



Patented  
Medicine Prices  
Review Board

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prix des médicaments  
brevetés

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# Verification of Foreign Patented Drug Prices (2000)

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## Purpose

The purpose of this report is to verify foreign price information as reported by patentees in each of the seven countries listed in the *Patented Medicines Regulations* in accordance with the terms of reference approved by the Management Committee on September 4, 2001.

## Executive Summary

1. The top-selling 50 DINs were verified using the price information of the year 2000 as provided by the patentees.
2. Ex-factory prices for patented drug products were derived from publicly available formulary prices using regulated wholesale and pharmacy mark-ups in the six European countries.
3. The U.S. does not have regulated mark ups. For our purposes, ex-factory prices filed by patentees were compared with the Average Wholesale Prices (AWP) from the Red Book and Federal Supply Schedule (FSS) prices.
4. The verification process shows that patentees have, overall, been complying with the *Regulations* and have filed publicly available ex-factory prices for patented drug products with the PMPRB.
5. The verification process shows that, in the six European countries,
  - In 85% of the cases prices filed by patentees were equal to derived ex-factory prices compared to 83.6% in the 1998 study.
  - In 4.6% of the cases filed prices were less than derived ex-factory prices compared to 7.3% in the 1998 study;
  - In 10.2% of the cases filed prices were higher than derived ex-factory prices compared to 9% in 1998.

In the U.S.,

- Comparisons of filed prices with the AWP in the U.S. show that in all but one case, filed prices were less than AWP. Prices filed by patentees were 8% to 29% below the AWP. Publicly available sources suggest that AWP includes, on average, a 20% mark up on manufacturers' selling price.
- Comparisons of filed prices with direct prices, which are the manufacturers' price to pharmacies, show that 53% of the cases filed prices were equal to or less than direct prices. The differential between filed prices and direct prices were less than 5.0% for the remaining observations where filed prices were higher.

➤ In 82.5% of the cases filed prices were equal to or less than the FSS prices published in the Internet.

6. The PMPRB staff is in contact with the companies to inquire about the drug products that are not in compliance. Appropriate actions will be taken when and if necessary.

## **Background**

The PMPRB produced a report “Evaluation of the Foreign Price Verification Process” approved by the Executive Committee on January 16, 2001. The report was produced following the Auditor General’s recommendation that the PMPRB should find cost effective methods to check the accuracy of price information submitted by patentees to enhance public confidence in the price review process. The report inter alia recommended that every three years a foreign price verification study be undertaken in accordance with the terms of reference approved by Management Committee, to ensure accuracy of the foreign price information reported to the PMPRB. It was suggested in the operational details of the report that Policy and Economics Analysis Branch be responsible for conducting the foreign price verification study, similar to that conducted in 1998.

Following is an analysis of the results of the verification process. A country by country description outlining the steps necessary to derive ex-factory prices from publicly available sources is provided in Appendix 1. Appendix 2 provides the list of DINs that were verified for the report. Appendix 3 provides the sources that were used for information on publicly available foreign prices.

### ***VERIFICATION OF FOREIGN PRICES FOR THE TOP 50 SELLING PATENTED DRUG PRODUCTS, 2000***

As per the terms of reference, the top selling 50 drug products were verified for the purposes of this report. Each DIN was verified by pack size for two classes of customers: wholesale and pharmacy. There were 479 DIN-pack size combinations to be verified for the two classes of customers. All but two of these top sellers in 2000 were introduced into the Canadian market in the 1990s. One drug product was introduced in 1987 and the other in 1989.

#### **The Six European Countries:**

Table 1 and Table 2 provide a summary of the results for wholesale and pharmacy markets in the six European countries and show for each country: the number of DINs; the total number of DIN and pack sizes; the number of observations where the filed prices are equal to derived ex-factory prices (the two prices are considered equal if the deviation between filed prices and derived ex-factory prices are within one percentage point); the number of observations where filed prices are less than derived ex-factory prices; the number of observations where ex-factory prices filed by patentees are greater than the derived ex-

factory prices. Also, the range of deviations between derived and filed ex-factory prices where filed prices are greater than derived ex-factory prices are shown.

The number of drug products and the number of observations varied by country reflecting the fact that not all drugs are sold in every country and/or not all drugs are sold in the same strength or dosage form in every country.

