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Reimbursement and clinical guidance for pharmaceuticals in Sweden

Do health-economic evaluations support decision making?

Although a number of countries now demand health-economic evaluations to support decisions related to reimbursement and clinical guidance, knowledge about the actual use of economic evidence and information on cost-effectiveness is still relatively scarce. In general, studies have suggested that the use of economic evaluations to support decision making are more important at the central than at the decentralized level [1]. Studies also suggest that the professional expertise of the decision making body is of vital importance for the use of economic evaluations, rather than existing formal requirements and guidelines [2].

Introduction of the new Pharmaceutical Benefits Board (Läkemedelsförmånsnämnden, LFN) on 1 October 2002 has markedly changed the principles of pricing and reimbursement of drugs in Sweden. The Board is required to make decisions on the reimbursement status of pharmaceuticals based on evidence of cost-effectiveness. Pharmaceutical companies must therefore when relevant submit economic evaluations as part of their applications for reimbursement. Previously all drugs with a price approved by the National Social Insurance Board (Riksförsäkringsverket) were reimbursed [3]. It was possible but not required for manufacturers to support their application with an economic evaluation.

This contribution examines experience to date regarding the use of health-economic evaluations and information on cost-effectiveness to support decision making by the LFN. Comparison with experiences from relevant committees in other countries is made for the purpose of identifying similarities and differences. The article also presents a summary of other important reforms in the Swedish pharmaceutical market since 1997, including activities and use of health-economic evaluations by local formulary committees organized by the 21 county councils.

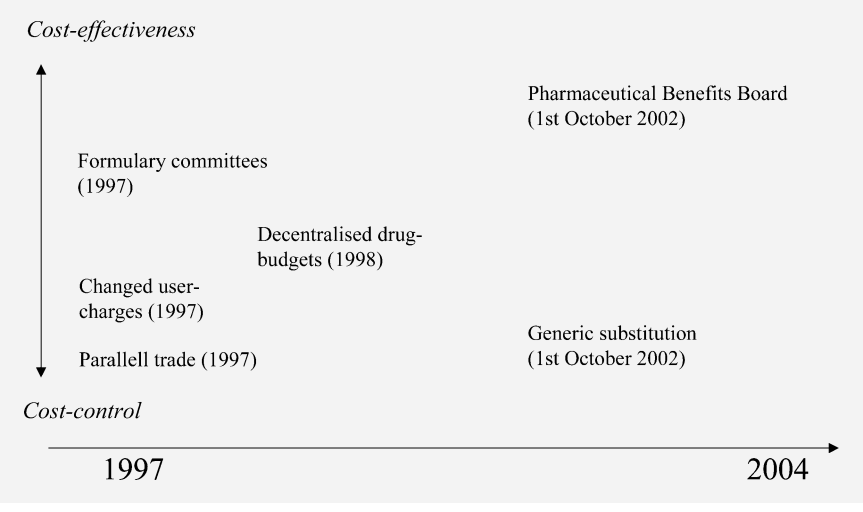

Fig. 1 ▲ **Important reforms in the Swedish pharmaceutical market since 1997**

Important reforms since 1997

Figure 1 presents the important reforms in the Swedish pharmaceutical market since 1997 and the extent to which their purpose has been primarily to contain costs or to promote cost-effectiveness. Increased user charges, parallel trade, and the introduction of generic substitution have clearly been oriented towards cost containment, while other reforms have been more oriented towards promoting a rational and cost-effective use of pharmaceuticals.

User charges, parallel trade, and generic substitution

The increase in out-of-pocket expenses for patients from 1 January 1997 had a clear but short-term impact on the development of drug expenditures. The announcement of this change initiated hoardings among patients at the end of year 1996, with a result-

ing drop in sales in the following year (see **Table 1**). Studies suggest that both parallel trade and especially generic substitution have had important effects on the development of expenditures [3, 4, 5]. Expenditure growth for drugs in 2003 and 2004 was kept at a record low 2–3%, compared to 9% in 2002 (see **Table 1**). This can be explained mainly by price reductions for simvastatin and omeprazol, previously the two best selling drugs in Sweden, following patent expiration and generic substitution from October 2002 [5]. It can also be noted that new and innovative pharmaceuticals introduced in the Swedish drug market during 2003 and 2004 have resulted in only small volume sales.

