

**Institute for Safe Medication Practices**  
**200 Lakeside Drive, Suite 200, Horsham, PA 19044**  
[www.ismp.org](http://www.ismp.org)

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CONTACT: Renee Brehio, Media Relations, ISMP  
704-831-8822, [rbrehio@ismp.org](mailto:rbrehio@ismp.org)

**ISMP Survey on Drug Shortage “Gray Market”  
Shows Widespread Impact on Hospitals**

**Horsham, Pa---**Widespread accounts of frustration, outrage, and serious compromises to patient care came across loud and clear from the purchasing agents and pharmacists at 549 hospitals who participated in a recent Institute for Safe Medication Practices (ISMP) survey on “gray market” activity associated with drug shortages.

When crucial medications become scarce and no longer available through the usual channels, gray market distributors have jumped in with sometimes questionably obtained supplies that they attempt to sell to hospitals at exorbitant costs. ISMP’s survey, conducted in July and August of 2011, asked the individuals responsible for obtaining medications in hospitals how they have been affected by or handled gray market solicitations and purchases.

Following are brief highlights of survey findings; an in-depth analysis that includes actual practitioner comments was published in the August 25, 2011 issue of the *ISMP Medication Safety Alert!* newsletter. For a copy, go to: [www.ismp.org/Newsletters/acutecare/showarticle.asp?ID=3](http://www.ismp.org/Newsletters/acutecare/showarticle.asp?ID=3)

- **Gray Market Solicitations Are Common.** More than half (56%) of all respondents reported receiving **daily** solicitations from up to 10 different gray market vendors. Most were by phone (90%), email (76%) and fax (68%).
  
- **Buying from Gray Market Sellers Is Increasing.** About half (52%) of all respondents reported purchasing one or more pharmaceutical products from gray market vendors in the last two years. Most (80%) reported that their purchases had increased in the last two years a drug shortages began hitting record highs.

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- **Gray Market Pricing Can be Ten Times or More Higher than Usual.** About a third of respondents from small, critical access hospitals (31%) and community hospitals (35%) who had purchased a gray market product in the past two years reported price mark-ups of 10 times or more the contract price (900% mark-up). More than half (53%) of respondents from university hospitals reported pricing that high. Similar findings were reported in a recent survey by Premier.
  
- **Purchases Are Not Always Being Authenticated.** Some states have enacted regulations requiring that the authenticity of all pharmaceutical products be documented at purchase; half (50%) of survey respondents in those states still reported buying medications on the gray market, and only 35% received the required documentation. Among all respondents, only 23% said that they require documentation of authenticity from the gray market vendor before purchase.
  
- **Some Hospitals Are Resisting the Gray Market.** The most common reasons that respondents gave for not purchasing medications from gray market vendors in the last two years were: concerns with authenticity (74%), ethical concerns (66%), cost (69%), and concerns about the storage conditions prior to purchase (58%).
  
- **Errors and Other Patient Care Issues Can Occur with Gray Market Purchases.** Up to 12% of respondents reported awareness of a product authenticity issue, medication error, or adverse drug reaction associated with the use of gray market products in the last two years. Most cited errors associated with using a different strength of a product than usual stock, issues with improper storage of drugs that must be refrigerated, sale of recalled or stolen products, illegal importation of pharmaceuticals, questionable chain of custody, and sale of counterfeit products and placebos.

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ISMP suggests a four-pronged strategy to end the gray market domination of products in short supply:

- **Greater Food and Drug Administration (FDA) Authority to Address Shortages.** Legislative action to give FDA expanded authority to manage shortages is being explored. Another important step would be to require manufacturers to stop deliveries to wholesalers/distributors when the company knows their products are or soon will be in short supply.
- **Stronger Regulations Regarding Distribution of Pharmaceutical Products.** Manufacturers and authorized distributors should not ask pharmacies to deal with this issue alone. They should welcome regulatory action, such as a national authentication law that limits distribution of medications to only authorized or appropriately licensed distributors of record. Respondents suggested that distributor pricing be standardized even during shortages to prohibit price gouging.
- **Hospitals Working to Minimize Need for Purchasing from Gray Market Vendors.** Several local coalitions have been formed to identify shortages, determine appropriate use limitations, and cooperatively borrow to avoid using the gray market. Respondents also suggested learning the best ways to order drugs in short supply, such as back/direct ordering from the manufacturer instead of the wholesaler, as well as seeking alternatives for drugs in short supply and implementing safety strategies around these products to avoid errors.
- **Regulatory and Law Enforcement Action against Counterfeiting and Theft.** Earlier this year, five drug makers formed a coalition that is seeking to amend the law that makes little distinction between stealing a load of cigarettes or a supply of chemotherapy drugs, so that criminal penalties can be maximized. A bill has been proposed in Congress to grant police better tools for investigation of drug theft as well as stronger penalties.

ISMP has published additional suggestions for healthcare professionals on coping with drug shortages, which are available online at: [www.ismp.org/Newsletters/acutecare/articles/20101007](http://www.ismp.org/Newsletters/acutecare/articles/20101007).

**About ISMP:** The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit charitable organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents more than 35 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. ISMP is a federally certified patient safety organization (PSO), providing healthcare practitioners and organizations with the highest level of legal protection and confidentiality for patient safety data and error reports they submit to the Institute. For more information on ISMP, or its medication safety alert newsletters and other tools for healthcare professionals and consumers, visit [www.ismp.org](http://www.ismp.org)