**Table 1 Top Selling Patented Drug Products by Country : Filed Price vs Derived EX-Factory Price(Wholesale)**

| Top Selling Patented Drug Products by Country : Filed Price vs Derived EX-Factory Price wholesale |           |                     |   |                                       |  |  |          |           |           |           |           |       |
|---|-----------|---------------------|---|---------------------------------------|--|--|----------|-----------|-----------|-----------|-----------|-------|
| Comparis on Country   | # of DINs | # of DIN-Pack sizes | Filed Price= Derived EX-Factory Price (within 1%) | Filed Price< Derived EX-Factory Price | Avg % diff. where filed price < derived ex-factory price | Filed prices > Derived Ex-Factory price Ranges |          |           |           |           |           |       |
|   |           |                     | # Obs   | # Obs                                 |  | # Obs  | 0.5-10.0 | 10.0-20.0 | 20.0-30.0 | 30.0-40.0 | 40.0-50.0 | >50.0 |
| France  | 24        | 27                  | 24  | 3                                     | -1.02  | 0  | 0        | 0         | 0         | 0         | 0         | 0     |
| Germany   | 33        | 80                  | 73  | 0                                     | 0  | 7  | 6        | 1         | 0         | 0         | 0         | 0     |
| Italy   | 24        | 24                  | 23  | 1                                     | -30  | 0  | 0        | 0         | 0         | 0         | 0         | 0     |
| Sweden  | 36        | 74                  | 63  | 3                                     | -4.9   | 8  | 6        | 2         | 2         | 1         | 0         | 0     |
| Switzerland   | 24        | 50                  | 37  | 3                                     | -9.9   | 10   | 5        | 3         | 1         | 0         | 0         | 1     |
| U.K.  | 39        | 44                  | 37  | 2                                     | -1.5   | 5  | 1        | 4         | 0         | 0         | 0         | 0     |

Table 1 show that the compliance rate is highest for France and Italy. For every DIN, filed prices are either equal to or below derived ex-factory prices. On the other hand, prices submitted for Switzerland has the highest number (10) of cases where filed prices are greater than derived ex-factory prices followed by prices for Sweden (8), Germany (7) and the U.K. (5). It should be noted that deviations between filed prices and derived ex-factory prices are within the 0.5% to 10.0% range for majority of the observations where filed prices are higher.

**Table 2 Top Selling Patented Drug Products by Country : Filed Price vs Derived EX-Factory Price**

| Top Selling Patented Drug Products by Country : Filed Price vs Derived EX-Factory Price Pharmacy |           |                     |  |  |  |   |          |           |           |           |           |       |
|--|-----------|---------------------|--|--|--|---|----------|-----------|-----------|-----------|-----------|-------|
| Comparison Country   | # Of DINS | # of DIN-Pack sizes | Filed Price= Derived EX-Factory Price (with in 1%) | Filed Price < Derived EX-Factory Price | Avg % diff. where filed price < derived ex-factory price | Filed Price > Derived EX-Factory Price Ranges |          |           |           |           |           |       |
|  |           |                     | # Obs  | # Obs                                  |  | # Obs   | 0.5-10.0 | 10.0-20.0 | 20.0-30.0 | 30.0-40.0 | 40.0-50.0 | >50.0 |
| France   | 16        | 17                  | 16   | 1                                      | -7.6   | 0   | 0        | 0         | 0         | 0         | 0         | 0     |
| Germany  | 21        | 60                  | 50   | 0                                      | 0  | 10  | 2        | 0         | 0         | 0         | 0         | 8     |
| Italy  | 16        | 16                  | 9  | 3                                      | -8.9   | 4   | 3        | 0         | 0         | 0         | 1         | 0     |
| Sweden   | 28        | 56                  | 48   | 2                                      | -8.3   | 6   | 3        | 2         | 0         | 0         | 1         | 0     |
| U.K  | 29        | 32                  | 25   | 3                                      | -12.4  | 0   | 0        | 0         | 0         | 0         | 0         | 0     |

Table 2 shows verification results for ex-factory prices to pharmacies. Ex-factory prices to pharmacies could not be derived for Switzerland.

