Access to newly licensed medicines
Late Submission - British Heart Foundation Scotland

Wednesday 16 January 2013

British Heart Foundation (BHF) Scotland warmly welcomes the Committee’s inquiry in this area and is grateful for the opportunity to contribute to it. The approval process managed by the Scottish Medicines Consortium (SMC) appears to work well for cardiovascular drugs and in general it seems to work faster than the equivalent process managed by the National Institute for Clinical Excellence (NICE) in England. Both Wales and Northern Ireland have their own decision-making processes that are closely aligned to NICE.

The Scottish system also differs from that south of the border in that it automatically considers all newly licensed medicines whereas NICE only looks at those referred to it by the Department of Health. This means that new medicines should usually be available to appropriate patients in Scotland sooner than elsewhere in the UK in theory, but in practice the speed of introduction of new medicines is determined by decisions within area health boards and individual clinicians.

The committee has heard in previous sessions much about the particular issues regarding the introduction of new drugs for the treatment of certain cancers, particularly those drugs which can only benefit a very small number of patients, are relatively high in cost, and whose effectiveness has been demonstrated in small trials. The introduction of new drug treatments for cardiovascular disease present different issues for the SMC and area health boards to consider. Cardiovascular drugs tend to have been subject to large-scale trials, will be relatively low in unit cost, but, because they may be of benefit to a much larger proportion of the population, will often have potentially large impacts upon health board budgets.

Whilst SMC approval will have been dependent upon cost effectiveness, this will partly be based on future savings accruing from fewer hospital admissions, better clinical outcomes, fewer side-effects, etc. In the short term, however, health boards continue to face tough decisions about the affordability of the introduction of any new medicines following SMC approval. Whilst cardiovascular drugs have relatively low unit costs compared to, for example, cancer drugs, they will almost certainly be more expensive than the established treatment, or will be used in addition to the established treatment. This can have impacts not just on the wider drugs budgets, but potentially on the funding of other essential and, in our view, high priority services such as cardiac rehabilitation or specialist heart failure nursing.
Whilst the SMC advises on which new medicines *are accepted for use* in the NHS in Scotland, it is effectively the local drugs and therapeutic committees that decide which new medicines *should* be used within each health board area by the decisions they make regarding whether a medicine should be added to the local formulary. Whilst it is inevitable that at times these local committees will come to different conclusions from one another, it is important to promote the consistency of decision-making processes and to ensure transparency.

The Scottish Government has published guidance for health boards (CEL 17 (2010)), reminding them that decisions regarding the provision of NHS services remain matters for those Boards and that clinicians remain responsible for clinical decisions regarding the care of individual patients. However it also identifies the need to adopt consistent and standardised approaches to the introduction of newly licensed medicines whilst reflecting their local circumstances as the key to ensuring that patients continue to receive medicines of established cost-effectiveness and of therapeutic value.

The guidance also sets out timescales for boards to reach decisions about whether to include new medicines in their formulary (90 days after publication of SMC advice) and making information about the decision public via their website (within 14 days of the decision). NHS Boards are expected 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. This approach should ensure that external organisations can monitor consistency of decision-making amongst NHS boards, but a quick look at a number of NHS board websites suggests that this information is not easy to locate.

Finally, it is worth noting that whilst there are these robust processes in place which support the introduction of effective new medicines into the NHS in Scotland, there remain pressures on high priority non-pharmacological interventions (such as cardiac rehabilitation and specialist heart failure nursing services), for which there is also a strong evidence base and have been shown to be cost-effective. For example, cardiac rehabilitation has been shown to reduce deaths from heart disease by 26% at two to five years, and is highly cost-effective, costing around £477 per patient\(^i\). Despite this evidence, far too many heart patients are still not assessed or referred for rehabilitation— the latest figures from ISD Scotland show, for example, that only 3.1% of heart failure patients and 7.4% of unstable angina patients were referred for rehabilitation in 2011\(^ii\).

In summary, BHF Scotland are supportive of the current SMC approach but have concerns about the subsequent equitable application of decisions, and
also how the cost pressures of introducing new medicines may have consequences for other valuable services.

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i DH England Commissioning Pack costing-model (published 2010) is based on a cost of £477 per patient. For more information, see: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_117673.pdf