

Under its transparency initiative, the Board is to make publicly available the results of the reviews of new patented drugs by Board Staff, for purposes of applying the PMPRB's price guidelines. This is the first such report. It is an important initiative which we hope will provide another valuable source of information about new patented drugs. The Board looks forward to feedback on this initiative.

Evidence/ References considered by HDAP:

Available on the PMPRB website, under Publications, Patented Medicines; Reports on New Patented Drugs; PREVNAR.

Report on New Patented Drugs – Prevnar

Brand Name (generic):	Prevnar (pneumococcal 7- valent conjugate vaccine, diphtheria CRM ₁₉₇ protein)
DIN:	02244081 - 1 na/vial
Patentee:	Wyeth-Ayerst Canada Inc.
Indication (as per the product monograph):	Prevnar is indicated for the active immunization of infants and children from 6 weeks until 9 years of age against invasive disease, ¹ pneumonia and otitis media caused by <i>S. pneumoniae</i> due to the capsular serotypes included in the vaccine (4, 6B, 9V, 14, 18C, 19F, and 23F). The routine schedule is 2, 4, 6, and 12-15 months of age.
Notice of Compliance:	June 7, 2001
Date of first sale:	June 20, 2001
ATC Class:	JO7AL: Pneumococcal vaccines.

Application of the Guidelines

Scientific Review: The PMPRB's Human Drug Advisory Panel recommended that Prevnar be reviewed as a category 2 new drug (breakthrough or substantial improvement) based on the following information:

- Prevnar is the only pneumococcal vaccine that has shown a good immune response in the age group of infants and toddlers from six weeks to two years of age against invasive disease, pneumonia and otitis media caused by *S. Pneumoniae* due to the seven capsular serotypes included in the vaccine.
- Based on the scientific evidence available, Prevnar is an effective product in the treatment of infections caused by *S. Pneumoniae* [see in particular Evidence/References 6 and 7].
- Although there are three other pneumococcal vaccines on the Canadian market (i.e., Pneumo 23, Pneumovax 23, Pnu-Imune 23), none of them are indicated for administration in children under two years of age. According to the Canadian Immunization Guide 1998, these three pneumococcal vaccines are only recommended in children two years of age or older with certain medical conditions (e.g., asplenia, splenic dysfunction, sickle-cell disease, chronic respiratory disease, cirrhosis, alcoholism, chronic renal disease, nephrotic syndrome, diabetes mellitus, HIV infection and other immunosuppression conditions). They are not recommended for younger children and infants because of poor antibody response. Although Prevnar is indicated for immunization until 9 years of age, the primary use will likely be in children less than two years of age. No direct alternatives are available for immunization of this group.

1. Invasive disease was defined as isolation and identification of *Streptococcus pneumoniae* from normally sterile body sites in children presenting with an acute illness consistent with pneumococcal disease.

Price Review:

An International Price Comparison (IPC) test was conducted. The Canadian price of Pevnar was found to be within the Guidelines as it did not exceed the median of the prices for the same drug sold in the countries listed in the *Patented Medicines Regulations*.

Country	Price per vial
Canada	76.0000
France	77.9246
Germany	75.1978
Italy	76.3192
Sweden	85.8240
United Kingdom	82.5962
United States	75.4510
International Median	77.1219

The comparators and dosage regimens referred to in the Summary Reports have been selected by PMPRB Staff and the HDAP for the purpose of carrying out the PMPRB's regulatory mandate which is to review the prices of patented medicines sold in Canada to ensure that such prices are not excessive. The publication of these reports is also part of the PMPRB's commitment to make its price review process more transparent.

The information contained in the PMPRB's Summary Reports should not be relied upon for any purpose other than its stated purpose and is not to be interpreted as an endorsement, recommendation or approval of any drug nor is it intended to be relied upon as a substitute for seeking appropriate advice from a qualified health care practitioner. ■

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Sources:

France: Sempex, August 2001*

Germany: Rote Liste, July 2001*

Italy: L'informatore Farmaceutico, September 2001*

Sweden: Prislsta, September 2001*

US: Average prices of Red Book, September 2001 and US Department of Veterans Affairs website

* Derived from publicly available formulary price using regulated wholesale mark-ups set out in PMPRB Study Series S-0215