Achieving Better Value for Money in Supply of Medicines

1. Introduction

The Cabinet Committee on Health, in April 2005, considered a range of issues which was prepared to effect savings or at least ameliorate the rate of increase in the cost of the various community drugs schemes and of drugs in hospitals. A range of measures was agreed upon.

The CEO of the HSE established in November 2005, a Pharmaceuticals Steering Group to implement the Cabinet Committees decisions.

A joint HSE/DOHC Team was agreed by the Steering Group and charged with examining all aspects of the drugs supply chain and entering new arrangements with the manufacturers, wholesalers and Community Pharmacists.

In mid 2006 the HSE/DOHC Team reached agreement with the Irish Pharmaceutical Healthcare Association (IPHA) and the Association of Pharmaceutical Manufacturers of Ireland (APMI). These agreements are for a period of four years, commencing on 1st September, 2006 (IPHA) and on 10th October 2006 (APMI). The savings of both agreements is estimated at €250m over the four years.

2. Pharmaceutical Wholesale and Distribution Services

Following completion of agreement with manufacturers, negotiations then commenced with the Pharmaceutical Distributors Federation (PDF). This body represents the three main wholesalers in the Irish market who supply approximately 90% of all medicines to community pharmacies and hospitals in Ireland. The three main wholesalers are:- United Drug, Cahill May Roberts and Uniphar.

Early in the negotiations with the PDF a legal issue arose. PDF indicated to the HSE/DOHC Team that, based on legal advice available to them, they would not be able to negotiate in relation to medicines delivered to community pharmacists.

The HSE/DOHC Team sought its own legal advice on the issue identified by the PDF advice. The legal advice obtained by the HSE/DOHC Team made it clear that the negotiations with PDF to determine wholesale distribution fees would be contrary to the Competition Act, 2002. This advice was submitted by the Department of Health and Children to the Office of the Attorney General. The Attorney General endorsed the advice received by the HSE/DOHC Team. In summary the legal advice was that Section 4 (1) of the Competition Act, 2002 prohibits all agreements between undertakings, decisions by associations of undertakings and concerted practices which have as their objective or effect the restriction or distortion of competition, including agreements to fix prices, unless the agreement, decision or concerted practice meets certain conditions.
Individual wholesalers and individual pharmacy contractors are undertakings and the PDF and IPU are associations of undertakings for the purposes of Section 4 (1) of the Act.

In light of the advice it was not possible for the HSE to engage with the PDF in relation to fees. This was communicated to the PDF in mid December 2006.

In order to determine new margins for wholesale services and remain in compliance with competition legislation, the HSE/DOHC Team began a public consultation process. Also, following a competitive procurement process INDECON were commissioned to provide an economic analysis of the Irish and EU wholesale market.

**Integration of wholesale and distribution services with retail sector**

United Drug has no equity interest in retail pharmacy in the Republic of Ireland. However, in a note to the audited accounts of United Drug (Wholesale) Limited, the following statement is made:

"Guarantees have been given by the Company in respect of borrowing facilities of certain customers".

It is the understanding of the HSE/DOHC Team that significant guarantees have been made available to retail pharmacists to assist in the start-up costs and hereby counteract "the creep of multinational chains". [INDECON Report (March 2007) P. 19]

Cahill May Roberts are owned by Celesio AG. Celesio AG also owns Unicare, a retail chain of 60 pharmacies.

Uniphar is a co-operative owned by approximately 450 Community Pharmacists. Uniphar sponsors IPOS (Independent Pharmacy Ownership Scheme). Uniphar owns both the former Phelan and Walsh chain groups.

Thus, there is significant vertical integration at wholesale/retail levels in the country.

### 3. Existing Wholesale Margins

Prices are regulated at the level of the manufacturers by way of the agreement between the State and the manufacturers. This price to wholesaler is the basis for all prices in the market.

Added to the price to wholesaler is a margin of 15% which is part of the cost reimbursed by the Primary Care Reimbursement Service (PCRS) in respect of the various community drug schemes.

