NHS Health Board responses to Questionnaire on Access to newly licensed medicines and Individual Patient Treatment Requests (IPTRs)

**NHS Ayrshire and Arran**

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>How many individual patient treatment requests did the board receive in 2011/2012?</td>
<td>In 2011/12 NHS Ayrshire &amp; Arran received 39 individual patient treatment requests.</td>
</tr>
<tr>
<td>2</td>
<td>How many individual patient treatment requests has the board received to date in 2012/2013?</td>
<td>From 1&lt;sup&gt;st&lt;/sup&gt; April 2012 until 30&lt;sup&gt;th&lt;/sup&gt; June 2012 NHS Ayrshire &amp; Arran received 19 individual patient treatment requests. (Total amended from 16. 12/09/12)</td>
</tr>
<tr>
<td>3</td>
<td>How many of the individual patient treatment requests received by the board were approved in 2011/2012?</td>
<td>22 (56%) individual patient treatment requests in 2011/12 were approved.</td>
</tr>
<tr>
<td>4</td>
<td>How many of the individual patient treatment requests received by the board have been approved to date in 2012/2013?</td>
<td>13 (68%) of individual patient treatment requests have been approved between 1&lt;sup&gt;st&lt;/sup&gt; April 2012 and 30&lt;sup&gt;th&lt;/sup&gt; June 2012.</td>
</tr>
<tr>
<td>5 (a)</td>
<td>How many of the individual patient treatment requests received by the board were rejected in 2011/2012?</td>
<td>17 (44%) individual patient treatment requests considered in 2011/12 were rejected.</td>
</tr>
<tr>
<td>5 (b)</td>
<td>What reason was recorded for rejecting these requests?</td>
<td>The patient’s circumstances were not considered to be significantly different from the general population of patients covered by the medicines licence/population from clinical trials appraised by SMC/NHS HIS.</td>
</tr>
<tr>
<td>6 (a)</td>
<td>How many of the individual patient treatment requests received by the board to date in 2012/2013 have been rejected?</td>
<td>6 (32%) individual patient treatment requests between 1&lt;sup&gt;st&lt;/sup&gt; April 2012 and 30&lt;sup&gt;th&lt;/sup&gt; June 2012 have been rejected.</td>
</tr>
<tr>
<td>6 (b)</td>
<td>What reason has been recorded for rejecting these requests</td>
<td>The patient’s circumstances were not considered to be significantly different from the general population of patients covered by the medicines licence/population from clinical trials appraised by SMC/NHS HIS.</td>
</tr>
</tbody>
</table>

**NHS Ayrshire and Arran**

27 August 2012
<table>
<thead>
<tr>
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<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>How many individual patient treatment requests did the board receive in 2011/2012?</td>
<td>13</td>
</tr>
<tr>
<td>2</td>
<td>How many individual patient treatment requests has the board received to date in 2012/2013?</td>
<td>6</td>
</tr>
<tr>
<td>3</td>
<td>How many of the individual patient treatment requests received by the board were approved in 2011/2012?</td>
<td>11</td>
</tr>
<tr>
<td>4</td>
<td>How many of the individual patient treatment requests received by the board have been approved to date in 2012/2013?</td>
<td>6</td>
</tr>
<tr>
<td>5</td>
<td>a) How many of the individual patient treatment requests received by the board were rejected in 2011/2012?</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>b) What reason was recorded for rejecting these requests?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Applicant to assess whether they are able the level of impact the additional treatment they recommended would have on the patient and if their health has still not improved then to come back to the group.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. More information requested from applicant on number of hospital admissions, the impact on quality of life and what other medical options have been tried.</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>a) How many of the individual patient treatment requests received by the board to date in 2012/2013 have been rejected?</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>b) What reason has been recorded for rejecting these requests?</td>
<td></td>
</tr>
</tbody>
</table>

**NHS Borders**

6 September 2012
NHS Dumfries and Galloway

1. How many individual patient treatment requests did the board receive in 2011/2012? **24**

2. How many individual patient treatment requests has the board received to date in 2012/2013? **8**

3. How many of the individual patient treatment requests received by the board were approved in 2011/2012? **15**

4. How many of the individual patient treatment requests received by the board have been approved to date in 2012/2013? **7**

5. a) How many of the individual patient treatment requests received by the board were rejected in 2011/2012? **9**

b) What reason was recorded for rejecting these requests?
   i) 4 rejected because other treatment options were available
   ii) 5 rejected because application failed to demonstrate exceptionality

6. a) How many of the individual patient treatment requests received by the board to date in 2012/2013 have been rejected? **1**

   b) What reason has been recorded for rejecting these requests?

