Access to newly licensed medicines
ABPI Scotland

Thank you for the opportunity to present evidence to Tuesday’s Health and Sport Committee session on access to medicines in Scotland. It proved to be an interesting debate, however we were disappointed that the NHS representation at the committee was comprised entirely of individuals from health technology assessment (HTA) or medicines management who asserted that HTA and medicines management systems worked perfectly. As you pointed out, clinicians’ views expressed in the written evidence and MSPs experience of discussing the issues with their constituents would suggest otherwise.

SMC should be rightly proud of the speed and efficacy of their processes, but this does not equate to speed of access to new medicines in Scotland. When a patient can get the medicine they need should be the arbiter of rapid access, not how quickly our HTA process works. If a patient’s and/or clinician’s experience is one of delay, further equivocation and additional layers of local decision making then it negates the benefits of the SMCs rapid HTA.

In listening to Tuesday's debate there were a number of issues that the Committee seemed to be interested in pursuing and that perhaps warrant further discussion. These were:

1. A wider assessment of value and scrutiny

A number of committee members and witnesses referred to the pressing need for a wider definition of value in health technology assessment, particularly in the context of the integration of health and social care and the challenges faced by our healthcare system. ABPI would support the creation of a working group led by SMC to evaluate options for the wider assessment of value and alternatives to the sole use of the QALY in assessment of certain categories of medicines where the limitations of the QALY have been recognised.

**Recommendation:** Creation of a short life working group on the wider assessment of value.

The industry recognises the need for Heath Technology Assessment to assess the cost effectiveness of new medicines. Many of the committee and witnesses also acknowledged that to ensure patients in Scotland get the most benefit for every pound spent on health care similar scrutiny should be applied to all NHS spending decisions.

2. Decision making post SMC acceptance

A number of the committee recognised that from the patient’s perspective further rounds of repetitive analysis, decision making and bureaucracy was
impossible to justify. ABPI would support the removal of additional hurdles to access for SMC accepted medicines.

A number of witnesses informed the committee that GP’s were able to prescribe medicines before the medicine was added to the local formulary. The same witnesses also indicated there is near 100% formulary compliance. It is unlikely that these two statements are compatible. Although legally clinicians have the right to prescribe the medicines they feel are in the best interest of their patients, in reality administrative barriers and pressure from Boards not to prescribe off formulary makes it very unlikely. There also seemed to be some confusion over the role of local decision making bodies in assessing the safety of a medicine. It should be made clear that the EMEA grants licences to new medicines that have proven their safety and efficacy. The on-going monitoring of safety issues (pharmacovigilance) is then managed by the MHRA.

**Recommendation:** The committee should explore the removal of further, local decision making on access on medicines that are already SMC accepted as cost effective.

3. Impact of SMC decisions on clinical trials in Scotland

The committee, witnesses, written evidence from various groups and the clinicians published in the Scotland on Sunday on 16th September acknowledged that our failure to use new medicines which become internationally recognised standard treatment negatively impacts on Scotland’s ability to conduct clinical research. Bodies like SMC require comparators to be the standard care, if Scotland is not using these medicines, pharmaceutical are not able to place trials in Scotland. Not only does this have significant negative economic impact, there is a strong body of evidence that patients outcomes are improved in areas where clinical research is conducted. Furthermore, without clinical trials our ability to retain, develop and attract the best clinical research talent is compromised. ABPI would be happy to furnish the committee with further evidence from pharmaceutical companies on the criteria for placing clinical trials.

4. Communication

The committee’s desire to see further improvements in communication was welcomed. CEL 17 has been in place since 2010 so the variance in communication around Board decision making is difficult to justify. Both industry and patient groups are not seeking anything new here, simply that the commitments given in CEL 17 and subsequent updates are met.

5. Metrics on access and uptake of new medicines

Both industry and NHS witnesses agreed that metrics on access and uptake would be a useful tool in helping to develop future practice. Based on the principle of what gets measured gets done, ABPI would welcome
the introduction of metrics to assess the uptake of new, SMC approved medicines across Scotland.

**Recommendation:** NHS Boards produce metrics on uptake of SMC approved medicines and adherence to CEL 17.

6. IPTRs

There seemed to be some agreement that processes around IPTRs continued to lack consistency and transparency and that the submission criteria would benefit from review. In our submission and in evidence we referred to the conclusions of a multi-disciplinary short life working group on IPTR. We are pleased to share for the Committee’s attention a letter on these findings recently submitted to the Cabinet Secretary for Health

Thank you once again for the committee’s time in considering the issue of access to medicines in Scotland and if we can be of any further assistance to you or the wider committee please do not hesitate to contact me.

**ABPI Scotland**

20 September 2012
Dear Cabinet Secretary

The IPTR process in NHSScotland

I am writing to update you on a meeting that recently took place on Individual Patient Treatment Request (IPTR) arrangements at the instigation of ABPI Scotland.

