Access to newly licensed medicines
ABPI Scotland

The ABPI (Association for the British Pharmaceutical Industry) represents innovative research-based biopharmaceutical companies, large, medium and small, leading an exciting new era of biosciences in the UK.

Our industry, a major contributor to the economy of the UK, brings life-saving and life-enhancing medicines to patients. Our members supply 90 per cent of all medicines used by the NHS, and are researching and developing over two-thirds of the current medicines pipeline, ensuring that the UK remains at the forefront of helping patients prevent and overcome diseases.

The ABPI is recognised by government as the industry body negotiating on behalf of the branded pharmaceutical industry, for statutory consultation requirements including the pricing scheme for medicines in the UK.

ABPI Scotland welcomes the opportunity to submit this evidence to the Committee.

Introduction
ABPI Scotland is pleased to submit this written evidence ahead of the September 18 2012 hearing by the Health and Sport Committee into Access to Medicines. The public, clinicians and the industry want to see access to new medicines for patients in Scotland. Aligned with this desire, in June 2012 the Scottish Government published Health and Wealth in Scotland: A Statement of Intent for Innovation in Health, which recognises that access to new medicines is an important element in delivering innovation into the heart of NHSScotland. The 2012 Scotland Against Cancer Conference, run by Cancer Research UK, also highlighted that the future of cancer research “needs access to the latest medicines so that they can provide standard care to encourage new drug research to be located in Scotland”. The challenge for the NHS and the Scottish Government Health Department is to realise the benefits for patients from these treatments within constrained budgets. The evidence suggests that access to new medicines for patients in Scotland is problematic and variable and the uptake of new medicines in Scotland is low and slow in comparison with other countries.

Section 1: Context

1. The discovery, research, development and clinical trials of a medicine takes on average over a decade and costs over £1 billion. As the public purse does not fund this process, companies shoulder the risk so the price reflects both the investment made to bring the successful medicine to patients and the costs of those which failed in development. In the UK, under the Pharmaceutical Price Regulation Scheme, and unlike the situation for any other supplier to the NHS, government caps the profits
that can be made by the medicines industry. UK Government Department of Health (DoH) figures show that the price of medicines in the UK is amongst the lowest in Europe; lower than Germany, Ireland, Belgium, Finland, Netherlands, Austria, France, Sweden, Spain and Italy.\textsuperscript{iv}

2. The NHS in Scotland has an unparalleled opportunity to invest in new medicines due to the significant sums of money being saved as a consequence of several high use medicines becoming available at lower prices after losing their patent exclusivity (see Section 4.5 below).

3. Unlike any other area of NHS spending, at present all new medicines undergo Health Technology Assessment (HTA) by the Scottish Medicines Consortium (SMC) to establish whether they are value for money (“cost effective”) in the context of their clinical benefit to patients\textsuperscript{v}. Thereafter a medicine that is “accepted for use” by SMC (either with or without a restriction on that use) undergoes further local examination at NHS Board level before a subsequent decision is made whether or not to place the medicine on the local prescribing formulary. Clinicians cannot generally prescribe any item that is not on their local formulary.

4. Given the requirement to manage NHS resources carefully, the industry accepts the need for HTA and acknowledges the high level of expertise and professionalism of the SMC. However, we believe that there are some disease areas which are not served well by current HTA methods and therefore patients with these diseases risk being further disadvantaged. Methodological and societal discussions are required, with the potential to lead to further evolution of HTA methods.