   Application failed to demonstrate exceptionality

NHS Dumfries and Galloway
10 August 2012
The information from NHS Fife is detailed below:

1. How many individual patient treatment requests did the board receive in 2011/2012?

39 IPTRs were received.

2. How many individual patient treatment requests has the board received to date in 2012/2013?

12 IPTRs were received.

3. How many of the individual patient treatment requests received by the board were approved in 2011/2012?

32 cases were approved.

4. How many of the individual patient treatment requests received by the board have been approved to date in 2012/2013?

8 cases were approved.

5. a) How many of the individual patient treatment requests received by the board were rejected in 2011/2012?

6 cases were rejected.

b) What reason was recorded for rejecting these requests?
Case 1 – Case for exceptionality has not been made. Not approved by SMC.
Case 2 – Not approved by SMC. Not clear that recommended alternatives have been tried.
Case 3 – Case for exceptionality not established. Part of suggested rationale seems to be substitute prescribing for illicit drug use.
Case 4 – On the basis of the limited information provided the Panel felt unable to support.
Case 5 – Case for exceptionality not established. SMC approved alternatives available and not yet tried.
Case 6 – Insufficient information / evidence. Requested further information but none received.

6. a) How many of the individual patient treatment requests received by the board to date in 2012/2013 have been rejected?

1 case was rejected.

b) What reason has been recorded for rejecting these requests?
Case 1 – Exceptionality not established. SMC approved alternatives available in Department Guidelines.

Further additional information:

In 2011 / 2012 1 case was not considered.

In 2012 / 2013 2 cases were withdrawn and 1 case is still awaiting decision

NHS Fife
16 July 2012
1. How many individual patient treatment requests did the board receive in 2011/2012?

April 2011 – March 2012 - 20 requests

2. How many individual patient treatment requests has the board received to date in 2012/2013?

April 2012 – July 2012 – 5 requests

3. How many of the individual patient treatment requests received by the board were approved in 2011/2012?

April 2011 – March 2012 - 17 approved

4. How many of the individual patient treatment requests received by the board have been approved to date in 2012/2013?

April 2012 – July 2012 – 5 approved

5. a) How many of the individual patient treatment requests received by the board were rejected in 2011/2012?

April 2011 – March 2012 - 3

b) What reason was recorded for rejecting these requests?

The patient’s circumstances were not considered to be significantly different from the general population of patients covered by the medicines licence/population from clinical trials appraised by SMC/NHS HIS

6. a) How many of the individual patient treatment requests received by the board to date in 2012/2013 have been rejected?

April 2012 – July 2012 - NONE

b) What reason has been recorded for rejecting these requests?

Not applicable

NHS Forth Valley
12 September 2012
NHS Grampian

1. Many individual patient treatment requests did the board receive in 2011/2012? – 15 (fifteen): NB Number withdrawn has been less than 5.

2. How many individual patient treatment requests has the board received to date in 2012/2013? – 8 (eight)

3. How many of the individual patient treatment requests received by the board were approved in 2011/2012? – 8 (eight)

4. How many of the individual patient treatment requests received by the board have been approved to date in 2012/2013? – Less than 5

5. a) How many of the individual patient treatment requests received by the board were rejected in 2011/2012? – Less than 5.

   b) What reason was recorded for rejecting these requests? – in all cases the first part of decision-making was not proven.
   - limited published peer reviewed evidence; use would not provide an opportunity for cure, long-term remission, significant extension of life or avoidance of permanent disability.
   or
   - patients clinical circumstances are not significantly different to that of the patient group in the trials and the patient would not gain more benefit than the trial cohort.

