

National Centre for Pharmacoeconomics

Guidelines for Inclusion of Drug Costs in Pharmacoeconomic Evaluations



Version 3.1

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

Version Control

Version No.	Date	Description of Changes
3.0	06 January 2022	Updated to reflect changes associated with the IPHA agreement 2021 to 2025
3.1	12 January 2022	Changed wording from 'IPHA rebate' to 'Framework Agreement rebate'.

List of Abbreviations

CDS	Community Drug Schemes
CPU	Corporate Pharmaceutical Unit
DPS	Drug Payment Scheme
FA	Framework Agreement
GMS	General Medical Services Scheme
HSE	Health Service Executive
HT	High Tech Drug Arrangements
HTA	Health Technology Assessments
LTI	Long Term Illness
NCPE	National Centre for Pharmacoeconomics
PAF	Pricing Application Form
PAS	Patient Access Scheme
PCRS	Primary Care Reimbursement Service
VAT	Value Added Tax

1 INTRODUCTION

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. Estimates of drug costs should be applied consistently across rapid reviews and Health Technology Assessments (HTAs) submitted to the National Centre for Pharmacoeconomics (NCPE). Drug costs should reflect the total cost of the medicine to the Health Service Executive (HSE).

The total drug cost to the HSE consists of five principle components:

1. Price to Wholesaler (also known as the ex–manufacturer price, ex-factory price)
2. Wholesale Mark up
3. Pharmacy Fees
4. Rebate on Sales
5. Value Added Tax (VAT)

Other terms are also used to describe drug cost as a medicinal product moves through the drug supply chain. For example, the Primary Care Reimbursement Service (PCRS) reimbursement price = Price to Wholesaler + Wholesale Mark-Up.

The levels of each of these components and therefore the total drug cost to the HSE will vary depending on the setting, eligibility of the patient and the formulation of the drug prescribed. The three main reimbursement schemes for calculating drug costs are:

- Community Drug Schemes (CDS)
Numerous reimbursement schemes are administered by the PCRS. For the purposes of this document we define the community drug schemes as the most common schemes, the General Medical Services Scheme (GMS), Drugs Payment Scheme (DPS) and Long-Term Illness (LTI) scheme, but excluding the High Tech Drug Arrangements.
- High Tech Drug Arrangements (HT)
- Hospital Drugs

This document will outline how each of the individual drug price components is quantified. Example calculations are then provided for each of the three main pricing scenarios. Finally, factors relating to the calculation of drug costs are outlined.

2 PRICE TO WHOLESALER AND SOURCES OF DRUG COSTS

In the case of new drugs, the price to wholesaler included in submissions to the NCPE should correspond with the price to wholesaler specified in the pricing application form (PAF) submitted to the Corporate Pharmaceutical Unit (CPU) of the HSE. The proposed Irish price to wholesaler on the PAF must be less than or equal to the average basket price of fourteen EU Member States including Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden 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 wholesaler should include all the basket countries where a price has been set at the time of reimbursement application.¹

For existing drugs, the price to wholesaler may not be available directly. The NCPE uses the prices that are listed in the reimbursement files of the PCRS which represent the price paid to pharmacists by the HSE.² This is known as the PCRS Reimbursement Price which consists of the *Price to Wholesaler + Wholesale Mark-up (excl. VAT)*. This list is updated on a monthly basis and is available at: <https://www.sspcrs.ie/druglist/pub>. Knowing the appropriate wholesale mark-up, the price to wholesaler can be calculated from this list. There is no formal reimbursement list for hospital only drugs. The website of the Corporate Pharmaceutical Unit includes up to date Reimbursement Prices for a number of hospital only drugs (<https://www.hse.ie/eng/about/who/cpu/>).

If prices are not available from the PCRS files or NCPE website, we suggest contacting the Corporate Pharmaceutical Unit and/or the manufacturer directly.