Switzerland used to publish ex-factory prices to pharmacies in their formulary. They no longer publish the formulary and pharmacy prices are not posted on the web site. Further work will be required to look for ways to derive ex-factory prices to pharmacies. It should be noted, however, that the filed prices for pharmacies was checked with pharmacy prices as published in the 1999 formulary. Prices did not change from 1999 to 2000 and in 95% of cases filed prices were equal to pharmacy prices published in the 1999 formulary.

Table 2 reveals that companies had the highest compliance rate in France and the U.K. Filed prices were never higher than derived ex-factory prices.

Companies filed higher prices for 10 out of 60 cases in Germany. In 8 out of these 10 cases the deviation between filed and derived ex-factory prices was higher than 50%. In Sweden 6 out of 56 cases filed prices were higher than derived ex-factory prices. In Italy, 4 out of 16 DINs filed prices were greater than derived ex-factory prices.

Overall, out of 479 DIN-pack size combinations for wholesale and pharmacy prices patentees had complied with the *Regulations* by filing prices equal to publicly available ex-factory prices for 407 or 85% of the cases compared to 83.6% in 1998; in 22 or 4.6% of the cases filed prices were less than derived ex-factory prices compared to 7% in 1998. In 49 or 10.2% of the cases filed prices were greater than derived ex-factory prices compared to 9% in 1998.

The PMPRB staff is in contact with the companies to inquire about the drug products that are not in compliance. Appropriate actions will be taken when and if necessary.<sup>1</sup>

<sup>1</sup> In 1998 companies resubmitted prices for DINs for which filed prices were higher than derived ex-factory prices when contacted.

## The U.S

The U.S. has no legislated mark ups that would enable the PMPRB to derive ex-factory prices as in the six European countries. They have a different health care system than the six European countries and have no national drug formularies. Two sources were used to verify U.S. prices: The Red Book and the drug prices listed under the Federal Supply Schedule (FSS) prices. According to the report *Prescription Drug Coverage, Spending, Utilization and Prices* published by the Department of Health and Human Services in April 2000, the process by which drug prices are determined in the U.S. is highly complex, involving numerous interactions and arrangements among manufacturers, wholesalers, retailers, insurers, pharmacy benefit managers (PBMs), and consumers.<sup>2</sup> The report suggested that the AWP published in the Red Book includes, on average, a 20% mark-up on manufacturers' prices.

Prices filed with the PMPRB were compared with AWPs published in the Red Book for 36 DINs or 65 DIN-pack size combinations. Comparison of prices showed that of all but one DIN, prices filed by patentees were 8% to 29% below the AWPs. Filed prices were 26.6% higher than AWP for one DIN.

The Red Book also publishes a "direct price" which is manufacturers' price to pharmacies. The direct price was available for 13 DINs or 34 DIN-pack size combinations. In 18 or 53% of the cases filed prices were equal to or less than direct prices. With the exception of 1 DIN, the deviation between filed prices and direct prices were less than 5.0%.

The U.S. prices were also verified using FSS prices. In 1998 the PMPRB began requiring that patentees file corresponding FSS prices.<sup>3</sup> As of January 1, 2000, the FSS prices were incorporated into the International Price Comparison test used in implementing the Board's Guidelines. The verification process shows that in 82.5% or 66 out of 80 of the cases filed prices were either equal to or less than FSS prices posted in the Department of Veterans Affairs web site.

There are other sources of U.S. prices, for example, Medispan which publishes wholesale acquisition cost (WAC) and the IMS. The PMPRB used Medispan in the past, however, discontinued its use as it was not found to be cost effective. The PMPRB staff will re-evaluate the cost effectiveness of acquiring Medispan or other sources for verification purposes in the future.

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<sup>2</sup> Report to the President, Prescription Drug Coverage, Spending, Utilization and Prices, Department of Health and Human Services, April 2000, Chapter 3. The web site for the full report is: <http://aspe.os.dhhs.gov/health/reports/drugstudy/index.htm>.

<sup>3</sup> See the October 1999, January 2000 and October 2000 issues of the PMPRB NEWSletters for detailed information on the Board's decision to require FSS prices for purposes of applying the Guidelines.



# APPENDIX 1

## *Methodology*

### France

In France, the national government publishes a list of approved drug products and prices for which it reimburses a portion of the prescription cost; the consumer or their private insurance pays the remainder. The list of reimbursed drug products along with their negotiated prices, are made available in SEMPEX. SEMPEX is published by the Medical-Pharmaceutical Publishing Company (SEMP).

