

On the Radar Screen: Natural Health Product Regulations & Drugs Coming Off Patent

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Natural Health Product Regulations



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Staged Approach to Regulation

- **Previously, Natural Health Products (NHP) regulated under the Food and Drugs Act**
- **NHP regulations cover items not requiring a prescription**
- **Staged approach began January 2004**





Staged Approach to Regulation

- 2006 • Good manufacturing practices and site licences**
- 2008 • Any new NHP will obtain an 8-digit NHP product licence (NPN)**
- 2010 • NHPs currently with a DIN will transfer to NPN or DIN-HM (homeopathic medicine)**





Staged Approach to Regulation

- **No new DINs issued to NHPs effective January 1, 2004**
- **NHPs (with existing DINs) continue using DIN until December 31, 2009**
- **January 1, 2010, all NHP must have a product licence and market authorization from the NHP Directorate**





Impact on Drug Plans

- **Impact on plans that cover non-prescription items, particularly vitamins and minerals**
- **Contract wording may be a key determining factor**





Next Steps

- **Internal NHP team monitoring situation:**
 - **Numbering system: update the database as needed**
 - **Awaiting process for notification of newly approved products**



Drugs Coming Off Patent



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Key Message

**Are you optimizing the
benefits from patent
expiration?**





Objectives

- 1. Estimate potential cost savings**
- 2. Strategies to optimize potential cost savings**





Drugs with Recently Expired Patents

| Product | Use | Patent Expired |
|---------|---------------|----------------|
| Losec | Ulcers/Reflux | Jan. 2004 |
| Paxil | Depression | Nov. 2003 |
| Celexa | Depression | Jan. 2004 |





Drugs with Recently Expired Patents are Expensive

| Product | Top 10 DIN | Share of Drug Costs |
|---------|------------|---------------------|
| Losec | 2 | 2.4% |
| Paxil | 4 | 2.1% |
| Celexa | 7 | 1.5% |



Drugs with Recently Expired Patents are Expensive and Highly Used

| Product | Top 10 DIN | Average Cost/Rx | # Rxs/100 Claimants |
|---------|------------|-----------------|---------------------|
| Losec | 2 | \$103 | 9.3 |
| Paxil | 4 | \$72 | 11.9 |
| Celexa | 7 | \$57 | 10.2 |





Methodology

Assumptions:

- **2003 reference year**
 - **Utilization and market size same**
- **Price of brands remain the same**
- **Patent expiry and generic availability occur at the same time**





What if 40% of Claimants Switch to the Generic?

| Product | Brand Cost (30 days) | Generic Cost (30 days) | Savings on Total Drug Spend | Total Savings on Drug Spend |
|---------|-------------------------|---------------------------|-----------------------------------|-----------------------------------|
| Losec | \$66 | \$42 | 0.4% | 0.9% |
| Paxil | \$52 | \$33 | 0.3% | |
| Celexa | \$40 | \$26 | 0.2% | |





What if 100% of Claimants Switch to the Generic?

| Product | Brand Cost (30 days) | Generic Cost (30 days) | Savings on Total Drug Spend | Total Savings on Drug Spend |
|---------|-------------------------|---------------------------|-----------------------------------|-----------------------------------|
| Losec | \$66 | \$42 | 0.9% | 2.2% |
| Paxil | \$52 | \$33 | 0.8% | |
| Celexa | \$40 | \$26 | 0.5% | |





Potential vs. Actual Savings

Factors affecting claimant switch rate:

- **Product interchangeability (provincial formularies)**
- **Physician prescribing patterns**
- **Patient willingness to switch**
- **Plan design**





Strategies

- **Generic substitution plans**
- **Dynamic Therapeutic Formulary (DTF)**
- **Changes in reimbursement levels**





Take-Away Points

- **Generic substitution is one strategy that currently exists**
- **Optimize current strategies for cost savings**
- **New strategies exist**





Key Message

**Are you optimizing the
benefits from patent
expiration?**

