research opportunities within NHSScotland, the Health and Sport Committee noted industry concerns that there had been a reduction in the research access and spend in Scotland by the pharmaceutical industry.

The Committee called on the Scottish Government to urgently investigate and report back to the Committee on whether there is a decline in the number of Phase III trials placed in Scotland and consider any steps that may be needed to increase their number as well as maximising the overall number of clinical trials (Paragraph 96 of the Report).

The Committee also recommended that NHS Boards take a more systematic approach to collating and updating data on clinical trials (both national and international) with a view to facilitating greater access to participation in such trials for patients in Scotland where appropriate (Paragraph 97 of the Report).

Scottish Government’s Response

The Scottish Government has not been presented with any robust evidence to suggest a decline in Phase III commercial clinical trials being placed in Scotland. We will though explore the subject further to determine if there is a diminution in the number of Phase III trials for particular conditions.

The Scottish Government believes that there may be scope to increase the number of trials conducted in Scotland and NHS Research Scotland (NRS) will be working closely with the pharmaceutical industry to improve the efficiency and effectiveness of the NHS clinical research offering. NRS has invested heavily in infrastructure to support both current and future research needs.

The Scottish Government Chief Scientist Office will also explore the creation of a Scottish clinical trial register to raise patient and clinician awareness of ongoing
clinical trials and allowing them to express an interest in participating.

8 October 2013