Table 1

Drug expenditures in Sweden 1993–2004 (billions of crowns), pharmacy retail price (*parentheses* percentage of total market) (from [3] and Apoteket http://www.apoteket.se)

	Drug expenditures	Change since the year before (%)	Prescription submarket	Hospital submarket	Over the counter submarket
1993	14.1	+12.6	10.8 (77%)	2.0 (14%)	1.3 (9%)
1994	15.6	+15.6	12.2 (78%)	2.1 (13%)	1.4 (9%)
1995	17.4	+12.7	13.8 (79%)	2.1 (12%)	1.5 (9%)
1996	20.1	+17.9	16.4 (82%)	2.1 (10%)	1.6 (8%)
1997	18.2	−9.5	14.4 (79%)	2.2 (12%)	1.7 (9%)
1998	20.8	+14.3	16.5 (80%)	2.6 (12%)	2.6 (8%)
1999	23.3	+12.0	18.5 (79%)	3.0 (13%)	1.8 (8%)
2000	25.1 23.6[a]	+7.7 –	19.9 (79%) 19.3[a] (82%)	3.3 (13%) –	1.9 (8%) –
2001	25.1[a]	+6.3	20.6[a] (82%)	–	–
2002	27.3[a]	+8.8	22.6[a] (83%)	2.6[a] (10%)	2.1[a] (8%)
2003	27.9[a]	+2.2	22.8[a] (82%)	2.9[a] (10%)	2.2[a] (8%)
2004	28.6[a]	+2.5	22.8[a] (80%)	3.5[a] (12%)	2.3[a] (8%)

[a] *Human use pharmaceuticals only*

Local formulary committees

Formulary committees organized by the 21 county councils have been regulated by a separate act since 1997. Each county council is required to set up at least one committee (some large county councils have more than one) for the purpose of "promoting safe and cost-effective use of pharmaceuticals." To reach this objective every committee has a list of recommended drugs. They also organize seminars and workshops, analyze prescription patterns (at group level), and issue special guidance for selected products. Decisions on what drugs to include in the recommended list, as well as development of guidance, are usually prepared by expert groups linked to the committee.

Formulary committees have from the start shown an interest in health-economic evaluations. A survey in 1998 indicated that committee members ranked the criterion of cost-effectiveness high in relation to other decision criteria, and that they preferred a societal instead of a narrow budget perspective on resource use [6]. In practice, however, it is not clear to what extent local committees have used health-economic evaluations and information on cost-effectiveness to support decision making. A survey of local committees (early 2000) found only three examples of cost-effectiveness studies being used for guiding the decisions [7]. Most decisions on guidelines were based on simple price comparisons. Further, the expertise of committees indicates that health-economic evaluations are of minor importance. Fewer than 1% of committee members in 2002 were health economists [8]. The fact that recommendations vary across committees – the 38 different committees issued in total 25 different lists of recommended drugs in 2002 – suggests that different decision criteria may be used, and that recommendations are influenced by existing variations in prescription patterns.

The focus of formulary committees since their regulation in 1997 has been to promote substitution to lower priced and well documented products within therapeutic areas with large sales volumes. In addition, the formulary committees have issued guidance related to specific drugs (usually new and expensive) and the prescribed volume (based on defined daily dose per inhabitants) within selected therapeutic areas. Guidance on prescribed volumes and use has most frequently been oriented towards a more controlled use of drugs with a large potential budget impact (e.g., PPIs) or for ecological reasons (antibiotics), but in some cases (e.g., antidepressants among the elderly) the committees have actually tried to increase prescribing.

Anecdotal evidence and results from surveys suggests that formulary committees were not very successful during their first years of operation in changing prescription behavior among physicians [9]. Compliance with recommendations has been higher in areas where physician groups receive incentive payments to meet this objective [10]. Even in these areas, however, it has been easier to promote substitution between similar drugs and more difficult to influence the prescribing volume.

Since 1 October 2002 the promotion of substitution by formulary committees has become less relevant because the law now mandates generic substitution between substitutable products as determined by the Medical Products Agency (Läkemedelsverket). As a result, treatment guidance rather than product recommendations has gained in importance among the formulary committees.