5. Subsequent to SMC decisions, the industry has deep concerns that medicines assessed as cost effective by SMC face further hurdles before they reach patients. These additional hurdles generally lack transparency, clear processes and clear timelines, and vary across Health Boards, leading to slow decisions and delayed uptake in Scotland. The graph below indicates the opportunity to give access to new medicines for patients by the rapid HTA assessment performed by SMC. It goes on to show a systematic failure to deliver access for patients in comparison to other UK countries.
Explanatory note: Average uptake per capita per new medicine (numbers shown above lines) since 2007/08 which have received a recommended or restricted use decision in NICE and also an approved or restricted decision by SMC. For some medicines a positive decision was reached following resubmission to SMC, these have been included in the analysis. First four years since launch in any UK country, only medicines with at least four years of uptake data are included.\textsuperscript{vi} 

6. Sharing the industry’s concern at the slow rate of uptake of new medicines, the Scottish Government issued guidance on the introduction of new medicines to NHS Boards in 2010 (CEL 17)\textsuperscript{vii}, clarified in 2011 (CMO 3)\textsuperscript{viii}. Further guidance was required in 2012 (CMO 1)\textsuperscript{ix} setting new defined timescales for the processes. This latest Guidance was issued in February 2012, for implementation by April 2012. 

7. While clearly these guidance letters are welcomed and clarify the aims of Scottish Government, industry has a concern that in general Health Boards have not reviewed their internal processes sufficiently to ensure that the defined timelines can be met. As formal systems are not in place to measure compliance with this guidance, the ABPI have been tracking
the on-line publication of formulary decisions by NHS Boards' Area Drug and Therapeutic Committees over the past 6 months i.e. since the latest guidance was implemented. The analysis presented later in this document (Section 3, paragraph 5) suggests that these guidelines are not being met by many NHS Boards.

Section 2: SMC and HTA in Scotland

1. The SMC is a widely respected HTA body that operates as a consortium of Scottish NHS Boards and in partnership with clinicians, patient representatives and the medicines industry, to high standards of openness and transparency.

2. The SMC’s methodology uses the Quality Adjusted Life Year measure (The QALY combines two factors into one measure - the quantity of life (how long you live) and the quality of that life,) which it states is “a widely used economic indicator, or tool, that allows a consistent approach to comparing the value of different medicines.”

3. While clearly bringing consistency and transparency to the HTA process, there is increasing recognition that the QALY may not be sensitive enough to take account of the changes in the health status of patients in some disease areas. In cancer, for example, there is evidence of limitations, such as the lack of a measure of vitality in the EQ-5D which is one of the most commonly used health related quality of life measurement systems. Similarly, in other long-term conditions such as central nervous diseases, the QALY is frequently relatively insensitive to clinical changes.

4. In addition the value of some medicines is beyond just the patient, but also to their carer and possibly social services. Methodologies that take a wider perspective on ‘value’ will be of increasing importance to Scotland as health and social care come together.

5. There is also recognition that when treating patients with very rare diseases, given the significant cost of developing the medicine and the small number of patients likely to receive the medicine, in many cases it is highly unlikely that the medicine will be able to meet the indicative cost per QALY threshold generally required to be categorised as ‘cost-effective’; the small number of people requiring these medicines means that they are likely to cost more per patient than more commonly prescribed medicines. While the SMC has modifiers which can be applied in such circumstances, industry questions whether these are sufficient in all cases. Patients living with rare conditions, in particular those with severe conditions should not be further disadvantaged because of the suitability of the HTA process in assessing medicines for their condition. Other jurisdictions have acknowledged that different assessment models may be needed in such
circumstances. In England for example, historically very few medicines for rare diseases were assessed (with the relatively recent exception for cancer therapies). More recently, the Advisory Group for National Specialist Services (AGNSS) was set-up to pilot new methods for assessing high-cost drugs for patients with rare conditions, specifically including measures reflecting a wider perspective of ‘value’ than traditionally used in most HTA assessments. The UK Government has shown support for this initiative and from April 2013, NICE will take over this role, building on the AGNSS methodologies. A consultation on new methodologies will take place in 2013/14 xii

6. Research commissioned by ABPI Scotland shows that there have been 96 SMC decisions, on medicines for very rare conditions between 2001 and July 2012. While the SMC accepted (or accepted with restrictions) the majority of these medicines (51%), a large minority (49%) were not recommended (NR). xiii This compares to 29 % not recommended when all medicines are considered. It should be noted that for 18 of these orphan indications the pharmaceutical companies decided not to submit their new medicine to the SMC for assessment, on the understanding that this would result in an automatic ‘not recommended’. In many cases this lack of a submission reflected that companies’ belief that the current system is ill-equipped to assess these medicines.