Retail and wholesale mark-ups are controlled by the Ministry of Solidarity, Health, and Social Welfare. The Ministry issued a decree on April 28, 1999 setting the new wholesale mark-up on reimbursed pharmaceutical products. The mark-up is fixed at 10.74% for all drug products priced less than or equal to 150.00F. For drugs priced over 150.00F, there is a 10.74% mark-up on first 150.00F and a 6% mark-up on the cost above 150.00F(see the methodology below).

SEMPEX provides both the price at which pharmacies purchase drugs from either the manufacturer or wholesaler; and the price that pharmacies sell the drug product. Using either of these prices, and the legislated mark-ups, it is possible to derive the price charged by manufacturers to wholesalers and pharmacies.

### **Methodology to derive Ex-factory Prices:**

Direct method is to use the pharmacy purchase price (PAHT) listed in SEMPEX. This price represents the price at which pharmacies purchase a drug from either a manufacturer or a wholesaler.

### **Derivation of Wholesale Prices**

If the PAHT is less than or equal to 150.00 F:  
Ex-Factory price = PAHT / 1.1074

If PAHT is greater than 150.00 F:

Step 1:  $150.00/1.1074 = 135.45$

Step 2:  $(PAHT - 150.00)/1.06 = X$

Ex-Factory price =  $135.45 + X$

### **Pharmacy Prices**

The pharmacy price (PAHT) listed in SEMPEX is the ex-factory price to pharmacy.

## Germany

In Germany, individuals are either covered by state health insurance or a private health insurer. The public and private drug plans reimburse pharmacies for the drugs dispensed to their beneficiaries at the prices published in the Rote Liste.

Although the Rote Liste does not publish ex-factory prices, it is possible to derive publicly available ex-factory prices given the regulated wholesale and retail mark-ups provided in the *Pharmaceutical Price Regulation*. Prices listed in the Rote Liste include a 16% value added tax (VAT).

### Methodology to derive Ex-factory Prices:

The derivation of ex-factory prices to pharmacies is a two-step procedure. First, the retail price net of the 16% German VAT must be determined by dividing the Rote Liste price by 1.16. Then the net retail price must be found in Table 1 and the indicated mathematical operation must be performed to derive the price at which pharmacies in Germany purchase the drug product from either the manufacturer or from a wholesaler.

**Table 3 Derivation of the Price to Pharmacies given the Retail Price**

| Retail price in DM (RF) | Calculations used to derive the Pharmacy Price |
|-------------------------|--|
| RP 4.03                 | RP/1.68  |
| 4.04 RP 4.26            | RP-1.63  |
| 4.27 RP 12.31           | RP/1.62  |
| 12.32 RP 12.97          | RP-4.71  |
| 12.98 RP 22.42          | RP/1.57  |
| 22.43 RP 25.10          | RP-8.14  |
| 25.11 RP 35.15          | RP/1.48  |
| 35.16 RP 37.91          | RP-11.40                                       |
| 37.92 RP 54.34          | RP/1.43  |
| 54.35 RP 60.50          | RP-16.34                                       |
| 60.51 RP 78.09          | RP/1.37  |
| 78.10 RP 91.39          | RP-21.09                                       |
| 91.40 RP 1,382.95       | RP/1.30  |
| 1,382.96 RP             | (RP-231.25)/1.08263                            |

To derive the ex-factory price to wholesalers requires an additional step. The price to pharmacies, calculated in Table 3, must be found in Table 4 and the indicated operation performed to derive the publicly available ex-factory price to wholesalers.