Decentralized drug budgets

Since 1998, when drug budgets were decentralized by the national government, the 21 county councils have developed their own models on how to allocate drug budgets among primary care centers and other providers. The process has been

Abstract

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Abstract
Introduction of the new Pharmaceutical Benefits Board (LFN; 1 October 2002) has markedly changed the principles of pricing and reimbursement of drugs in Sweden. The Board is required to make decisions based on information on cost-effectiveness, and pharmaceutical companies must submit economic evaluations when relevant as part of their applications for reimbursement. This study examined experience to date regarding the use of health-economic evaluations and cost-effectiveness information by the LFN. We also describe activities and the use of cost-effectiveness analysis by Swedish local formulary committees organized by the 21 county councils. It is concluded that economic evaluations have supported decision making by LFN, although cost-effectiveness seems to be of varying importance in different situations. While the use of health-economic evaluations and the outcome of decision making by LFN are similar to comparable committees in other countries, there is presently a gap in this sense between the LFN and Swedish local formulary committees. Coordinated decision making is much needed but may be difficult to implement as the perspective, expertise, and objectives of the two public authorities differ.

Keywords
Cost-effectiveness · Reimbursement · Clinical guidance · Pharmaceuticals · Sweden

slow, largely due to resistance among prescribing physicians to accept responsibility for drug expenditures. By 2002 only three county councils had implemented decentralized responsibility for prescription expenditures [10]. The situation did not change during 2003. The long-range plan of most county councils, however, is to integrate expenditures for prescription drugs with the existing budget responsibility for other health care inputs. The principal model being developed is to allocate most of the responsibility to primary care centers, based on prescriptions of so-called "general drugs" to inhabitants within the catchments areas of different centers. This means that primary care centers are responsible for 80–90% of expenditures for prescription drugs depending on the definition of "general drugs" in each county council. The remaining responsibility for "specialist drugs," usually expensive drugs prescribed by certain specialists, is usually allocated to the relevant specialist department at hospitals.

Surveys of attitudes among prescribing physicians indicate an increased cost-awareness in those county councils that have decentralized responsibility for drug expenditures to primary care centers and hospital departments [11]. Not surprisingly, as primary care carries most of the responsibility, this effect is greater among general practitioners than specialists [11]. It is far from clear, however, whether this difference in attitude also means that general practitioners are prepared to consider information about cost-effectiveness in their decision making to a greater extent than before.

The new Pharmaceutical Benefits Board

On 1 October 2002 a new act on pharmaceutical benefits came into effect. At the same time a new public authority was created, the LFN. According to the act, drug benefits are to be identical all over the country and subject to national regulation, as before. The change consisted in the fact that drugs issued on prescriptions for which a sales price has been established are no longer automatically reimbursed within the benefit scheme, as was the case before. Instead, the LFN determines specifically whether a pharmaceutical is to receive a subsidy. Following negotiations with the manufacturer the LFN also determines the price of a drug. In order to be reimbursed a drug must satisfy the criteria laid down in the new act. The LFN bases its decisions on the following four principles:

- The *principle of human dignity*, according to which healthcare is provided equally for all individuals.
- The *principle of need and solidarity*, according to which those with the greatest medical need are provided more healthcare resources than others.
- The *cost-effectiveness principle*, according to which the costs of a pharmaceutical preparation must be reasonable from medical, humanitarian, and socioeconomic points of view.
- The *marginal-utility principle*, which is part of the cost-effectiveness principle.

Broadly speaking, the new benefit scheme is product oriented. It is primarily the cost-effectiveness of various *products* that is to be assessed and not medical indications. This is not in line with generally accepted principles of health-economic evaluation, in which cost-effectiveness is always linked to a particular use of a product rather than the product in itself. The LFN may make exceptions, however, and can decide that a drug is to be reimbursed only for certain indications and/or subgroups of patients. This means that the LFN may decide to reimburse a drug for a narrower indication than the one for which the drug has been licensed for marketing. The professional expertise of LFN is mixed, with medical competence in a dominant position. Of the 11 members, however, two are professional health economists and a further two represents consumer and patient groups. In addition, several health economists are to be found in the administrative staff, responsible for all contacts with manufacturers, and preliminary analysis of applications, including health-economic evaluations.