- **Recommendation 1:** The SMC should establish a Short Life Working Group with representation from NHS Boards, ABPI, academia, patients and potentially the public to examine ways to approach HTA for medicines that fall into those categories where the current approach is not fully effective, as summarised above. This Group should make recommendations to the Scottish Government and SMC for changes in the way these medicines are appraised

**Section 3: Post SMC Processes**

1. The patient perspective, as evidenced by every MSP’s postbag, is still that there is inequity of access and availability of new medicines in comparison i) between Scotland and the rest of the UK and Europe, and ii) between NHS Boards in Scotland. There is also a political debate on the use in England of a Cancer Drug Fund (CDF) to pay for the provision of particular medicines. This highlights the point that for patients in England, a ‘no’ from NICE doesn’t automatically mean that they won’t get the treatment they need, whereas for the same patient in Scotland a no from SMC means that they won’t receive that treatment. The point of this is not talk about the CDF, or to call for a Scottish equivalent, but simply to point out the
inequality that exists; it is less about what the mechanism is or what it is called, but simply the fact that there is a mechanism in England that is ultimately benefiting patients.

2. CMO (2012) 1 requires NHS Boards to make decisions within 90 days of the SMC advice to the Board, confirming whether the medicine is available as a treatment option within the NHS Board formulary in accordance with the agreed treatment protocol(s). The 90 day target is based on the EU Transparency Directive recommendation on acceptable timescales for decision making\textsuperscript{xiv} and, as such, NHS Boards’ processes should be adapted to achieve local decisions on medicines within this period. NHS Boards must then publish that advice within 14 days of the Board’s decision.\textsuperscript{xv}

3. CMO (2012) 1 also requires NHS Boards “to present formulary decisions in a consistent and transparent way. As a minimum, NHS Boards are expected to maintain on their website, an up to date list of SMC accepted medicines with standard advice to confirm whether these medicines are included or not included within the NHS Board formulary.”\textsuperscript{xvi}

4. The current experience of clinicians and patients is that the high expectations of the guidance documents above in supporting the timely uptake of new medicines are not being met, with considerable variation between NHS Boards on the introduction of new SMC-accepted medicines onto local formularies. ABPI Scotland has been tracking whether local formulary decisions have been published for SMC ‘accepted’ medicines since CMO(2012)1 came into force.

5. Medicines with an SMC notification of acceptance made at the first meeting after CMO (2012) 1 came in to force on 1 April 2012, had 90 days for a decision to be made by Boards and a further 14 days to publish that decision. Medicines notified to Boards in mid-April should therefore have had a formulary decision in mid July with publication by the end of July. SMC made five decisions to accept medicines – three medicines for one indication each and a fourth medicine for two indications. N.B. In 5 Health Boards there is no information for patients on the formulary status of any new medicines available on the Health Board website.

\begin{enumerate}
\item A snapshot review of formulary decisions published online in early August shows:
\end{enumerate}
i. **Medicine 1:**

- Not included, pending protocol: 5
- Not included (reason stated): 5
- No decision published: 3
- Not included (reason stated): 1
- No information available: 1

ii. **Medicine 2 (First indication):**

- Included on formulary, pending protocol: 1
- Not included, pending protocol: 2
- No decision published: 3
- Placed on formulary: 1
- No information available: 5
iii. **Medicine 2 (second indication):**

- Included on formulary, pending protocol: 7
- Not included, pending protocol: 5
- Placed on formulary: 1
- No information available: 1

iv. **Medicine 3:**

- Included on formulary, ‘case depending’: 1
- Not included, pending protocol: 4
- No decision published: 3
- Placed on formulary: 1
- No information available: 5
v. **Medicine 4:**

![Pie chart](image)

6. Another factor contributing to delays in patients' access to SMC accepted medicines is the interpretation of the wording in CEL(2012)1 stating that medicines can be included or not included on formulary "subject to protocol". ABPI Scotland’s own research shows that this exception option may be being used on a more regular basis. The 90 day limit should include any redrafting of protocols as patients are not served by the option frequently used by Boards of delaying inclusion of an SMC accepted medicine "subject to protocol", which effectively stops the clock. There is limited evidence that NHS Boards are making the necessary process changes. The above charts demonstrate that all SMC medicines are not being made available within 90 days, and that some NHS Boards are not doing so 'pending protocol' reviews, but to patients that equates to the same thing; that they do not have access to medicines that they should have access to.