**Table 4 Derivation of Ex-Factory Price to Wholesalers given a Pharmacy Purchase Price**

| Pharmacy Purchase Price (PPP) in DM | Calculation Used to derive the Wholesale Price |
|-------------------------------------|--|
| Less than 2.00                      | PPP/1.21                                       |
| 2.01 - 2.08                         | PPP- 0.35                                      |
| 2.09 - 4.00                         | PPP/1.20                                       |
| 4.01 - 4.09                         | PPP- 0.67                                      |
| 4.10 - 6.00                         | PPP/1.195                                      |
| 6.01 - 6.13                         | PPP-0.98                                       |
| 6.14 - 8.50                         | PPP/1.19                                       |
| 8.51 - 8.70                         | PPP-1.36                                       |
| 8.71 - 14.00                        | PPP/1.185                                      |
| 14.01 - 14.33                       | PPP-2.19                                       |
| 14.34 - 21.00                       | PPP/1.18                                       |
| 21.01 - 24.56                       | PPP- 3.20                                      |
| 24.57 - 100.00                      | PPP/1.15                                       |
| 100.01 -121.75                      | PPP-13.04                                      |
| 121.75 -1,500.00                    | PPP/1.12                                       |
| 1,500.00                            | (PPP-120.53)/1.03                              |

## Italy

In Italy, the national government reimburses consumers for all or some of the cost of drugs. The level of reimbursement depends upon the nature of the drug product. The price charged by pharmacists is regulated by the government as are the combined wholesale and retail mark-ups. In Italy the regulated retail prices are publicly available and are published in “L’Informatore Farmaceutico”, the Italian directory of medicines and manufactures. These Prices are inclusive of wholesale and retail mark-ups and the Italian VAT of 10%.

The wholesale mark up is 6.65% and the pharmacy mark up is 26.7%. Therefore the ex-factory price is 66.65% after excluding the VAT. This was confirmed by our contact at the *Ministerio della Sanita*.

Italy has a separate set of regressive mark ups for European Agency for the Evaluation of Medical Products (EMA) approved drugs. The EMA was established by the Council Regulation No.230/93 of 22 July 1993 in London, U.K. The agency is in charge of coordinating scientific resources existing in EU member states with a view to evaluating and supervising medical products for both human and veterinary use. On the basis of the Agency’s opinion, the European Commission authorizes the marketing of innovative products and arbitrates between member states for other medical products in case of disagreement. For further information visit EMA web site at <http://www.emea.eu.int>

Five DINs among the DINs verified were EMEA approved drugs. Only one of the five DINs derived ex-factory price was equal to filed price when the EMEA approved drug mark-ups was applied. For the remaining four DINs, filed prices were equal to derived ex-factory prices when mark-ups for non-EMEA approved drugs were applied.

**Methodology to derive Ex-factory Prices:**

**Wholesale Prices:**

The given price is the retail price with VAT.

Retail price with VAT / 1.10 = Retail price without VAT

Retail price without VAT \* 0.6665 = Ex-Factory price

Ex-factory prices derived using this methodology was equal to the ex-factory prices for wholesalers in the PMPRB database. We did not derive ex-factory prices to pharmacies. The derived ex-factory prices were always lower than the ex-factory prices to pharmacies in our database.

**Table 5 Derivation of Ex-factory Prices for EMEA approved drug products**

| Public Price ( Lit Excl VAT) | Wholesale Margin                         | Pharmacy Margin                            |
|------------------------------|--|--|
| Up to 300,000                | 6.65%                                    | 26.70%                                     |
| 300,001 -550,000             | 6.65% on Lit300,000+1.25% on remainder   | 26.70% on Lit300,000+15.0% on remainder    |
| 550,001 -1,250,000           | 4.2% on Lit550,000+1.0% on remainder     | 21.38% on Lit550,000+14.5% on remainder    |
| 1,250,000 -2,500,000         | 2.41% on Lit1,250,000+0.75% on remainder | 17.53% on Lit1,250,000+14% on remainder    |
| Over 2,500,000               | 1.58% on Lit2,500,000+0.50% on remainder | 15.76% on Lit2,500,000+13.50% on remainder |

**Pharmacy Price**

Retail price with VAT / 1.10 = Retail price without VAT

Retail price without VAT \* 0.733 = Ex-Factory price

## Sweden

In Sweden, manufacturers must negotiate a mutually acceptable price with the National Social Insurance Board to be included in the government's reimbursement system. Wholesale mark-ups are unregulated and are normally 3.2% of the manufacturer's prices. Each year The National Corporation of Swedish Pharmacies (Apoteksbolaget) publish a price list called the "Prislista", which contains the retail prices of all the drug products, in all package sizes that Apoteksbolaget pharmacies carry. Prices shown in the Prislista are exclusive of the local VAT. Although the Prislista contains pharmacy retail prices, it also contains the set of rules for the calculation of these wholesale prices given a retail price. These rules are shown in Table 6.