For the hospital sector (2006: €280m) a different regime applies. Currently supplies to hospitals are invoiced at the ex-factory price plus 15%\(^1\) wholesale margin for orders up to a value of €634.87. Where orders are for more than this

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\(^1\) It should be noted that the standard wholesale margin of 15% was intended to be applied to the ex-factory price (eg-factory price was €85, a margin of 15% amounted €12.75, so that the total amount reimbursed was €97.75). However, the practice developed whereby the margin was instead, calculated by reference to the ex-wholesale price (ie 15% of €100, being €15. This meant that, in fact, a margin 17.6% of the ex-factory price was paid. In an effort to partially remedy this, the HSE has, since the implementation of the new IPHA Agreement, calculated the wholesale margin on new items dispensed since 1 September 2006 at 15% of the ex-factory price of the drug.
amount and provided order is for a given manufacturer and placed with a specific wholesaler, the 15% wholesale margin is discounted.

4. Response to Public Consultation

On 20th December 2006 the HSE published a Call for Public Submissions into the provision of pharmaceutical wholesale and distribution services to both Community Pharmacy Contractors and other Healthcare locations in the Republic of Ireland in the three national daily newspapers in Ireland, and also on the HSE’s website. Initially five weeks were allowed for receipt of submissions, though this was extended where extensions were requested, with the final submission being accepted on 13th February 2007.

A total of 161 submissions (including 143 from community pharmacy contractors) were received.

During the public consultation process the Team met with:
- United Drug
- Cahill May Roberts
- Uniphar
- Touchstone
- IPHA
- DHL Excel

The HSE/DOHC Team commissioned INDECON to undertake a review of Pharmacy Wholesale Margins. The three full line wholesalers also met separately with INDECON.

The INDECON Report informed the deliberations of the HSE/DOHC team.

The three full line wholesalers were invited to submit proposals based on the maintenance of current service levels.

An assessment of wholesale margins was also obtained from the National Centre for Pharmacoeconomics.

5. Assessment of Cost of Current Wholesale/Distribution Service

There is no doubt that the wholesale market is very competitive. It is also obvious that the retail pharmacists exercise their significant buying power over the wholesalers/distributors and now enjoy a very favourable business model.

Arising from the public consultation our understanding of the key components of the current business model are as follows:

Discounts/Rebates:

Retailers are paid the reimbursement price (price to wholesaler +15% margin\(^2\)) in respect of community drugs schemes. The reality is that wholesalers provide to retailers very significant discounts and rebates. It is estimated that wholesalers currently pay over an average of half of their margin to retailers in the form of rebates and discounts.

\(^2\) Although, due to the way the margin was applied, it equates to 17.6% of the ex-factory price. See footnote 1 above.
Thus, if the ex-factory price is €85, then the reimbursable price is €100.\(^3\)
However the average cost to retailers is estimated at €92.

**Credit Terms:**

In 2003 a supplementary report for the Pharmacy Review Group stated that, on average, about 43% of a retail pharmacy’s total income is reimbursed by the State (within an average period of 4 weeks), through the community drug schemes. The remainder comes from over the counter drugs, non reimbursed sales and non drug items. Further the retail pharmacies also enjoy extremely favourable credit terms extended to them by the three main wholesalers.

**Stocks:**

“Wholesalers carry stock for retail and hospital providing a just in time service. Both retail and hospitals have space limitations and cannot hold any significant levels of stock”.

This, in turn, necessitates up to two deliveries per day to each retailer – each retailer may receive 3 or 4 deliveries per day from combined wholesalers

The existing business model compels the wholesalers to compete on extra services and cost efficiency. Wholesalers perform the following broad functions in the supply chain of the pharmaceutical industry:

1. They provide services that add value to both pharmaceutical manufacturers and retailers. These additional services include sales analyses, marketing assistance, and product recalls.

