National Centre for Pharmacoeconomics

Guidelines for Inclusion of Drug Costs in Pharmacoeconomic Evaluations

Version 1.13

Please Note: This document may be updated periodically, therefore please refer to www.ncpe.ie to obtain the most recent version.

Record of Updates

Version	Date	Description of changes
1.1-1.4	01.04.2010 – 14.05.2010	**Draft versions**
1.5	10.06.2011	**Page 5 & 6:** Amendment – rebate is payable on price to wholesaler.
1.6	27.07.2010	**Page 5:** Source of PCRS reimbursement prices included.
1.7	11.05.2011	**Page 3 & 6:** Reduction in wholesale mark-up on the High Tech Drugs scheme (HTDS). **Page 7:** Clarification regarding application of VAT on the HTDS.
1.8	05.07.2011	**Page 3 & 6:** Reduction in wholesale mark-up on all schemes.
1.9	28.03.2012	**Page 7:** Increase in VAT rate 1.01.12
1.10	14.08.2012	**Page 3:** Removal of recent changes to pharmacy and wholesale margins
1.11	12.06.2013	**Page 4:** Change to wholesale mark-up for high tech fridge items. **Page 5**: Update to GMS and DPS dispensing fee charges
1.12	07.08.2013	**Page 4 & 5**: Change to pharmacist mark-up for DPS and LTI schemes
1.13	13.03.2014	**Page 5:** Review of figures in Tables 1 & 2.

Background

The purpose of this document is to provide guidance for inclusion of costs for the drug of interest, its comparator(s) and concomitant drugs in pharmacoeconomic evaluations. Reimbursement prices for drugs vary depending on the setting, eligibility of the patient and the formulation of the drug prescribed. Estimates of drug costs should be applied consistently across pharmacoeconomic evaluations submitted to the NCPE. Drug costs should reflect the direct cost of the medicine to the HSE.

This document provides guidance on:

1. The source of prices for estimating drug costs
2. Inclusion of the rebate for drugs on the Community Drug Schemes
3. Distribution margins for drugs reimbursed under the Community Drug Schemes
4. Cost of hospital only drugs
5. Cost of comparator drug(s)
6. Sensitivity analysis

1. The source of prices for estimating drug costs

In the case of new drugs, the price to the wholesaler should not exceed the currency adjusted average price to the wholesaler in nine EU Member States including Austria, Belgium, Denmark, Finland, France, Germany, the Netherlands, Spain and the UK. If any new medicine is not available in all of the nominated EU States, the Irish price to the wholesaler should not exceed the price to the wholesaler in the nominated EU States where the new medicine is available. ***The price to the wholesaler should include all the basket countries where a price has been set at the time of the pharmacoeconomic submission.***

The wholesale mark-up on all items is 8% of the price to the wholesaler on the HTDS. [1,2] On the GMS, DPS and LTI schemes the wholesaler mark-up for fridge items is 12% and for all else is 8%.

For existing drugs, the NCPE uses the same prices that are listed in the reimbursement files of the Primary Care Reimbursement Service (PCRS) which represent the price paid to pharmacists by the HSE and are available at: http://www.sspcrs.ie/druglist/search.jsp. This data is updated on a monthly basis. If prices are not available from the PCRS files we would contact the Corporate Pharmaceutical Unit and/or the company directly.

2. Inclusion of the rebate for drugs on the Community Drug Schemes

Each month pharmaceutical manufacturers and importers must rebate to the PCRS 4% of the value, at the level of the price to the wholesaler (i.e. ex-factory price level), of all medicines dispensed under the Community Drug Schemes. This should be accounted for in the drug cost estimates (see Tables 1 and 2).

3. Distribution margins for drugs reimbursed under the Community Drug Schemes

GMS and DP/LTI schemes:

The pharmacy dispensing fee structure is based on a sliding scale as follows: €5 for first 1,667 items, €4.50 for next 833 items and €3.50 for the remaining items per month.[1] The average dispensing fee per item between November 2012 and March 2013 was estimated at €5.00 on the GMS. On this basis, we currently recommend including a dispensing fee of €5.00 per item for the GMS and the DP/LTI schemes.

- **GMS, DPS & LTI Scheme:** The pharmacy reimbursement price is determined from the pharmacy purchase price + dispensing fee.

Table 1. The pharmacy reimbursement price of Drug A (pack size: 28 tablets) on the GMS and DP/LTI scheme (non-fridge items)

	GMS, DPS and LTI
a. Price to the wholesaler	€34.35
b. Pharmacy purchase price (28 tablets)*	€ 37.10
c. Plus pharmacy dispensing fee	+ € 5.00
d. Minus rebate of 4% of price to wholesaler	- €1.37
Total cost to the HSE (b+c+d)	**€ 40.72**

***Source:** PCRS GMS Drug File June 2010.

High Tech Drugs Scheme:

The ex-wholesale price (i.e. price to the wholesaler plus wholesale margin) is paid to wholesalers directly by the HSE. In addition, a set patient care fee of €62.03 per patient per month (ref: PCRS September 2008) is paid by the PCRS to the pharmacy to cover dispensing costs (Table 2). (Note: the patient care fee is a set monthly fee not a fee per item).