7. In Appendix 1 we include a flowchart, based on one published by the Scottish Government in CMO(2012)1 explaining the steps that can be taken following the SMC’s acceptance of a medicine for use. We have marked the chart to show the extra stages that are carried out at Health Board level. While some of these activities, such as modifying local protocols, may well be required, it is hypothesised that they are contributing to the delays in decision making in some Health Boards. Industry questions whether these delays are reasonable.

8. It is worth noting that the recent inclusion of national consensus meetings to discuss selected SMC-accepted medicines (for example on Dabigatran, which took place on September 21st 2011) has added one of the extra
steps referenced above. Despite the outputs being “national” statements, individual Boards have still chosen to then develop their own individual protocols. ABPI Scotland does not see how this consensus review, using a process that does not meet the SMC’s standards of evidence and transparency, can have added value. Many Health Boards have still not made decisions on these medicines publically available.

- **Recommendation 2:** The Scottish Government should reinforce to Health Boards that they must make formulary decisions publically available, as per CMO 21012(1). The 90 day limit for decisions on inclusion of SMC accepted medicines onto local formularies should also include the introduction or amendment of local protocols.

9. The Health and Sport Committee is, we understand, considering the Individual Patient Treatment Request process in the context of a series of petitions to the Scottish Parliament. ABPI Scotland will be pleased to support this specific investigation and would only wish to state the following in the context of the Committee’s review on access to medicines:

   a. We fully acknowledged that the IPTR process is not meant to be a means of gaining access for all patients to medicines which are ‘not accepted’ by the SMC. However it is the ABPI view that patients and clinicians are not being well served by IPTR. Recent surveying of leading Scottish oncologists suggests considerable difficulties and dissatisfaction [see appendix 2].

   b. As a consequence of these concerns, a working group bringing together representatives of clinicians, patients and the medicines industry has reported to the Cabinet Secretary for Health and the Health and Sport Committee on ways to make the IPTR process more effective for clinicians and patients. A summary of their recommendations is in Appendix 3, but 2 of the key points are as follows:

      i. The view of what the IPTR process is for, and in what circumstances it should be used, differs between government, clinicians and NHS Boards.\textsuperscript{ix}

      ii. The process, eligibility criteria and usability of the IPTR process continues to vary between NHS Boards such that there are very different rates of IPTR submissions and acceptances.\textsuperscript{xx}
Section 4: Affordability

1. ABPI Scotland believes that the biggest barrier to patients being able to access new medicines while in the care of NHSScotland is the increasing efforts to contain spending on medicines, justified on the basis of affordability.

2. Medicines inflation is not out of control – indeed in the most recent year, the medicines bill increased by less than 2%, this rate being below the national rate of inflation. The proportion of the overall NHS Boards’ revenue budgets spent on medicines has increased from 17.93% to 18.30% over the past five years [See Appendix 4].

3. Branded (or proprietary) medicines are initially priced to take account of their development costs. However, once they lose patent protection, significantly cheaper ‘generic’ copies are allowed on the market, providing the opportunity for savings to the payer and possibly wider usage at this lower price. The increase in spending on medicines has been driven almost entirely through more items being dispensed rather than being driven by the cost of new medicines. Over 80% of prescription items are generic rather than branded.\textsuperscript{a}

a. Prescribing volumes have increased from 69.5 million items in 2002/03 to 94.6 million items in 2011/12. NHS ISD states that this growth “reflects not only the availability of new or more effective medicines, but also increasing patient expectation and demographic changes and latterly the implementation of clinical guidelines and recommendations”. The trend continues: the rate of increase in prescribing volumes between 2010/11 and 2011/12 was 3.8% compared to 2.4% between 2009/10 and 2010/11.\textsuperscript{b,c} Prescription charges were reduced for three years before being abolished in 2011.

b. Of the top ten items prescribed in NHSScotland by volume, only one is branded. Of the top ten prescribed by cost, 4 are branded\textsuperscript{d} [See Appendix 5].