2. They provide services with generous discounts, and credit arrangements together with a “Just in Time” delivery.

3. These services are at a cost to the wholesalers with the retail pharmacies benefiting. The submissions indicate the following margins:
   - Rebate given to Irish Pharmacy is an average 8 percentage points of the 15 percentage point wholesale margin
   - Cost of operating retail and distribution business is about 5.5%
   - The net margin is between 2% and 2.5%

4. The wholesalers maintain this net margin must be maintained to ensure a reasonable return for them.

The current business model has developed over many decades primarily built on the availability of a wholesale margin of 15% and on the power of retail pharmacies to extract beneficial trading arrangements. The wholesalers now expect their current net margin to be maintained by the Exchequer.

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\(^{3}\) To be precise, if the 15% wholesale margin were to be applied to a drug with an ex-factory price of €85 correctly, the reimbursable cost would be €97.75. See further footnote 1 above.
The current arrangements in respect of Wholesale/Distribution services are not transparent. Equally costs are being incurred by wholesalers (on delivering generous trading terms to retail pharmacies) which are not appropriate for the Exchequer to reimburse.

It is clear that the existing arrangements for the distribution and wholesaling of medicines need to be reviewed. The following statements from the submissions received are very pertinent.

- A situation where the majority of the 15% gross margin given to wholesalers for the distribution of medicines to community pharmacy ends up at retail pharmacy is not an appropriate model.
- Retail pharmacy should be paid properly but separately for the services it provides.
- Levels of payment to distributors should be directly linked to the service provided rather than to the value of the product being distributed or indeed dispensed.
- Different models of distribution, including direct from the manufacturer exist.

7. Conclusion

The existing business model must be changed.

The State should pay for the necessary logistics costs in having medicines delivered from the factory gate to retail pharmacies and hospitals and this payment should be at a level to ensure continuity of supply, quality and that the risk of counterfeits entering the supply chain are minimised. However, substantial reductions in cost can and should be made.

While many aspects of the arrangements between wholesalers and community pharmacists are purely commercial matters between themselves there has to be transparency in relation to the costs involved as the HSE should only reimburse the appropriate costs. The HSE has an obligation to ensure that the reimbursement price for this service is fair and transparent and reflects the price at which the market values this service.

The HSE intends to implement a new reimbursement price for community wholesale services in late 2007, and should also review this reimbursement price on a regular basis to ensure that the price continues to reflect market values.

It is anticipated that similar implementation arrangements to those used for the implementation of the new IPHA prices in March 2007 will also be required in this instance.

The recommendations set out below must be regarded as transitional. The HSE should remove itself from interacting with the wholesaler sector as it now operates. Future procurement from manufacturers should be for medicines delivered to community pharmacists. For wholesale services for hospitals, the HSE should procure a delivery service by competitive tendering process within two years. This time frame would give the market ample time to prepare for this change. The transition needs to be managed to avoid unnecessary market disruption. The HSE is proposing to implement new arrangements on an interim basis pending the completion of the tender process.
Hence, the recommendation is that the new arrangements would be phased in over the period 2007 and 2008. As all consultations, deliberations were based on existing service levels being maintained, the recommendations are also based on existing service levels being maintained in the future.

We are recommending separate rates for the two sectors i.e. community pharmacies and hospitals.

**Community Pharmacy**

As with the IPHA Agreement, a two staged price reduction is recommended (The INDECON Report suggested that reductions in margins needed to be carefully managed). The new reimbursement price is:

- With effect from 1/01/08: plus 8% to ex-factory price (ex-factory price paid to manufacturer)
- With effect from 1/01/09: plus 7% to ex-factory price

**Hospital**

The new and interim arrangements, with effect from 1/01/08, for a maximum period of two years are as follows:

- Basic wholesale price: IPHA price +5% (Note A below)

The following discounts may be availed of by the hospitals:

- Electronic Ordering - 1%
- Bulk Order with a value over €2,000 - 0.5%
- Out of hours runs (by agreement with hospitals) - 0.5%
**Note A:**

The basic wholesale price of plus 5% is for a standard level of service, to be set out in a formal national service level agreement.

**Note B:**

The above hospital pricing structure is for a full line wholesale distribution service for all supplies purchased by hospital pharmacies.

**Note C:**

More favourable terms to the above may be negotiated by individual hospitals with wholesalers.

12th September 2007