3 WHOLESALER MARK-UP

Wholesale mark-up is applied to the price to wholesaler before a rebate is deducted if applicable.

Community Drug Schemes

The wholesale mark-up for fridge items is 12% and for all else is 8%.³

High Tech Drug Arrangements

The wholesale mark-up on ALL items is 8% of the price to the wholesaler under the High Tech Drug Arrangements.⁴

Hospital Drugs

If a hospital purchase order for products from a single pharmaceutical company exceeds €634.57 (excluding VAT) no wholesale mark-up is applied.¹

4 REBATE ON SALES

Patented Exclusive Medicines

Each month pharmaceutical manufacturers and importers of patented exclusive medicines must rebate to the PCRS a percentage of the value, at the level of the price to the wholesaler, of all medicines reimbursed by the HSE. This includes:

- Community drug schemes
- High Tech Drugs
- Hospitals and all medicines supplied to the HSE or State-funded hospitals providing hospital services
- any other publicly-funded entities and State agencies in each case whose functions include the provision of medicines.

From January 2022 this percentage is 7.75%. This should be accounted for in the drug cost estimates. No 7.75% rebate will be payable on the specific classes of medicines which are the subject of the price reductions applied under clause 7, clause 8, and clause 9 of the Framework Agreement on the Supply and Pricing of Medicines 2021¹.

Patent expired non-exclusive biologic medicine

The 2021 Framework Agreement provides for a rebate of 12.5% at the level of price to wholesaler for patent expired non-exclusive biologic medicines.¹ In practice, the discount may be applied by the company by reducing the price to wholesaler by an equivalent amount in addition to the other rebates required by the Framework Agreement with the

introduction of a biosimilar. Therefore, a rebate of 12.5% should be applied at the level of price to wholesaler for patent expired non-exclusive biologic medicines except where the price to wholesaler has already been reduced to take account of this discount.

5 PHARMACY FEES

Pharmacy fees vary depending on the scheme employed.

Community Drug Schemes

The pharmacy dispensing fee structure is based on a sliding scale as follows: €5 for the first 1,667 items, €4.50 for the next 833 items, and €3.50 for the remaining items per month.³ In certain circumstances when a drug is dispensed on a phased basis, phased dispensing fees may also be claimed.⁵ In these cases a phased dispensing fee of €3.27 per drug item for each dispensing phase other than the first dispensing phase is also payable in addition to the normal dispensing fee.

An average dispensing fee should be applied in submissions. Based on our analysis of published PCRS fee data from January to April 2018 we currently recommend applying a dispensing fee of €5.48 per item on the community drug schemes.

High Tech Drug Arrangements

A set patient care fee of €62.03 per patient per calendar month is paid by the PCRS to the pharmacy to cover dispensing costs and pharmacy advisory service (Note: the patient care fee is a set monthly fee per patient not a fee per item).³

For medicines on this scheme that require less frequent than monthly dispensing, pharmacists are paid a non-dispensed patient care fee by the PCRS in subsequent months. The patient care fee in this instance is reduced to €31.02. A non-dispensed patient care fee may only be paid for a maximum of three consecutive months in respect of a particular patient between each dispensing.³

Hospital Medicines

Pharmacy fees are not applied to hospital medicines.

6 VAT

VAT should be excluded from cost-effectiveness evaluations but included in the budget impact analysis at the appropriate rate.^{6,7}

- Zero rate of VAT applies to oral medicines (including inhalers).^{8,9}
- VAT at the standard rate of 23% applies to non-oral medicines (which includes topical preparations and injections).^{8,10}
- A range of VAT rates from 0% to 13.5% applies to clinical nutritional products such as low protein products. The VAT range is dependent on the product type.¹²
- Zero rate of VAT also applies to non-drug products such as ostomy and urinary appliances and anti-embolism hosiery.¹²
- Revenue previously applied a human blood exemption to pharmaceutical products derived from human blood plasma. However, this is no longer the case. From 1 January 2020 pharmaceutical products derived from human blood plasma are subject to the standard rate of VAT of 23%.¹³
- Non-oral contraceptive products are subject to a reduced rate of VAT at 13.5%.¹²

Community Drug Schemes

VAT is applied to the sum of the PCRS reimbursement price and the dispensing fee. VAT is not applied to the dispensing fee if the product is not subject to VAT.^{10,12}

High Tech Drug Arrangements

VAT is applied to the PCRS reimbursement price. VAT is not applied to the patient care fee.

