

## OPINION SECTION

### Reimbursing Side Effects of Pharmaceutical Drugs - a Scandinavian Speciality

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**Abstract:** Pharmaceutical insurance applies to drugs which are approved by Swedish licensing authorities and are marketing in Sweden. This paper reviews the pharmaceutical insurance.

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As Medical Director I evaluate applications for life, sickness, waiver of premium and accident insurance. I also evaluate claims submitted to Pharmaceutical Insurance, which is handled by Trygg-Hansa. This scheme is a Scandinavian speciality, little known in North America. Its background, design, claims, costs and results are reviewed in this article.

#### **Patient Insurance and Pharmaceutical Insurance**

Both the Swedish medical community and its governing bodies have always disliked medical litigation of the type prevalent in the U.S. and some other countries. When, in the early seventies, there were signs that patients (and some lawyers) were increasingly active in this field, two no-fault insurance schemes were started.

Patient Insurance started in Sweden in 1975. It was introduced by the government and premiums are paid mainly by the State. It reimburses patients who have sustained injuries

“which could have been avoided” in connection with diagnostic procedures (endoscopy, radiology, etc.) or treatment (surgery, radiation treatment, etc.). If the injury “could have been avoided” the case is decided without legal proceedings.

It was, however, recognized that side effects of pharmaceutical drugs could not be reimbursed under the Patient Insurance scheme, since side effects cannot be avoided. As a complement Pharmaceutical Insurance was started in 1978 as a voluntary undertaking by companies marketing pharmaceutical drugs in Sweden. Its premiums are paid by the companies. It reimburses patients who have suffered rare and significant side effects, or severe variants of common side effects. The decision if a claim is to be reimbursed is made without legal proceedings. Finland and Norway have similar insurance schemes.

#### **Which side effects are reimbursed ?**

Pharmaceutical Insurance can accept claims for side effects caused by pharmaceutical

drugs approved by the Swedish licensing authorities and marketed in Sweden. The same applies to pharmaceutical drugs undergoing clinical trials. "Alternative remedies," such as herbal preparations, homeopathic pills, etc. are not included. The pharmaceutical drug must have been obtained in Sweden and used according to accepted medical practice (if not, the claimant can direct his claim to Patient Insurance).

There must be a strong probability that the injury is due to a side effect of the pharmaceutical drug. This means that the injury should be noted as a side effect in the FASS (the Swedish equivalent of the PDR), or adequately documented in the medical literature. The injury has to be fairly severe. Injuries which decrease ability to work for less than three months are usually not reimbursed. Psychiatric side effects (depression, psychotic reactions, hallucinations, etc.) are reimbursed only if they are direct consequences of a somatic side effect. Rare side effects are more likely to be reimbursed than common ones, since they are less likely to have been considered by the patient's doctor. Finally, the severity of the side effect has to be considered in relation to the disease for which the pharmaceutical drug was prescribed, and to the general medical condition of the patient. The numerous and serious side effects of cytotoxic and similar pharmaceutical drugs are usually not reimbursed when used for the treatment of malignant tumors.

No reimbursement is given for lack of effect of a pharmaceutical drug, or if the injury was due to inappropriate activity when the drug was used (e. g., driving after taking a sleeping pill). Injury due to abuse of a pharmaceutical drug is likewise not reimbursed.

#### **Which costs can be reimbursed ?**

Sweden's state medical care system absorbs a large share of every citizen's costs for medical care. At present there is an upper limit of 1800 Sw.Cr (U.S.\$ 230) per person, per year. Costs above that limit are paid by the state (one of

several reasons why Swedish taxes are high).

Pharmaceutical Insurance will only reimburse costs not paid by the state medical care system or other sources. When a claim is accepted, reimbursement can be made for a number of such costs. It is made for medical consultations, hospital care, nursing care, physiotherapy, transportation, etc. Permanent defects (e. g., loss of hearing, paraplegia) are reimbursed, as well as loss of current and future income. An example of how a claim is settled is given in Fig. 1. In addition, costs incurred by family members costs (e. g., funeral expenses) are reimbursed.

#### **How are claims handled ?**

The patient fills out a claim form and the attending doctor adds medical information. The claim is then submitted to the insurance company (Trygg-Hansa) which may request additional information (medical records, etc.). outside medical expertise may also be consulted, particularly for establishing if the injury was due to a side effect.

I then review the claim with the company's claim specialists, and they decide if the claim will be reimbursed. If the patient is not satisfied, the company's decision can be appealed to a review board (Lakemedelsskadenämnden). This board has four members appointed by the Swedish Cabinet. Legal competence is well represented and the pharmaceutical industry has only minority representation.

#### **How are claims reimbursed ?**

Reimbursement follows Sweden's general legal standards for damages. Payments are, however, limited to 5 mil. Sw.Cr. (U.S.\$ 700,000) per person, per year. If several claimants are to be reimbursed for the same side effect (serial injury), the upper limit is 150 mil. Sw. Cr. (U.S.\$ 21,000,000) per year for that particular side effect.

The most serious and costly side effect that Pharmaceutical Insurance has reimbursed so

far is HIV infection via blood factor concentrates. As of the end of 1994, a total of 97 HIV-infected persons have been reimbursed with a total of 57 mil. Sw. Cr. (U.S. \$ 8,000,000). In addition, five HIV infected partners of those patients have received a total of 2,4 mil. Sw. Cr. (U.S. \$ 34,000).

**Has Pharmaceutical Insurance been a good thing ?**

About 450 claims are handled every year, and 25-30 percent of these are reimbursed. About 10 percent of refused claims are appealed to the review board, which reverses about 10-20 percent of appealed decisions.

Pharmaceutical Insurance seems well accepted by all concerned. only a few legal proceedings related to side effects are in progress against pharmaceutical companies in Sweden.

**Case description:** A 50-year-old woman, working in a restaurant, starts taking a NSAID because of hip osteoarthritis. After a week she develops a severe Stevens-Johnson syndrome, initially requiring hospitalization because of nutrition problems. Off work for a total of two months. Complete recovery. Claim submitted to Pharmaceutical Insurance.

**Evaluation of claim:** Known, rare and severe side effect. Clear time relationship: drug – side effect. Drug used for comparatively benign condition.

Her claim was reimbursed as follows:

|  |             |
|--|-------------|
| Ordinary income during two months period   | \$4550      |
| Reimbursed by employer and state   | \$-3650     |
| Actual loss of income  | \$900       |
| Smart money  | \$680       |
| Extra costs for hospitalization, medical consultations, pharmaceutical drugs, transportation, assistance at home, etc. | \$760       |
| <b>Total reimbursement to patient U.S.\$</b>   | <b>2340</b> |

**Fig. 1.** Example of how a side effect claim is decided and the claimant reimbursed. It should be pointed out that Swedish smart money reimbursement (i.e. money paid to the patient for pain and suffering) are generally low.