6. a) How many of the individual patient treatment requests received by the board to date in 2012/2013 have been rejected? – Less than 5.

   b) What reason has been recorded for rejecting these requests?

   1 - not authorised – First part of decision-making not proven: the patient circumstances did not allow the case to be made that Grampian should put aside its general policy not to use a licensed medicine where SMC has yet to provide advice.

| Table 1: NHS Grampian IPTR summary |
|----------------|----------------|----------------|----------------|----------------|
| Period        | Authorised | Not-authorised | Withdrawn | Total |
| 2011/12       | 8          | <5             | <5         | 15   |
| 2012/13 (YTD) | <5         | <5             | <5         | 8    |

NHS Grampian
10 September 2012
NHS Greater Glasgow and Clyde

1. How many individual patient treatment requests did the board receive in 2011/2012?

Between April 1\(^{st}\) 2011 and March 31\(^{st}\) 2012 there were 101 IPTRs submitted for NHSGGC patients.

2. How many individual patient treatment requests has the board received to date in 2012/2013?

Between April 1\(^{st}\) 2012 and July 31\(^{st}\) 2012 there were 28 IPTRs submitted for NHSGGC patients and recorded on the relevant databases. However, it should be noted that there may be some IPTRs that either have not completed due process or have not yet been forwarded for addition to the IPTR database at the time of responding to this request for information.

3. How many of the individual patient treatment requests received by the board were approved in 2011/2012?

58 of the IPTRs submitted in the 2011-12 financial year were approved (57%).

4. How many of the individual patient treatment requests received by the board have been approved to date in 2012/2013?

17 of the IPTRs submitted in the 2012-13 financial year until the end of July 2012 were approved (61%).

5. How many of the individual patient treatment requests received by the board were rejected in 2011/2012?

43 of the IPTRs submitted in the 2011-12 financial year were rejected (43%). Of these, 4 rejected IPTRs were subject to appeal, 2 of which were subsequently approved.

b) What reason was recorded for rejecting these requests?

The reason for rejection was not routinely recorded against the standardised SG terminology in the 2011-12 financial year and the following data in table 1 has been obtained by reviewing the actual submitted IPTRs retrospectively.
<table>
<thead>
<tr>
<th>Documented reason for rejection</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>The patient’s circumstances were not considered to be significantly different from the general population of patients covered by the medicines licence/population from clinical trials appraised by SMC/NHS HIS</td>
<td>36</td>
</tr>
<tr>
<td>The patient’s circumstances were considered to be significantly different, but it was felt this was unlikely to result in a significant benefit gain from this medicine over what would be normally expected</td>
<td>0</td>
</tr>
<tr>
<td>Incomplete form and/or insufficient detail to make an appropriate decision</td>
<td>1</td>
</tr>
<tr>
<td>Other reasons (e.g. failure to try other alternative medicines that would normally be trialled prior to IPTR submission)</td>
<td>6</td>
</tr>
</tbody>
</table>

Table 1: Documented reasons why IPTRs received in the 2011-12 financial year were rejected

6. How many of the individual patient treatment requests received by the board to date in 2012/2013 have been rejected?

11 of the IPTRs submitted between April and the end of July of the 2012-13 financial year were rejected (39%)

b) What reason has been recorded for rejecting these requests?
Of the IPTRs rejected between April and the end of July of the 2012-13 financial year, all 11 were rejected because the patient’s circumstances were not considered to be significantly different from the general population of patients covered by the medicines licence/population from clinical trials appraised by SMC/NHS HIS

NHS Greater Glasgow and Clyde
6 September 2012
NHS Highland

1. How many individual patient treatment requests did the board receive in 2011/2012? 7

2. How many individual patient treatment requests has the board received to date in 2012/2013? 1

3. How many of the individual patient treatment requests received by the board were approved in 2011/2012? 5

4. How many of the individual patient treatment requests received by the board have been approved to date in 2012/2013? 1

5. a) How many of the individual patient treatment requests received by the board were rejected in 2011/2012? 2

b) What reason was recorded for rejecting these requests? 1. Limited evidence supporting efficacy and safety, 2. limited evidence supporting efficacy and safety and not cost-effective.