Table 2. The reimbursement price of Drug B (pack size: 2 injections) on the HTDS (March 2011). (Non-fridge item)

Drug B (pack size: 2 injections)*	
a. Price to the wholesaler	€1,140.57
b. Ex-wholesale price*	€1,231.82
c. Plus monthly patient care fee	+ €62.03
d. Minus rebate of 4% of price to the wholesaler	- € 45.62
Total cost to the HSE (b+c+d)	**€1,248.22**

Source: PCRS High Tech Drug File June 2011.

* VAT should be included for the budget impact analysis but not the cost-effectiveness analysis.

VAT:

VAT at a rate of 23% is included on non-oral medicines (which includes topical preparations and injections). VAT should be excluded from cost-effectiveness evaluations but included in the budget impact analysis at the appropriate rate for non-oral medicines. VAT is applied to the total drug cost (ex-wholesale price plus

pharmacy margins) on the GMS, DP and LTI schemes. VAT is not applied to the patient care fee but it is applied to the ex-wholesale price on the HTDS.

4. Cost of hospital only drugs

The cost of hospital drugs should reflect what the HSE pays for the drug, so that the evaluation is relevant for decision making. If a hospital purchase order for products from a single pharmaceutical company exceeds €635, the ex-manufacturer price typically applies. For off-patent proprietary drugs and generic drugs, very high discounts may be negotiated, and the list price may not be a realistic reflection of the cost to the HSE. Therefore, in certain circumstances, it may be appropriate to take account of discounted prices in order to reflect the cost to the HSE.

5. Cost of comparator and concomitant drug(s)

The costs of the comparator and concomitant drug(s) should be the most recent price for the month during which the submission is prepared. The cost for each drug will be based on the product, formulation and pack size which gives the lowest cost, provided that it represents a realistic choice for use in clinical practice. If the drug is due to go off-patent or if it is already off-patent and will be subject to a future price cut, this should be accounted for in the base case of the cost-effectiveness evaluation and budget impact analysis.

6. Sensitivity analysis

Drug costs should be varied in the one-way sensitivity analysis by at least +/-20%.
A graph of the drug cost versus the ICER should be presented in the submission.

References

1. Statutory Instrument No 300 of 2011. Health Professionals (reduction of payments to community pharmacy contractors) regulation 2011
2. Personal communication with HSE June 2013.

Appendix 1.

This document only includes guidance on the direct cost of drugs to the HSE. It does not include information about additional costs, which may be associated with drug monitoring, preparation or administration. However, these costs will be included in the cost-effectiveness and budget impact analysis and the following checklist maybe used as a guide (Table 1.1).

Table 1.1. Methodological checklist on reporting cost estimation for medicines in economic evaluations.

Item	Recommendation
Drug name	Generic name should always be reported, but include proprietary (trade) name if necessary for identification purposes (not endorsement). Indicate whether the comparator is on or off patent
Dosage	Details of posology, including dose, dose frequency and dosage form (e.g. sustained-release preparations) should be reported. Where complex dose administration is necessary (e.g. by body surface area for chemotherapeutic agents), calculation details should be presented
Route of administration	Both the route of administration and costs relating to drug administration
Source of drug cost data	Must be referenced, and details given of what the estimate includes
Cost year	Must be reported and be the most recent available
Pharmacy charges	The costs to the payer of pharmacy services (e.g. professional and dispensing fees) need to be valued where applicable
Sales taxes	Must be reported and deducted if the economic evaluation is being performed from societal perspective. If the evaluation is being conducted from the perspective of the payer and the tax cannot be reclaimed, it should be included
Co-payments	Patient co-payments should be deducted from the overall costs if the perspective of the evaluation excludes direct non-medical costs
Hospital discounts	The base-case analysis should report on drug costs that reflect nationally agreed values. Wholesale discounts that may be available locally should be included in sensitivity analyses.
Hospital pharmacy costs	The economic evaluation should consider additional pharmacy costs, where appropriate, which might include the reconstitution of parenteral preparations, compounding of lotions and creams etc.
Therapeutic drug monitoring cost	The costs of therapeutic drug monitoring (e.g. measurement of plasma concentrations, pharmacodynamic response, or biochemical assay) should be included if specified to be a required component of therapy
Wastage	The cost of drug wastage (e.g. from vials or calendar packs) should be considered where appropriate. This should include wastage from patient non-compliance with therapies

Source: Pharmacoeconomics 2009: 27 (8) 635-643.