

Pharmaceutical Price Regulation Scheme 2014 – implications for NICE

Background

1. Following an appeal against the Final Appraisal Determination (FAD) for the appraisal of trastuzumab emtansine for treating HER2-positive, unresectable locally advanced or metastatic breast cancer after treatment with trastuzumab and a taxane, which was upheld, NICE has considered the relevance of the 'PPRS Payment Mechanism' of the Pharmaceutical Price Regulation Scheme (PPRS) 2014 to the assessment of the cost effectiveness of new branded medicines. This statement presents NICE's position.

The 2014 PPRS

2. The PPRS is a voluntary agreement to control the prices of branded drugs sold to the NHS. It is negotiated between the Department of Health, acting on behalf of the UK government and Northern Ireland, and the branded pharmaceutical industry, represented by the ABPI. The Scheme was first introduced in 1957 and is renewed approximately every 5 years. The 2014 PPRS became effective on 1 January 2014 and will run for a fixed period of 5 years.¹
3. Joining the scheme is voluntary. Companies that do not join the voluntary scheme are automatically enrolled in a statutory scheme which enables the Secretary of State to limit any price that may be charged by any manufacturer or supplier and provides for any excess charged over that prescribed limit to be paid to the Secretary of State within a specified period. Members of the PPRS can leave that scheme at any time, subject to notice, and will then be subject to the statutory scheme.
4. The operation of the scheme is complex and it is not possible to describe it fully here. For the purposes of this paper, the essential feature of the 2014 scheme is the 'PPRS Payment Mechanism' in which the growth rate in sales of NHS branded medicines supplied by companies in the scheme is underwritten by those companies, above agreed levels. The calculation of the growth rate includes sales of new products (defined as products introduced after 31st December 2013 following the granting of an EU or UK new active substance marketing authorisation) but excludes exceptional central procurements (such as national stockpiles), centrally supplied vaccines, parallel imports and sales by companies with sales of NHS branded medicines of less than £5m in the previous calendar year. Where the growth rate exceeds the agreed level, companies must make a cash payment to the Department of Health. That

¹ The full text of the 2014 PPRS is available from URL:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/282523/Pharmaceutical_Price_Regulation.pdf

payment ('the PPRS payment') is calculated by applying a percentage to relevant categories of sales during the relevant quarter. For each year the percentage used to determine PPRS payments will be the same for each company participating in the scheme.

5. The categories of sales to which the percentage is applied to determine the PPRS payment due from a company do not include that company's new products as defined above. However new products are included in the calculation of the growth rate of sales for all medicines, that is, they are taken into account in determining whether the agreed growth level has been exceeded and a PPRS payment will be required, and determining the size of the percentage.
6. The arrangement for payments to central government in return for exceeding the agreed growth level replaces the provision for mandatory list price cuts in earlier versions of the PPRS.
7. The 2014 scheme operates on the same over-arching basis as previous versions of the PPRS, that is, the approach of capping profits made on medicines supplied to the NHS. This is based on a principle of identifying the relevant capital employed, restricting the associated costs and limiting the allowable return. However in previous versions of the PPRS, members whose assessed profit exceeded the target by more than the stated upper margin of tolerance were required to reduce list prices for one or more individual products (of their choosing) by an equivalent amount or repay the excess to the Department of Health. In the 2014 scheme, if the assessed profit of a company exceeds the cap then the PPRS payment is calculated as set out above, that is, as a percentage of relevant sales. The company would then negotiate one or more of the following as the means of making that payment: (a) direct repayment of the excess profit (b) price reductions in the following accounting year, or (c) a delay or restriction of agreed price increases.
8. The 2014 PPRS makes reference to the NICE technology appraisals programme. Paragraphs 4.5 to 4.9 make it clear that NICE should continue to appraise the clinical and cost effectiveness of new drugs and does not require any change to its methods for doing so. Paragraph 4.9 states: "The basic cost-effectiveness threshold used by NICE will be retained at a level consistent with the current range and not changed for the duration of the scheme".

The impact of the 2014 PPRS on NICE

9. In this section we explore whether the 2014 PPRS should be material in NICE's work and, if so, whether and how it should be taken into account. This includes considering whether it is possible to 'operationalise taking the PPRS into account', that is, whether it is possible to incorporate the impact of the PPRS

payment mechanism introduced in the 2014 version into the methodology for technology appraisals. When referring to 'the 2014 PPRS' in this section we are referring in particular to the PPRS payment mechanism, as it is this element of the scheme which was considered potentially relevant in the trastuzumab emtansine appeal decision.