Hospital Medicines

VAT is applied to the price to wholesaler provided the conditions outlined in Section 3 (Wholesale Mark-up) are met.

7 EXAMPLES OF DRUG COST CALCULATIONS FOR ECONOMIC EVALUATIONS

Community Drug Schemes

Examples of calculations of drug costs on the community drug schemes are outlined in tables 1 and 2 respectively.

Table 1 Calculating the total drug cost to the HSE for a patented exclusive fridge item on the Community Drug Schemes.

	Component	Adjustment	Cost (€)
A	Price to Wholesaler		€1,000.00
B	Wholesale Mark-up	12% of A	€120.00
C	Reimbursement Price	A+B	€1,120.00
D	Pharmacy Fees	€5.48	€5.48
E	Framework Agreement Rebate	-7.75% of A	-€77.50
	Total drug cost to the HSE (C+D+E)		€1,047.98

Table 2 Calculating the total drug cost to the HSE for an off patent non-exclusive item on the Community Drug Schemes

	Component	Adjustment	Cost (€)
C	Reimbursement Price*		€100.00
D	Pharmacy Fees	+€5.48	€5.48
	Total drug cost to the HSE (C+D)		€105.48
It is not necessary to calculate the price to wholesale in this example as the rebate is not applicable for off patent non-exclusive items and the reimbursement price is available on the reimbursement list.			

High Tech Drug Arrangements

The reimbursement price is paid to wholesalers directly by the HSE. Patient care-fees are paid to pharmacists as outlined in section 5 above. Sample calculations are shown in table 3.

Table 3 Calculating the total cost to HSE for patented exclusive medicines on the High Tech Drug Arrangements

	Component	Adjustment	Cost (€)
A	Price to Wholesaler		€1,000.00
B	Wholesale Mark-up	+8%	€80.00
C	Reimbursement Price	A+B	€1,080.00
D	Pharmacy Fees	+€62.03	€62.03
E	Framework Agreement Rebate	-7.75% of the price to wholesaler	-€77.50
	Total drug cost to the HSE (C+D+E)		€1,064.53

Table 4 Calculating the total cost to the HSE for a biosimilar medicine on the High Tech Drug Arrangements

	Component	Adjustment	Cost (€)
A	Price to Wholesaler		€1,000.00
B	Wholesale Mark-up	8%	€80.00
C	Reimbursement Price	A+B	€1,080.00
D	Pharmacy Fees	€62.03	€62.03
E	Framework Agreement Rebate	None	
	Total drug cost to the HSE (C+D)		€1,142.03

Table 5 Calculating the total cost to the HSE of a patent expired non-exclusive biologic medicine on the high tech drug arrangements*

	Component	Adjustment	Cost (€)
A	Price to Wholesaler		€1,000.00
B	Wholesale Mark-up	8%	€80.00
C	Reimbursement Price	A+B	€1,080.00
D	Pharmacy Fees	€62.03	€62.03
E	Framework Agreement Rebate	-12.50%	-€125.00
	Total drug cost to the HSE (C+D+E)		€1,017.03

*Where the price to wholesaler has already been reduced to account for the price reductions mandated for an exclusive biologic medicine when a biosimilar medicine is introduced and the price to wholesaler has not been further reduced instead of the application of a rebate.

Hospital Medicines

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 €634.57 (excluding VAT), the price to wholesaler typically applies.

The calculation of costs covered under the Oncology Drug Management System is in line with the calculation of costs for Hospital Drugs.

