



Drug Shortages: A closer look at products, suppliers and volume volatility.

Executive Summary

November 2011

The drug shortage problem is of increasing concern for patients, clinicians, and policymakers. While the issue is not new, stakeholders are seeking a deeper understanding of what's happening and why, and potential remedies to ensure access for patients.

A new report, *Drug Shortages: A closer look at products, suppliers and volume volatility*, by the IMS Institute for Healthcare Informatics looks at the current drug shortages situation – the magnitude of the problem, its causes and ways to prevent or resolve future shortages.

Using IMS Health's comprehensive, proprietary data on the drug supply chain, the IMS Institute examines the problem from an entirely new angle, and bases its analysis on the 168 drugs that were on the drug shortages list maintained by the Food and Drug Administration (FDA) and American Society of Health-Systems Pharmacists (ASHP) as of October 7, 2011.

KEY FINDINGS

1. The drug shortages problem is highly concentrated.

Over 80 percent of the products are generic and over 80 percent are injectables. This is a small part of the overall medicines market, yet includes a number of critical drugs used in the treatment of cancer, infection, cardiovascular disease, central nervous system conditions and pain. (see Figure 1).

2. A large number of suppliers are involved, but most drugs have only one or two sources of supply.

Over 100 companies supply products included on the shortages list, but over half of the products have only one or two suppliers. Thirteen companies have stopped supplying products on the shortages list leaving a growing number of products open to possible production disruptions by one manufacturer.

FIGURE 1

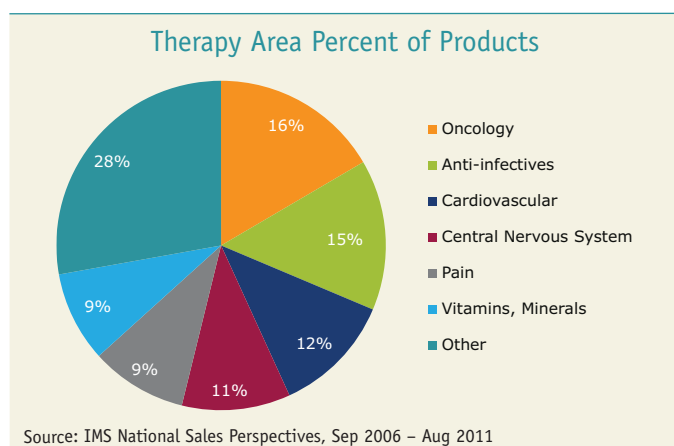


Chart notes:

Classification of products based on customized grouping of ATC classes. See Methodology, approach and sources section for details.

FIGURE 2

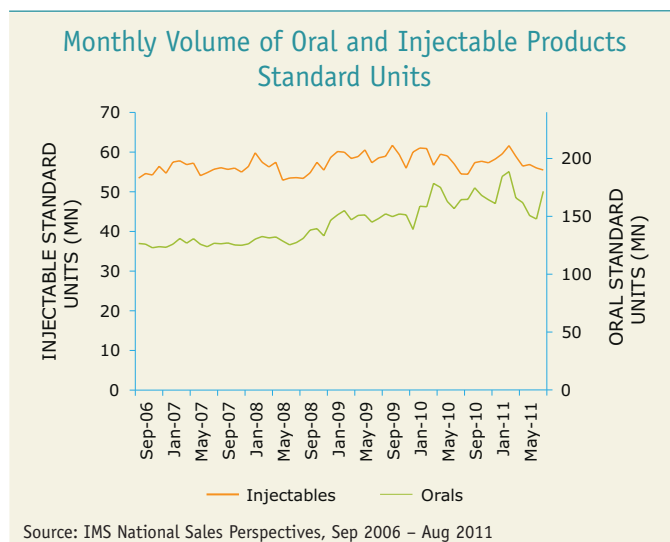


Chart notes:

Monthly Volume of Oral and Injectable Products Standard Units.

3. Total supply volume for many products has been stable or growing, but significant volatility exists among suppliers.

The total monthly supply volume by manufacturers to healthcare providers for all products on the shortages list has increased 4 percent over the past five years, and for over half of the individual drugs on the shortages list, total supply is relatively stable or has increased. However, there are recent signs of increased volatility in the month-to-month supply of these products by specific suppliers, causing disruption to providers. (see Figure 2).

4. For a group of 75 drugs, supply volume has fallen substantially.

A subset of products has experienced supply declines of more than 20 percent recently. For 13 states, the per capita supply of injectables has fallen more than 30 percent, suggesting significant treatment protocol disruption for patients.

RECOMMENDATIONS

The results of this study indicate the problem of drug shortages is much more complex, yet narrower, than expected. The underlying causes, while disruptive, are little understood and require more systematic research across the total supply chain.

To help the FDA, pharmacists and other stakeholders monitor drug shortages and identify new or worsening shortages, the IMS Institute recommends that the FDA or industry create an Early Warning System for drug shortages. This system should include systematic risk identification, continuous long-term demand forecasting, creation of a supply volatility index as a sentinel of problems, and comprehensive predictive modeling.

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