6. a) How many of the individual patient treatment requests received by the board to date in 2012/2013 have been rejected? none

b) What reason has been recorded for rejecting these requests? Not applicable

NHS Highland
8 September 2012
<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How many individual patient treatment requests did the board receive in 2011/12?</td>
<td>From June 2011 to March 2012 = 34</td>
</tr>
<tr>
<td>2. How many individual patient treatment requests has the board received to date in 2012/13?</td>
<td>April 2012 to thus far in August 2012 = 16</td>
</tr>
<tr>
<td>3. How many of the individual patient treatment requests received by the board were approved in 2011/12?</td>
<td>June 2011 to March 2012 = 17</td>
</tr>
<tr>
<td>4. How many of the individual patient treatment requests received by the board have been approved to date in 2012/2013?</td>
<td>April 2012 to thus far in August 2012 = 8 + 1 in progress due for closure 14.9.12</td>
</tr>
<tr>
<td>5. (a) How many of the individual patient treatment requests received by the board were rejected in 2011/2012?</td>
<td>From June 2011 to March 2012 = 17</td>
</tr>
<tr>
<td>(b) What reason was recorded for rejecting these requests?</td>
<td>• Insufficient information &amp; incomplete detail</td>
</tr>
<tr>
<td></td>
<td>• Other treatment options remain</td>
</tr>
<tr>
<td></td>
<td>• Insufficient information to proceed to panel</td>
</tr>
<tr>
<td></td>
<td>• Medicine not approved for requested use.</td>
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<tr>
<td></td>
<td>• Clinical benefit of non approved treatment not articulated and applications not demonstrated that patients can be considered as having factors that would make them exceptional to the current guidance.</td>
</tr>
<tr>
<td></td>
<td>• Application failed to demonstrate exceptionality in relation to referral criteria</td>
</tr>
<tr>
<td></td>
<td>How many of the individual patient treatment requests received by the board to date in 2012/2013 have been rejected?</td>
</tr>
<tr>
<td>---</td>
<td>-------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| (a) | What reason has been recorded for rejecting these requests? | • Other treatment options remain  
• Insufficient information to proceed to panel  
• Insufficient evidence for panel to reach a decision  
• Treatment not approved for the requested use.  
• Application failed to demonstrate exceptionality in relation to referral criteria |

NHS Lanarkshire  
5 September 2012
NHS Lothian

1. How many individual patient treatment requests did the board receive in 2011/2012?

NHS Lothian received 17 individual patient treatment requests in 2011/2012. This includes all new applications, resubmissions, urgent requests and requests to the IPTR from Cancer Medicines Management Committee for ratification.

2. How many individual patient treatment requests has the board received to date in 2012/2013?

NHS Lothian received 15 individual patient treatment requests in 2012/2013. This includes all new applications, resubmissions, urgent requests and requests to IPTR from Cancer Medicines Management Committee for ratification.

3. How many of the individual patient treatment requests received by the board were approved in 2011/2012?

13 individual patient treatment requests received by the board were approved in 2011/2012.

4. How many of the individual patient treatment requests received by the board have been approved to date in 2012/2013?

6 individual patient treatment requests received by the board have been approved to date in 2012/2013

5. a) How many of the individual patient treatment requests received by the board were rejected in 2011/2012?

4 individual patient treatment requests received by the board were rejected in 2011/2012.

b) What reason was recorded for rejecting these requests?

Please see enclosed reasons recorded for rejecting these requests.

6. a) How many of the individual patient treatment requests received by the board to date in 2012/2013 have been rejected?

9 individual patient treatment requests received by the board to date in 2012/2013 have been rejected

b) What reason has been recorded for rejecting these requests?