For off-patent proprietary drugs and generic drugs, very high discounts may be negotiated by the hospital, and the reimbursement 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. (Discounts in the form of Patient Access Scheme (PAS) may also be in place for patent protected proprietary medicines, See Section 0)

An example of the calculation of the total cost to the HSE for a hospital patented exclusive medicine is shown in Table 6.

Table 6 Calculating the total drug cost to the HSE for Hospital Patented Exclusive Medicines

	Component	Adjustment	Cost (€)
A	Price to Wholesaler		€1,000.00
B	Wholesale Mark-up	0% if conditions in section 2 are met	€0.00
C	Hospital Price	A+B	€1,000.00
D	Pharmacy Fees	N/A	
E	Framework Agreement Rebate	-7.75% of the price to wholesaler	€-77.50
	Total drug cost to the HSE (C+E)		€922.50

8 EXAMPLES OF DRUG COST CALCULATIONS FOR BUDGET IMPACT MODELS

Unlike the calculations of drug costs for economic evaluations, drug costs for budget impact models should include VAT. Not all medicines are subject to VAT. Types of medicines which are subject to VAT are outlined in section 6.

Community Drug Schemes

Table 7 Calculating the total drug cost to the HSE for a patented exclusive injection fridge item on the Community Drug Schemes including VAT

	Component	Adjustment	Cost (€)
A	Price to Wholesaler		€1,000.00
B	Wholesale Mark-up	12% of A	€120.00
C	Reimbursement Price	A+B	€1,120.00
D	Pharmacy Dispensing Fees	€5.48	€5.48
E	Framework Agreement Rebate	-7.75% of A	-€77.550
F	VAT	23% of C+D	€258.86
	Total drug cost to the HSE (C+D+E+F)		€1,306.84

Table 8 Calculating the total drug cost to the HSE for an off patent non-exclusive item on the Community Drug Schemes including VAT

	Component	Adjustment	Cost (€)
C	Reimbursement Price		€100.00
D	Pharmacy Fees	€5.48	€5.48
F	VAT	23% of Reimbursement Price and Pharmacy Dispensing fee	€24.26
	Total drug cost to the HSE (C+D+F)		€129.74

High Tech Drug Arrangements

Table 9 Calculating the total Drug Cost to the HSE for patented exclusive medicine on the High Tech Drug Arrangements including VAT

	Component	Adjustment	Cost (€)
A	Price to Wholesaler		€1,000.00
B	Wholesale Mark-up	8%	€80.00
C	Reimbursement Price	A+B	€1,080.00
D	Pharmacy Patient Care Fee	€62.03	€62.03
E	Framework Agreement Rebate	-7.75% of the price to wholesaler	€-77.50
F	VAT	23% of C	€248.40
	Total drug cost to the HSE (C+D+E+F)		€1,3112.93

Hospital Schemes

Table 10 Calculating the total drug cost to the HSE for a hospital patented exclusive medicine including VAT

	Component	Adjustment	Cost (€)
A	Price to Wholesaler		€1,000.00
B	Wholesale Mark-up	0% if conditions in section 2 are met	€0.00
C	Hospital Price	A+B	€1,000.00
D	Pharmacy Fees	N/A	
E	Framework Agreement Rebate	-7.75% of the price to wholesaler	€-77.50
F	VAT	23% of C	€230.00
	Total drug cost to the HSE (C+D+E+F)		€1,152.50

9 CALCULATING ANNUAL DRUG COSTS/CYCLE DRUG COSTS

Care should be taken when calculating annual drug costs. Drug costs are calculated on the basis that there is an average of 365.25 days in a calendar year. For the purposes of calculating drug costs for the community drugs and high-tech schemes, the NCPE recommended dispensing interval is 28 days. This applies also to dosage forms packed as a 30-day supply. Alternative dispensing intervals must be justified (e.g. products administered on a 6-monthly basis etc.).