### Methodology to derive Ex-factory Prices

Table 6 Derivation of Wholesale Prices in Sweden given a Retail prices

| Retail Price (RP) | Calculations Used to Get Wholesale Price |
|-------------------|--|
| RP 59.925         | $(RP-15.40)/1.30$                        |
| 60.015 RP 108.10  | $(RP-19.60)/1.18$                        |
| 108.10 RP 351.10  | $(RP-27.10)/1.08$                        |
| 351.10 RP 2170.10 | $(RP-30.10)/1.07$                        |
| 2170.10 RP        | $(RP-150.10)/1.01$                       |

The information available to the PMPRB is that the manufacturers' ex-factory price when it sells direct to pharmacies is the wholesale price as calculated above. To ex-factory price to wholesalers is the wholesale price less the wholesale mark-up. Wholesale distribution was assumed for all products and a wholesale markup of 3.2% was used.

Ex-Factory price can be derived by dividing wholesale price by 1.032, once the wholesale price was calculated.

### Pharmacy Prices

To get pharmacy prices use calculations in Table 6 since the given prices are pharmacy retail prices.

## Switzerland

In Switzerland, all residents are required to purchase medical insurance. Insurance companies reimburse patients for all of the costs of drugs approved by the Federal Office for Special Insurance (FOSI). The publicly available prices are listed in the "Compendium Price List"<sup>4</sup>. These prices are inclusive of 2.3% Swiss VAT.

**Table 7 Derivation Ex-Factory prices**

| <b>Public Price</b> | <b>Manufacturer's Portion of the public price in Fr</b> |
|---------------------|---|
| 0-19.95             | 53.13%  |
| 20-21.25            | 10.63-11.88   |
| 21.30-99.95         | 55.85%  |
| 100-113.70          | 55.85-69.55   |
| 113.75-199.95       | 60.72%  |
| 200-229.60          | 121.44-151.04   |
| 229.65-299.95       | 64.97%  |
| 300-352.15          | 194.91-247.06   |
| 352.20-399.95       | 68.92%  |
| 400-484.20          | 275.66-359.86   |
| 484.25-499.95       | 72.90%  |
| 500-633.35          | 364.50-497.85   |
| >633.4              | 76.925%   |

For every even listed price change (e.g. 20-21.25) in table 7, the manufacturer's portion of the public price is given by a one-to-one relationship to the public price. For the calculation purposes PMPRB used tables 8 and 9 to derive ex-factory prices

### **Methodology to derive Ex-factory Prices:**

To derive the ex-factory prices first take out 2.3 % VAT, by dividing the public price by 1.023 then use the calculations in Table 7<sup>5</sup>.

<sup>4</sup> For purposes of verification we used prices as published in the "Compendium Price List" of 2000. This is because the price list published in the web site is the most recent price, whereas, we are verifying prices for 2000.

<sup>5</sup> Pharmacy mark-ups are not available presently.

**Table 8 Markups on Ex-factory Prices**

| Ex-factory Price | Markup Price |
|------------------|--------------|
| 0-10.62          | 88.22%       |
| 10.63-11.87      | 9.37         |
| 11.88-55.84      | 79.05%       |
| 55.85-69.54      | 44.15        |
| 69.55-121.43     | 64.70%       |
| 121.44-151.03    | 78.56        |
| 151.04-194.90    | 53.91%       |
| 194.91-247.05    | 105.09       |
| 247.06-275.65    | 45.09%       |
| 275.66-359.85    | 124.34       |
| 359.86-364.49    | 37.17%       |
| 364.50-497.85    | 135.5        |
| >497.85          | 30.00%       |

**Table 9 Derivation of Ex-factory Prices**

| Public Price (PP) | Calculations to derive Manufacturer's price in Fr |
|-------------------|---|
| 0-19.95           | $PP \times 0.5313$                                |
| 20-21.25          | $PP - 9.37$                                       |
| 21.30-99.95       | $PP \times 0.5585$                                |
| 100-113.70        | $PP - 44.15$                                      |
| 113.75-199.95     | $PP \times 0.6072$                                |
| 200-229.60        | $PP - 78.56$                                      |
| 229.65-299.95     | $PP \times 0.6497$                                |
| 300-352.15        | $PP - 105.09$                                     |
| 352.20-399.95     | $PP \times 0.6892$                                |
| 400-484.20        | $PP - 124.34$                                     |
| 484.25-499.95     | $PP \times 0.7290$                                |
| 500-633.35        | $PP - 135.50$                                     |
| >633.4            | $PP \times 0.76925$                               |