Please see enclosed reasons recorded for rejecting these requests.
Applications Rejected 2011/2012

11/0001
This application request was for the prescription of Cannabinoid Oromucosal Spray for the management of Multiple Sclerosis (MS) related spasticity which was not responding to other available treatment options or there were other intolerable side effects. The Panel were advised that Cannabinoid Oromucosal Spray had not been SMC approved as there had not been an application to SMC – the medicine had therefore not been considered by the SMC. Because this medicine had not been considered by the SMC, the Panel noted that there was a lack of evidence and information on this treatment. The Panel noted that this medicine could be prescribed to 6% of MS patients and therefore did not meet the IPTR criteria – that the patient’s clinical circumstances (condition and characteristics) and potential response to treatment were significantly different to the general population of patients covered by the medicines license or the population of patients included in clinical trials for the medicine’s licensed indication appraised by the SMC. Panel members also commented that the patient’s employer could consider making adjustment to reduce pain and fatigue for the employee.

Decision The Panel was unable to support this application for the following reasons. The patient’s clinical circumstances (condition and characteristics) and potential response to treatment were not significantly different to the general population of patients.

11/0004
This application was for the use of an unlicensed medicine where a licensed version exists. The patient had a confirmed diagnosis of Lambert-Eaton Myasthenic Syndrome and had been treated with 3,4-diaminopyridine (3,4-DAP) and pyridostigmine – and had obtained more benefit from 3,4-diaminopyridine (3,4-DAP). The Panel agreed that the clinician could consider submitting an application to the Formulary Committee [FAF3, unlicensed medicines], as it applied to a particular group of patients.

Decision The Panel was unable to support this application but recommended that this treatment for this group of patients, be submitted to the Formulary Committee as a FAF3.

12/002
The Panel discussed the application for the Ross Procedure. The Panel agreed that this application could not be approved as more information was required on how this patient had factors different than the population and would likely gain significantly more benefit from this treatment.

Decision The Panel did not approve the above application as more information was required. The consultant would be invited to resubmit the application and would also be encouraged to attend the meeting to speak to the application. Panel members also suggested inviting a surgeon to attend the meeting as this was for a surgical procedure. The application should also be signed by the clinical director.
The Chair explained that this was a resubmission of a previous application. The application for the Ross Procedure that had been discussed at the January meeting had not been approved for the following reasons - more information was required on how this patient had factors different than the population and would likely gain significantly more benefit from this treatment. The Panel agreed that the resubmission could not be approved. The Panel felt that it would not be equitable to approve this application. The Panel agreed that there was not enough information on the individual clinical circumstances and why this patient had factors different than the population and would likely gain significantly more benefit from this treatment. The Panel commented that if this treatment would benefit a group of patients then this should be considered as a service development rather than an individual treatment request.

Decision The Panel did not approve the above application as more information was required on why the patient’s clinical circumstances were different from the population.

Applications Rejected 2012/2013
12/014
The Panel noted the SMC Report No. 490/08 (11.08.08). Teriparatide (Forsteo®) – not recommended for use within NHS Scotland for the treatment of osteoporosis in men at increased risk of fracture. The Chair explained that this treatment had been approved twice before at previous meetings.

Decision Before a decision was made, the Panel requested clarification on whether the patient was male or female and how this patient had factors different than the population and would likely gain significantly more benefit from this treatment than the general population.

12/016
The Panel noted the second application for Tocilizumab. The panel noted that only one other treatment had been tried before requesting Tocilizumab.

Decision Before a decision was made, the Panel requested further information on why other treatment options had not been tried.

12/017
The Panel noted the SMC Report No. 653/10. prucalopride (Resolor) – not recommended for use within NHS Scotland. Indication under review: for symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief. The Panel noted that there had been a number of other applications to previous IPTR meetings for prucalopride. At the March meeting it had been agreed that if there were any further applications for this treatment, the Panel would request an explanation of the pathway for patients with this condition.

Decision Before a decision was made, the Panel requested: _ Feedback from the clinicians on the previous applications for prucalopride
Clarification on whether the patient was female or male.

The patient should be made aware that the treatment was being used off label for an unapproved indication.