4. Meeting the increased demand of patients for medicines is costing NHSScotland progressively less in real terms given i) the current dominant use of generic medicines and ii) the fact that several commonly prescribed medicines which have collectively been responsible for preventing tens of thousands of deaths in Scotland are losing their patent protection over the period 2012 to 2015 allowing generic versions to replace them and thus add further potential for savings.
5. Future medicines spending predictions made by the Office of Health Economics show that loss of exclusivity (LOE) will save NHSScotland an estimated £316m in the years 2012-2015xxv. The graph below illustrates how we estimate the loss of exclusivity will impact upon sales. We are keen to know how these savings are being taken account of by NHSScotland and the individual NHS Boards, and to know where these savings are going, and whether or not they will be reinvested in medicines spending, or allocated to another part of the budget.

6. In recent years NHS Board policy towards medicines has been one of cost containment with increasing emphasis on “medicines management” whereby prescribing decisions by clinicians are monitored and policed in a way that is not replicated for other interventions. While ABPI Scotland welcomes the scrutiny placed on medicines to prove their effectiveness, clinically and in terms of cost/benefit, we believe that patients are best served when this is driven by quality and patient outcomes rather than a narrow expectation that the medicines budget is always the best place to cut costs.

- **Recommendation 3:** A forum should be set up, that includes ABPI and The Office of Health Economics, to share information on significant new product launches, patent losses and other factors affecting medicines budgets to facilitate long term projection and planning by the Scottish Government and NHS Scotland.
• **Recommendation 4:** The Health and Sport Committee of the Scottish Parliament examine the best use of the estimated £316 million of savings being made in the cost of medicines to NHSScotland between 2012-2015, with a view to identifying what proportion can and should be reinvested in meeting patient expectations of access to the latest medicines.

**Section 5: Conclusions**

1. ABPI Scotland is committed to working as a partner in the delivery of a world class NHSScotland that is driven by the need to achieve the best outcome for patients through support for innovation, decision making processes that are transparent, as rapid as the evidence allows, consistent and person-centred.

2. The future of medicines is one of increasing sophistication where a patient’s illness can be targeted by compounds that are effectively tailored to their specific condition. This offers a much higher level of efficiency and effectiveness of treatment. It also creates a challenge for the NHS to meet the expectations of patients/taxpayers from finite resources.

3. Over the last 50 years the majority of significant improvements in patient outcomes have been down to the development of new, innovative treatments, or example ending the need for ulcer surgery due to oral medication. Despite these and many other examples, we remain focused on a discussion about “if” patients in Scotland should get access to the latest most innovative treatments. At a time when Scotland faces unprecedented healthcare challenges, an ageing population and intense fiscal pressures surely now, more than ever, we need to radically rethink attitudes to introducing medicines in Scotland to move away from simply driving down costs to one of critically appraising where the investment in patients’ health through medicines can help Scotland address some of the health and social care challenges of the future. To continue to improve patient outcomes for the same or less resource we may need to change funding priorities in the NHS to ensure – and prove – that patients get the maximum benefit for every pound spent. This may mean looking at reducing spending in some areas to continue to support innovation in others.
APPENDIX 1

Flowchart from CMO (2012) Guidance (white boxes) with further annotation by ABPI Scotland (shaded boxes). The dark shaded elements represent additional steps not envisaged in the guidance, each with the potential to delay formulary inclusion and patient access to medicines. It is possible for a medicine accepted for use by SMC to undergo six further stages before being included on a local formulary.