For the community drug schemes, in situations where the dispensing interval of 28 days is not a multiple of the pack equivalent days' supply, the annual total drug cost to the HSE excluding pharmacy fees must be calculated separately to the calculation of annual pharmacy fees, so that the fees align. Pharmacy Fees should always be calculated separately to drug costs under the High Tech Drug Arrangements as the patient care fee is

a fee per patient per calendar month regardless of the number of dispensings or number of items dispensed (see section 5).

Example 1 – High Tech

The annual drug cost of drug X, including VAT, is required under the High Tech Drug Arrangements. The dosing regimen is one injection once every two weeks. Drug X is available as one injection pack size which therefore equates to a 14-day supply. The price to wholesaler is €1,000 per pack.

Table 11 Calculating the Annual Drug Cost to the HSE of Drug X including VAT

	Component	Adjustment	Cost (€)
A	Price to Wholesaler		€1,000.00
B	Wholesale Mark-up	8%	€80.00
C	Reimbursement Price	A+B	€1,080.00
E	Framework Agreement Rebate	-7.75% of the price to wholesaler	€-77.50
F	VAT	23% of C	€248.40
G	Net Cost per Pack Excluding Pharmacy Fees	C+E+F	€1,250.90
H	Annual Drug Cost Excluding Pharmacy Fees and assuming pack size is equivalent to 14 days supply	$G / ((\text{Pack Equivalent Days Supply}[14]) \times 365.25)$	€32,635.09
I	Annual Pharmacy Fees	€62.03 x 12 Calendar Months	€744.36
J	Total Annual Drug Cost to the HSE	H+I	€33,379.45

Example 2 – Lack of alignment between dispensing interval and pack equivalent days supply on community drug schemes

The annual drug cost of drug Y excluding VAT is required. The dosing regimen is one tablet daily. Drug Y is available in a pack of 30. The price to wholesaler is €1,000 per pack.

Table 12 Calculating the Annual Drug Cost of Drug Y

	Component	Adjustment	Cost (€)
A	Price to Wholesaler		€1,000.00
B	Wholesale Mark-up	8%	€80.00
C	Reimbursement Price	A+B	€1,080.00
E	Framework Agreement Rebate	-7.75% of the price to wholesaler	€-77.50
G	Total Cost per Pack to the HSE Excluding Pharmacy Fees	C+E	€1,002.50

H	Total Annual Drug Cost to the HSE (Excluding Pharmacy Fees) assuming pack size is equivalent to 30 days supply	$G/(\text{Pack Equivalent Days Supply}[30]) \times 365.25$	€12,205.44
I	Annual Pharmacy Fees	$365.25/(\text{Dispensing Interval [28]}) \times €5.48$	€71.48
J	Total Annual Drug Cost to the HSE	H+I	€12,276.92

The calculation of drug costs for economic models where a cycle length is less than one year should be calculated in a similar manner. The average number of days in year (365.25) is replaced by the cycle length in days.

10 PATIENT ACCESS SCHEMES

In the cases of patented proprietary medicines, substantial discounts may be negotiated in the form of confidential Patient Access Schemes (PAS). PAS may be considered in scenario analysis but should not be considered in the base case. Confidential discounts in the form of a PAS are usually applied at the level of Price to Wholesaler. Prices submitted under the terms of a PAS should be clearly broken down into price components in line with the example calculations provided.

11 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. If the drug has been assigned a reference price (see: <http://www.hse.ie/referenceprice/>) for drugs included in the reference price system) the reference price should be included in the base case analysis of the submission.

Discounts in the form of a PAS may also be in place for comparator and concomitant medicinal products. The list price should always be used to calculate the ICER in the base case. A plausible range of prices should be included in sensitivity analysis.

When calculating drug prices, consideration should be given to the implications the introduction of a generic or biosimilar product has for the price to wholesaler and rebates for the originator medicine as outlined in the Framework Agreement.¹

12 REFERENCES

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