Analysis of important decisions by the LFN

During the first 30 months of operation, i.e., from October 2002 to March 2005, the LFN made 107 decisions of "principal importance" (see **Table 2**). Information on these decisions is presented on the LFN homepage (http://www.lfn.se). It should be noted that other important cases may exist. Transparency is limited by the fact that manufacturers may redraw their confidential submissions before the LFN comes to a final decision.

In 82 of the 107 cases the drugs was approved for *unconditional reimbursement*, i.e., the drug is reimbursed for all its licensed indications without conditions. In 12 cases the LFN approved drugs for *limited and/or conditioned reimbursement*, and in these cases manufacturers are required to meet certain conditions determined by the LFN. In 13 cases applications *have been rejected*; in two of these rejections the applications for reimbursement were outside licensed indications, and therefore rejected by the LFN on formal grounds.

Orphan drugs: expensive, but small budget impact

It is clear from the 82 cases of full reimbursement that several orphan drugs were approved "unconditionally" by LFN although documentation of their cost-effectiveness was weak. Orphan drugs generally may be very expensive per patient and are likely to result in high costs per quality-adjusted life year (QALY). However, the number of patients is usually small, which means a modest total budget impact. Consequently, health-economic documentation is not required in the same way for orphan drugs as for drugs intended for a larger group of patients.

Cost-effective only for subgroups, with large potential budget impact

Pharmaceuticals approved for limited reimbursement chiefly consist of therapies aimed at treatment of large patient populations, for example, high cholesterol levels, overweight/obesity, diabetes, and osteoporosis. For these pharmaceuticals the subsidy has been limited to subgroups that are defined more narrowly than for licensed indications. The reason why the subsidy is limited to certain subgroups is that the drug has been found to be cost-effective only for some patient groups, frequently those at the highest risk of complications and those for whom the highest level of utility may be attained.

For example, reimbursement of Reductil and Xenical for obesity requires the patient either to have a body mass index (BMI) of 28 or higher and to be suffering from type 2 diabetes, or to have a BMI of 35 or higher. The relevant manufacturers are obliged to provide information about these conditions for reimbursement in their marketing to prescribing physicians. A further condition requires manufacturers to present data on the actual prescription volume.

Table 2

The significant decisions by the LFN, October 2002 – March 2005

82 reimbursed without limitation (i.e., for all licensed indications without conditions)

- Cost-effective or orphan drugs and similar with small budget impact.

12 with limited reimbursement and/or conditioned

- Crestor and Ezetrol (high cholesterol), cost-effective in subgroups only. Conditions for manufacturers: marketing to prescribing physicians must specify relevant subgroups; study of actual use in Swedish health care required; data on long-term effects on morbidity and mortality required.
- Lantus (diabetes), cost-effective in subgroups only (type 2 diabetes). Conditions for manufacturers: data on cost-effectiveness for use among patients with type 2 diabetes required.
- Reductil and Xenical (obesity), cost-effective in subgroups only. Conditions for manufacturers: marketing to prescribing physicians must specify relevant subgroups; study of actual use in Swedish health care required.
- Forsteo (osteoporosis). Cost-effective in subgroups only. Conditions for manufacturers: marketing to prescribing physicians must specify relevant subgroups.
- Testogel (testosterone therapy). Conditions for manufacturers: study of actual use in Swedish health care required.
- Yentreve (urinary incontinence), cost-effective in subgroups only. Conditions for manufacturer: reimbursed only for patients when first line treatment failed; marketing to prescribing physicians must specify relevant sub groups.
- Levemir (diabetes). Conditions for manufacturer: data on frequencies of hypoglycemic events requested.
- Raptiva (psoriasis). Conditions for manufacturer: reimbursement limited in time; additional data on quality of life and effectiveness from use in real clinical treatment are requested.
- Zyban (smoking quit treatment). Cost-effective in subgroups only. Conditions for manufacturer: reimbursement limited in time; marketing to prescribing physicians must specify relevant subgroups.
- Risperdal Consta (schizophrenia). Conditions for manufacturer: reimbursement limited in time; additional data on hospitalization and quality of life from use in real clinical treatment are requested.