NHS Board ADTCs review the SMC accepted medicine for inclusion on the NHS Board formulary. Account is taken of:

- Current NHS Board formulary guidance;
- An overview of its place in therapy within current treatment pathways;
- Local and national treatment protocol; and
- Resource & service implications.

A recommendation is made to the NHS Board.

**Further Delays may arise if:**

1. separate financial scrutiny
2. local price
3. national procurement tender

Medicine recommended for Formulary Inclusion?

- Yes pending protocol
- Yes

NHS Board makes its decision within 90 days of the SMC advice to the Board to confirm that the medicine is available as a treatment option within the NHS Board formulary in accordance with the agreed treatment protocol(s).

NHS Board publishes advice within 14 days of the Board’s decision to confirm that the medicine is available on the formulary.

NHS Board makes its decision within 90 days of the SMC advice to the Board to confirm that the medicine is not routinely available as a treatment option within the NHS Board formulary.

NHS Board publishes advice within 14 days of the Board’s decision to confirm that the medicine is not available on the formulary and the rationale for this decision.

NHS Board to signpost how the medicine can be applied for via the non-formulary request arrangements.
APPENDIX 2

These are findings from a survey of oncologists undertaken by on-line survey and telephone in February and March 2012. This work was undertaken by Morhamburn on behalf of the Scottish Cancer Industry Group. From a database of 168 oncologists across Scotland approached, 44 responded (26% response rate).

When asked how they would characterise their experience of using the IPTR process:

More than nine out of ten clinicians said that they were required to prove exceptionality of their patient, even though this word has been removed from guidance. 8.3% said they did not have to demonstrate exceptionality.

Of those who expected to demonstrate exceptionality of their patient:
APPENDIX 3
Recommendations of IPTR Review Group (May 2012)

There needs to be:

- 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.

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APPENDIX 4

Research was undertaken for ABPI Scotland by Morhamburn Limited. Each NHS Board was asked under FOI to state the budget and spend for medicines for the last three years. This information was compiled alongside the same information for the two previous financial years. The figures for spend by each NHS Board on medicines were presented alongside the revenue budget allocations to each of the 14 territorial NHS Boards as announced to Parliament.

The total medicines spending by NHS Boards increased from £1,214 million in 2007/2008 to £1,383 million in 2011/12. This equates to a rise of 13.89%. The medicines spend as a proportion of overall spend increased from 17.9% to 18.3% in this period.
APPENDIX 5

Source: ISD Prescribing Cost Analysis 2012

Top ten medicines in NHS Scotland – Branded medicines in BOLD; all other items are generic
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<th>Item</th>
<th>Usage</th>
<th>Item</th>
<th>Usage</th>
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<td>For controlling cholesterol</td>
<td>salmeterol with fluticasone</td>
<td>For respiratory conditions</td>
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<td></td>
<td></td>
<td>proprionate</td>
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<tr>
<td>omeprazole</td>
<td>For reducing stomach acid</td>
<td>atorvastatin</td>
<td>For controlling cholesterol</td>
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<td>As a blood thinning agent</td>
<td>tiotropium</td>
<td>For respiratory conditions</td>
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<td>As a painkiller</td>
<td>budesonide with formoterol</td>
<td>For respiratory conditions</td>
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<td></td>
<td></td>
<td>fumarate</td>
<td></td>
</tr>
<tr>
<td>paracetamol</td>
<td>As a painkiller</td>
<td>pregabalin</td>
<td>For epilepsy</td>
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<td>Sodium for thyroid hormone</td>
<td>blood glucose testing strips</td>
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<td>For dressing wounds</td>
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<td>For lowering blood pressure</td>
<td>quentiapine</td>
<td>For schizophrenia/mania</td>
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<td>For angina and lowering blood pressure</td>
<td>co-codamol</td>
<td>As a painkiller</td>
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<td>emollients</td>
<td>For skin conditions</td>
<td>enteral nutrition</td>
<td>As nutritional supplements</td>
</tr>
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11 September 2012