The aim of the meeting was to discuss the continuing concerns among ABPI member companies about the IPTR process, and to understand better the situation by speaking to other stakeholders. These other attendees included clinicians, pharmacists, a public partner, third sector groups and representatives of the research-based medicines sector.

While many of ABPI Scotland’s members have had concerns about how the IPTR process has been working in practice, further confusion as to the role of the IPTR process may have been created by the First Minister’s comments to the Scottish Parliament, during FMQs on March 15th 2012, where he intimated that the Scottish Government believes the IPTR route can make medicines available for patients in most cases:

“Even for medicines that are not approved by the SMC, it is not the case that they cannot be made available to patients in Scotland. We have the process of individual patient treatment requests. Through that process, 126 medicines not yet approved by the SMC have been requested in NHS Scotland. Of those requests, 87 have been approved, and 39 have not.”

While we do not dispute these figures, this statement is contrary to the experiences of our members, and we were keen to assess the views of other stakeholders who work with the IPTR process.

The group was in general agreement that the function and expectations of the IPTR process are unclear, with its role apparently meaning different things to different people. This has led to a situation where many patients, and in some
cases, their MSPs, believe that the IPTR process is in effect an appeals process for medicines not accepted for use by SMC in Scotland, a process whereby the patient can access the medication for the indication which has been turned down by SMC. It is the view of the group that this is a commonly held misunderstanding of the process.

There was also general agreement that it would be useful to come up with some ideas for initiatives that might help to improve the situation, both in the way that the IPTR process works on the ground and how it is understood by patients and other stakeholders.

We would like to share our ideas with you and your officials, in the hope of working together to take them forward. We would suggest that there is a need for:

- Additional clarity on access to medicines other than via the IPTR route; i.e. out-of-license use for rare diseases or off-label use (where a medicine is used for a purpose not included in its original license).
- Clarity on the wording of guidance on IPTRs - It needs to be clear exactly what situations IPTRs are for and what they are not for; and also how they are assessed.
- A national quality review panel, not to review individual IPTRs, but as a way to review how well the processes are working and to keep check on regional variation. This group should have a transparent membership, a patient representative and should publish top-level data as a means of driving-up standards. It should look for equitable processes and decisions across both approved and non-approved requests.
- An objective, transparent scoring system as a means of assessing IPTRs and their validity, to ensure uniformity and fairness across illness areas and geographically.
- The establishment of benchmarks from across Scotland of where we are with IPTRs; what is working and what is not. This would help to identify areas of good and bad practice and create a baseline.
- The sharing of best practice across Scotland.
- Information and training on the system – for all participants in the system, which should also be available to patient groups, MSPs and the pharma industry.
- Clarity on who sits on IPTR panels.
- More engagement with patient groups and decision makers. The justification for a decision is an important factor in that decision being accepted by patients, and for that decision to be seen as fair and consistent.

All those who input into the meeting are committed to working constructively to improve the IPTR process and make sure it works as well as it possibly can. We hope therefore to have further discussions as to the viability of our proposals, and to offer any help in implementing them that we are able to and would be grateful if you would ask your team to meet us so we can examine these proposals with them.
Yours sincerely

Fiona Hamill, Chair, ABPI Scottish Life Sciences Group
(On behalf of the Short Life Working Group)

**The attendees at the meeting were:**

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<th>Name</th>
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<tr>
<td>Fiona Hamill</td>
<td>Chair, ABPI Scottish Life Sciences Interest Group</td>
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<tr>
<td>Tracey Bowden</td>
<td>ABPI Scottish Life Sciences Interest Group</td>
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<td>Alison Culpan</td>
<td>ABPI Scottish Life Sciences Interest Group</td>
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<tr>
<td>Dr Robert Jones</td>
<td>Senior Lecturer and Honorary Consultant in Medical Oncology</td>
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<tr>
<td>Dr Janet Graham</td>
<td>Consultant Medical Oncologist</td>
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<tr>
<td>Mark Parsons</td>
<td>Principal Clinical Pharmacist</td>
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<tr>
<td>Mrs Helen Cadden</td>
<td>Public Partner, PAPIG, SMC</td>
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<tr>
<td>Natalie Frankish</td>
<td>Rare Diseases UK Scotland</td>
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**Unable to attend the meeting, but party to the discussions and the agreements were:**

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<tr>
<td>Dr Mark Drummond</td>
<td>Honorary Clinical Senior Researcher</td>
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<td>Professor Tessa Holyoake</td>
<td>Professor of Experimental Haematology</td>
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<td>Dr Duncan McLaren</td>
<td>Lead Clinician for GU Chemotherapy &amp; Radiation Trials</td>
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<tr>
<td>Dr Mhairi Copland</td>
<td>Clinical Senior Lecturer and Honorary Consultant</td>
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