10. The argument put forward by Roche in the context of the recent appeal as to why a decision on this point was required by NICE arises from the extent to which 2014 PPRS represents a substantial change from previous versions of the scheme. Payments to the Department of Health feature more prominently than in previous schemes, which had operated mainly through changes to the list prices of branded medicines. Because NICE economic analyses use list prices, any change to those would be automatically incorporated into the technology appraisal methodology and decisions on cost effectiveness, whereas the current NICE technology appraisal methodology does not contain provisions taking account of payments made to the Department of Health of the type generated by the 2014 PPRS scheme.
11. However, under the 2014 PPRS the growth in the NHS budget for branded medicines supplied by scheme members is underwritten by those companies, above agreed levels. It was argued by the appellant in the trastuzumab emtansine appraisal that failure to take account of the revised arrangements in the 2014 PPRS (in the absence of the previous direct link between the PPRS, list prices and therefore NICE appraisals) effectively overestimates the true costs of new branded medicines to the NHS. It was argued by Roche that NICE should take account of the impact of the 2014 PPRS mechanisms when considering the opportunity cost associated with trastuzumab emtansine, just as it had done under the price adjusting effects of the previous scheme.
12. Because the PPRS is an agreement between the industry and the Department of Health, NICE sought the view of the Department of Health. The Department stated that "the 2014 PPRS does not place obligations on, nor create expectations of, NICE other than where these are explicitly stated in that agreement". Noting the statement that the NICE cost effectiveness thresholds will be retained (see also paragraph 8 above), the Department stated that "this provision was included in the Scheme in the context of the assurance provided by the PPRS payment mechanism on the rate of growth in NHS expenditure on branded medicines within the scheme. The PPRS contains no other provisions which require NICE to adopt a particular approach or method for technology appraisals, or to make an adjustment to its considerations to take account of the payment arrangements set out in the Scheme agreement".
13. As noted earlier, the 2014 PPRS states that the current range of maximum acceptable ICERs as specified in the 'Guide to the methods of technology appraisal' should be retained. It is reasonable to conclude from this and from

the Department of Health comments in paragraph 12 above that there was no intention that the 2014 PPRS should alter the NICE approach to considering opportunity cost because the ‘threshold’ is the means by which opportunity cost is considered.

14. However, although it appears clear that the authors of the 2014 PPRS did not intend it to have an impact on NICE technology appraisals, it is important to note the view of the Appeal Panel in the trastuzumab emtansine appraisal that simply stating that the basic cost-effectiveness threshold will not be changed for the duration of the scheme was not sufficient to demonstrate that the PPRS was not relevant to technology appraisals [paragraph 40 of the appeal decision].
15. We have identified two key questions relevant in determining whether payments generated by the 2014 PPRS are relevant to technology appraisals because they impact on opportunity cost to the NHS and whether such payments can be taken into account in appraising individual products. First, can PPRS payments be linked to the price or cost of an individual product under appraisal? Second, would any such impact actually affect the opportunity cost of acquiring the product?
16. The Technology Appraisal programme can take into account nationally available discounts on list prices for the NHS in England in the following way:
 - ‘5.5.2 The public list prices for technologies (for example, pharmaceuticals or medical devices) should be used in the reference-case analysis. When there are nationally available price reductions, for example for medicines procured for use in secondary care through contracts negotiated by the NHS Commercial Medicines Unit, then the reduced price should be used in the reference-case analysis to best reflect the price relevant to the NHS. [...] Analyses based on price reductions for the NHS will only be considered when the reduced prices are transparent and consistently available across the NHS, and if the period for which the specified price is available is guaranteed.’
17. It is not possible for payments made under the 2014 PPRS Scheme to be attributed to individual products which would allow their prices to meet the criteria (transparent and consistently available across the NHS for a guaranteed period) set out above.
18. The calculation of the PPRS payment derives from applying the calculated percentage uniformly to each scheme member for all of the relevant sales, and this gives rise to an obligation to pay a global sum. Neither the calculation of the ‘excess’ profits nor the calculation of the PPRS payment are attributed to any particular product. This is where the payment mechanism differs from

earlier versions of the PPRS in which a general adjustment to list prices of all branded products was made, and those prices were automatically taken into account in economic analyses for NICE based on those prices.