13 denied reimbursement

- Cerazette (contraceptive), marginal benefit and cost-effectiveness not proven.
- Viagra, Cialis, and Levitra (erectile dysfunction)–Low degree of priority. (Appealed. To be decided by Supreme Administrative Court.)
- Elidel (atopic dermatitis), marginal benefit and cost-effectiveness not proven.
- Flutide suspension (asthma), marginal benefit and cost-effectiveness not proven.
- Imigran 100 mg (migraine), not cost effective at current price.
- Niferex (iron deficiency), marginal benefit and cost-effectiveness not proven.
- Robinul (bradycardia) and Aunativ (hepatitis B), indications not approved.
- Stocrin, new dose 600 mg (HIV), marginal benefit and cost-effectiveness not proven.
- Totelle (estrogen deficiency), marginal benefit and cost-effectiveness not proven.
- Xyzal (allergy)–Not cost-effective compared to available generics.

Rejections, when "low degree of priority" and if claims for a price premium are not supported by evidence

Among the rejected applications are three treatments for erectile dysfunction (ED), the reason being the "low degree of priority" for such disorders according to the LFN. It is worth noting that in the opinion of the LFN a patient suffering from severe ED has greater need for therapy than someone with less pronounced ED. The LFN also concluded that it is probably safe to assume that the relevant drugs (Viagra, Cialis, Levitra) are cost-effective for the former subgroup of patients. Even so, the LFN argued that it does not have the authority to impose the conditions needed to restrict reimbursement to this particular patient group.

Regarding the other rejected drugs the pharmaceutical companies concerned were not deemed to have demonstrated significant and clinically relevant difference in benefits compared with existing treatment alternatives. Hence, according to the LFN, the manufacturers had not proved that their claim for a price premium was warranted.

Use of cost-effectiveness and other criteria

It can be concluded that drugs are reimbursed without conditions (i.e., for all licensed indications) when cost-effectiveness and marginal benefits compared with competing alternatives have been established. In several cases simple price comparison with existing products has been sufficient to reach this conclusion. When there is a lack of alternative treatment therapies, particularly when the illness to be treated is severe (i.e., for those with greatest need), several cases illustrate the fact that even drugs with poor cost-effectiveness are reimbursed. Orphan drugs, usually very expensive for each patient but with little total budget impact, is a common example following this pattern. There is also a limited ability to demonstrate cost-effectiveness of orphan drugs, as the number of patients on treatment is small, and randomized clinical trials are more difficult to produce.

The most important use of information on cost-effectiveness seems to be for drugs with a large potential budget impact and when cost-effectiveness varies by indication and/or subgroups of patients. In such cases reimbursement is often limited to the relevant subgroups. The manufacturer must refer to subgroups when marketing the product. In some cases the LFN also demands prescription data and studies of long-term effects and cost-effectiveness from the manufacturer, presumably to reconsider its decision should actual prescribing behavior and/or long-term effects deviate from original assumptions. Restrictions such as specific volume agreements, preapproval procedures, and limited prescriptions to specialists have not been used.

Reimbursement is been denied when the manufacturer fails to proven marginal benefits and/or cost-effectiveness in comparison with existing alternatives. Exceptions have been applications for Viagra, Cialis, and Levitra, which were denied because of "low degree of priority" and difficulty in limiting reimbursement to patients with the greatest need. These three decisions were controversial, however, and three members of the LFN (including one health economist) openly expressed reservations about them. The relevant manufacturers also appealed the decisions to an administrative court which decided to grant the drugs limited reimbursement. Decisions by both the administrative court and later the administrative court of appeal were in turn appealed by the LFN. The three cases are now to be finally decided by the Supreme Administrative Court. It can be noted that both Bondil and Caverject, treatments for severe ED, are reimbursed without conditions. The argument by the LFN was that these two drugs are associated with a treatment procedure limiting use to patients with the most severe ED.

Discussion

Based on experience over the first 30 months of the LFN it can be concluded that health-economic evaluation and information on cost-effectiveness can support decision making related to reimbursement. The manufacturers are expected to submit health-economic evaluations as part of their applications for reimbursement when relevant, and, more importantly, the LFN possess the competence to assess the submitted economic documentation. Overall, however, the proportion of submissions to LFN supported by substantial health-economic analysis has been relatively small [12]. The great majority of decisions by LFN concern price changes on already subsidized products that do not require economic evaluation.