Provide information on the pathway for patients with this condition

12/019

[-----] gave some background information on this application. He explained that the patient had developed metastatic renal cell carcinoma. [-----] The panel noted that Nanoknife Electroporation treatment was not available in Scotland and only available at one private clinic in London. [-----] advised that there was no clinical evidence to suggest that this treatment would be effective. The Panel asked about other treatment options, including Radiofrequency Ablation (RFA). He explained that this had been considered but it was unclear whether it would be more effective than Nanoknife Electroporation.

Decision The Panel did not approve this application and felt that other options, including RFA, should be considered in further detail.

12/023

The Panel ratified the decision made by the Cancer Medicines Management Committee (CMMC).

12/024

The Panel ratified the decision made by the CMMC.

12/025

The Panel ratified the decision made by the CMMC.

12/026

The Panel ratified the decision made by the CMMC.

12/027

The Panel ratified the decision made by the CMMC.

NHS Lothian
22 August 2012
1. How many individual patient treatment requests did the board receive in 2011/2012?
   Two

2. How many individual patient treatment requests has the board received to date in 2012/2013?
   None

3. How many of the individual patient treatment requests received by the board were approved in 2011/2012?
   One

4. How many of the individual patient treatment requests received by the board have been approved to date in 2012/2013?
   N/A

5. a) How many of the individual patient treatment requests received by the board were rejected in 2011/2012?
   One

   b) What reason was recorded for rejecting these requests?
   The medicine which was requested was rejected as there was no additional evidence to that submitted to the SMC of clinical benefit. Additionally there was no evidence submitted that the this particular patients quality of life would be improved - the medicine was not likely to increase the symptom free period of the illness and would potentially cause additional problems for the patient.

   a) How many of the individual patient treatment requests received by the board to date in 2012/2013 have been rejected?
   N/A

   b) What reason has been recorded for rejecting these requests?
   N/A

NHS Orkney
17 July 2012
1. How many individual patient treatment requests did the board receive in 2011/2012? **ONE**

2. How many individual patient treatment requests has the board received to date in 2012/2013? **ONE**

3. How many of the individual patient treatment requests received by the board were approved in 2011/2012? **ONE**

4. How many of the individual patient treatment requests received by the board have been approved to date in 2012/2013? **ONE**

5. a) How many of the individual patient treatment requests received by the board were rejected in 2011/2012? **NONE**

b) What reason was recorded for rejecting these requests? **NA**

6. a) How many of the individual patient treatment requests received by the board to date in 2012/2013 have been rejected? **NONE**

b) What reason has been recorded for rejecting these requests? **NA**

**NHS Shetland**

12 September 2012
1. How many individual patient treatment requests did the board receive in 2011/2012?
   47

2. How many individual patient treatment requests has the board received to date in 2012/2013?
   17

3. How many of the individual patient treatment requests received by the board were approved in 2011/2012?
   35

4. How many of the individual patient treatment requests received by the board have been approved to date in 2012/2013?
   14

5. a) How many of the individual patient treatment requests received by the board were rejected in 2011/2012?
   12

b) What reason was recorded for rejecting these requests?
   The patient’s clinical circumstances did not imply that they were likely to gain significantly more benefit from the medicine than would be expected in the general population of patients covered by the medicine’s licence or in the population of patients included in the clinical trials appraised by SMC.

6. a) How many of the individual patient treatment requests received by the board to date in 2012/2013 have been rejected?
   3

b) What reason has been recorded for rejecting these requests?
   As above

NHS Tayside
10 September 2012
1. How many individual patient treatment requests did the board receive in 2011/2012?  
   None

2. How many individual patient treatment requests has the board received to date in 2012/2013?  
   None

3. How many of the individual patient treatment requests received by the board were approved in 2011/2012?  
   None

4. How many of the individual patient treatment requests received by the board have been approved to date in 2012/2013?  
   None

5. a) How many of the individual patient treatment requests received by the board were rejected in 2011/2012?  
   None
   b) N/A

6. a) How many of the individual patient treatment requests received by the board to date in 2012/2013 have been rejected?  
   None
   b) N/A

NHS Western Isles
6 September 2012