## **United Kingdom**

In the United Kingdom, all citizens have free and full access to drugs through the National Health Service (NHS). The national government regulates the overall profitability of each drug manufacturer. So long as the manufacturer's profit does not exceed the limit the manufacturer is free to price drugs at their discretion. The NHS accepts these prices and reimburses the pharmacists for the costs of all drugs dispensed to British citizens. There is a maximum wholesale mark-up of 12.5%. Pharmacists may not mark up the price of a drug product to the NHS, but may charge the patient a dispensing fee.

In the United Kingdom, the “Monthly Index of Medical Specialties“ (MIMS) contains the prices at which NHS pharmacies purchase drugs from wholesalers or manufactures. It is at these prices that the NHS reimburses pharmacists.

### **Methodology to derive Ex-factory Prices:**

In the U.K., as in France and Switzerland, no manipulation to the prices shown in MIMS is required to determine the ex-factory prices to pharmacists. To derive the ex-factory price to wholesalers it is necessary to remove the wholesale mark-up.

Ex-factory = NHS (wholesale price) / 1.125

## **U.S.A (Red Book)**

The US has by far the largest pharmaceutical market in the world. There is no universal health care system in the US. Private firms offer insurance and there are public insurance funds covering specific sectors of society. There are no regulated mark-ups.

Price setting by the manufactures to the wholesaler is free. The manufacture suggests a wholesale price to the wholesaler. This is the price listed in the Red Book as the “Average Wholesale Price” (AWP). Prices filed by the patentees with the PMPRB were compared with the AWP.

## **U.S.A (FSS)**

The U.S. prices were also compared with the Federal Supply Schedule (FSS) prices. The PMPRB started requiring patentees to file the FSS prices in 1998. As of January 1, 2000, the FSS prices were incorporated into the International Price Comparison test used in implementing the Board’s Guidelines. These filed FSS prices were compared with the FSS prices published in the Department of Veterans Affairs web site. The web site is [www.va.gov](http://www.va.gov).



## **APPENDIX 2**

### **List of the Top 50 DINs that were Verified by Country**

**SEVERED SECTION**

## APPENDIX 3

### Sources of Publicly Available Price Information

- France:** SEMPEX, 2000  
Société d'Éditions Médico-pharmaceutiques  
2, Rue Bélanger  
75140 Paris, CEDEX 03  
Tel: 33 1 49 96 22 46 Fax: 33 1 49 96 22 40
- Germany:** RÖTE LISTE, 2000  
Rote-Liste-Sekretariat in der BPI Service GmbH  
Karlstr. 21, 60329 Frankfurt a.M.  
Tel: 0 69 25 56 12 91 Fax: 0 69 23 17 89
- Italy:** L'INFORMATORE FARMACEUTICO, September, 2000  
Organizzazione Editoriale Medico Farmaceutica  
20157 Milan- Via Palizzi, 88  
Cas. Post 10434- C.C.P. 33882200  
Tel: 02 33 210 1 Fax: 02 33 210 200
- Sweden:** PRISLISTA, September, 2000  
Apoteket AB  
Förlagsorder  
131 88 Stockholm  
Tel: 08-466 1070 Fax: 08-466 1064
- Switzerland:** COMPENDIUM, 2000  
Documed SA, Case Postale 217, 4020 Bâle  
Tel: 061 315 111 1 Fax: 061 315 111 5
- U.K:** MONTHLY INDEX OF MEDICAL SPECIALITIES (MIMS), September, 2000  
Haymarket Medical Ltd.  
174, Hammersmith Road,  
London W6 7JP  
Tel: (020) 8943 5000
- US:** RED BOOK, 2000  
Five Paragon Drive  
Montvale, N.J 07645-1742  
Tel: (201) 358-7500, 1-800-222-3045
- FSS PRICES, December, 2000  
Department of Veteran Affairs (DVA)  
Web Site: <http://www.vapbm.org/PBM/prices.html>