It is clear from analysis of important reimbursement decisions that information on cost-effectiveness is important for the LFN, but that other parallel decision criteria such as clinical need and degree of priority are used as well. Hence, a single predetermined cutoff value in terms of accepted cost per QALY is not used [12]. The greatest use of health-economic evaluations and information on cost-effectiveness seems to be for drugs with a broad potential use (i.e., large potential budget impact) and when cost-effectiveness varies by indication and/or subgroup of patients. In these cases manufacturers can expect the LFN to demand more detailed subgroup analysis, information that will be used to support decisions oriented towards limited reimbursement. Subgroup analysis using relevant data is indeed important according to the guidelines for cost-effectiveness analysis issued by LFN ("General guidelines for economic evaluations from the Pharmaceutical Benefits Board LFNAR 2003, 2" http://www.lfn.se).

The use of economic evaluation by the LFN follows experience from similar committees in other countries [2]. In contrast, for example, to reimbursement committees in the Canadian province of Ontario and in Australia, however, the LFN has not yet issued "hard" restrictions on reimbursement, such as the use of special prescription forms or preauthorization requirements. Conditions have been placed on manufacturers rather than on prescribing physicians. Thus far these conditions have been limited to regulation of marketing, requests for studies of actual prescription patterns, and demand for further data on long-term effects and cost-effectiveness. It is not clear to what extent these conditions on manufacturers will have an impact on prescrib-

ing patterns, and it has not yet been tested how the LFN will act should not manufacturers comply, or whether prescribing patterns deviate from agreements made between the LFN and the relevant manufacturer.

It will also be interesting to follow the outcome in cases in which the LFN decision runs contrary to guidance of the local formulary committees. Chairmen of local formulary committees, usually powerful specialists, have previously communicated their position that local guidance may be even more restrictive than limited reimbursement by the LFN. Formulary committees have in fact also been criticized for being more restrictive in their recommendations than the LFN decision [13]. A much debated case was a joint effort by formulary committees in 2003 to promote prescription of generic simvastatin in parallel to the introduction of new statins (including Crestor) following limited reimbursement decisions by the LFN.

The difference between formulary committees and the LFN in terms of recommendations should not come as a surprise. In contrast to the LFN, county councils have responsibility for drug expenditures, which means that their perspective and objectives are not identical. In addition, most local formulary committees lack health-economic expertise. In recent years several county councils have faced large budget deficits, and this situation is not likely to change in the immediate future. Cost containment will continue to be an important objective among county councils, and this will probably have an impact on activities of the formulary committees as well. Coordinated decision making between the LFN and local formulary committees is much needed, but a necessary first requirement is probably a common perspective and similar objectives.

In several cases the LFN has issued guidance on how to use a particular drug when limiting reimbursement to specific subgroups. In this respect, decision making by LFN does not differ totally from decision making by the National Institute for Clinical Excellence (NICE) related to clinical guidance for the NHS in England and Wales [14, 15]. In contrast to NICE, however, the LFN must comply with the European Union transparency directive, which means (among other things) that the process should not take longer than 180 days. In most cases decisions are initiated by an application from a manufacturer and not by the LFN. Since in 2004, however, the LFN also assesses and reconsiders reimbursement status for drugs accepted before October 2002. In this process, which will take several years before completion, the LFN will set the overall agenda. Uncertainty and time pressure is overturned to the detriment of manufacturers.

In February 2005, LFN presented its first review of medicines used for treating migraine (Review of medicines used for treating migraine-a summary, http://www.lfn.se). Based on available documentation and its own modeling work the LFN decided to no longer reimburse the 100-mg tablet form of Imigran (sumatriptan) due to poor cost-effectiveness compared with other triptans. In parallel to this decision by LFN, the relevant manufacturer applied for reimbursement of a new medicine, Immigran Novum (sumatriptan) 100 mg, at a 42% lower price than Imigran. The Swedish Medical Products Agency also approved Imigran and Imigran Novum as interchangeable products. The first review by LFN means savings of 42 million Swedish crowns to society during 2005, as a result of lower priced drugs for treating migraine.

It will be interesting to see in what way health-economic evaluations and information on cost-effectiveness can support decision making when reviewing the remaining 48 defined groups of medicines. Problems are likely to appear in areas lacking updated studies and when head-to-head comparison of cost-effectiveness between competing treatment alternatives do not exist. The LFN also need to evaluate carefully how decisions to exclude drugs in the benefit scheme may negatively impact future competition in therapeutic areas.

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