19. Payments made in the context of the 2014 PPRS are based on (annual) forecast growth rates, adjusted for the outturn for the previous year. We cannot know how a company would calculate the exact effect of PPRS payments on their NHS product range to enable an imputed reduction in the cost of an individual product at the time of an appraisal, and then be able to guarantee the effect for the duration of the guidance. Even if we were confident in a company's ability to do so, we consider that it would be unreasonable to expect us to have to review the guidance every time the actual payment is set.
20. Similarly, the voluntary nature of the PPRS means that members can leave the scheme at any time, giving three months' notice. On leaving the voluntary scheme, companies automatically move to the statutory scheme, where branded products that were on sale on 1 December 2013 are subject to a 15% reduction in their maximum price. The consequences of the statutory scheme for individual products are different from those in the voluntary scheme. The potential of a company moving between schemes at short notice makes it virtually impossible to guarantee the effective cost of a medicine for the duration of NICE guidance. This is compounded by the fact that the PPRS is a 5 year scheme, ending on 31 December 2018.
21. We do not consider that payments made through the 2014 PPRS scheme can be shown to impact on the price of individual pharmaceutical products in a way which enables an imputed reduced price to be taken into account in a technology appraisal in compliance with paragraph 5.5.2 of the Technology Appraisals Methods Guide.
22. In forming this view we have also taken into account the fact that it is not clear how payments made under the 2014 scheme are being applied in the provision of NHS services. We understand that the payments are not mandated to inflate local drug budgets and so will not automatically or routinely allow local commissioners or NHS England to revise their assessment of the opportunity costs of branded medicines. The fact that there appears to be no direct link between payments made under the scheme and the opportunity costs of acquiring new branded medicines explains why the Department of Health does not expect the thresholds to change for the lifetime of the 2014 PPRS.
23. Our conclusion is that there is no basis for considering that payments made under the 2014 PPRS are a relevant consideration in an assessment of the opportunity cost of products within the PPRS in the context of the development of NICE guidance or that even if they were, that there is a practical means of taking them into account.

NICE position statement

24. On the basis of the considerations above, NICE has developed the following position statement:

- *NICE recognises that the 2014 PPRS includes a new element, the PPRS payment mechanism, which it has been suggested may be a relevant consideration in developing NICE guidance.*
- *In the Department of Health's view, the 2014 PPRS does not place obligations on, nor create expectations of, NICE other than where these are explicitly stated in that agreement. Paragraph 4.9 of the PPRS states that: "The basic cost-effectiveness threshold used by NICE will be retained at a level consistent with the current range and not changed for the duration of the scheme." This provision was included in the Scheme in the context of the assurance provided by the PPRS payment mechanism on the rate of growth in NHS expenditure on branded medicines within the scheme. The PPRS contains no other provisions which require NICE to adopt a particular approach or method for technology appraisals, or to make an adjustment to its considerations to take account of the payment arrangements set out in the Scheme agreement.*
- *NICE further understands that although forecasts of payments to be made by companies are to be included by the Department of Health in the allocation of funds for the NHS, they are not being distributed to clinical commissioning groups or NHS England area teams on the basis of the likely expenditure of branded medicines by individual commissioners. The NICE Guide to Methods of Technology Appraisal 2013 allows 'analyses based on price reductions for the NHS [to] be considered when the reduced prices are transparent and consistently available across the NHS, and if the period for which the specified price is available is guaranteed' [5.5.2].*
- *Considering that payments made by companies are based on annual forecasts, adjusted by the outturn of the year before, NICE has not been able to identify a basis on which a company could transparently show the effect of payments made in the context of PPRS on the acquisition cost of an individual branded medicine at the time of the appraisal, and to guarantee this exact effect for the duration of the guidance. This is compounded by the fact that the 2014 PPRS is due to end on 31 December 2018.*
- *NICE also notes that, as members of the PPRS can leave the voluntary scheme at short notice, no real 'guarantee' can be given that the effect of payments to be made in the context of the 2014 Payment Mechanism will be available to the NHS.*

- *On this basis NICE considers it reasonable to conclude that the 2014 PPRS Payment Mechanism should not, as a matter of course, be regarded as a relevant consideration in its assessment of the cost effectiveness of branded medicines.*

NICE

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