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# **Global Healthcare Issues: Managing Drug Shortages**

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# Global Healthcare Issues: Managing Drug Shortages



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**Drug shortages have wide impact in healthcare delivery...**



- Manufacturing quality issues
- Under-production
- Active Pharmaceutical Ingredient (API) shortages
- Changes in therapeutic preferences
- Spiking demand for product as others become unavailable
- High-demand, specialized products with few substitute therapy options

**Why are there drug shortages?**

- Reduced product quantity may not be partitioned enough to reach every market
- It may not be available in all forms (ampoule, capsule, solution, syringe, tablet, vial, etc.)
- Inventories may be depleted at a slower rate in markets which have less demand
- Product use may be limited/restricted in other markets
- Other providers may have a better method of sourcing and managing therapies which are in limited supply

**Why is product sometimes available to others and not me?**

- Identify “must have” medications with consistent supply issues
- Formalize a “Drug Shortage Management Protocol” (DSMP) to maneuver through periods of extended drug shortages
- Communicate DSMP with purchasing and clinical staff so they may collaborate on an ongoing basis

**Establish a “Drug Shortage Management Program”**



- Identify “must have” medications with consistent supply issues and/or with spiking demand
- Maintain higher minimal inventory levels
- Assess shelf life dates, use inventory prior to expiration
- Monitor key therapy market availability
- Avoid “stockpiling”, it ties up funds and contributes to inventory management issues

**The DSMP should apply to routine inventory management**

- In advance, determine specific substitutes (to the NDC level) which can fill the gap during a shortage
- Setup product in procurement database complete with sources
- Conduct additional training and document protocol changes in advance
- Integrate these measures into your DSMP

**Assertively develop and manage alternative therapy options**

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- What is their policy if preferred or standard product is not available?
  - How should use of alternative therapies be justified and documented?
  - Get the approval standards in writing and include them in your DSMP documentation
  - Monitor policy changes closely

**Consult primary payers regarding therapy options in advance**

- Routinely meet with manufacturer salespersons, contact their customer service units
- Inquire about specific “must have” therapy availability
- Determine how manufacturers allocate products to better position your organization
- If they provide email updates on urgent product availability issues, subscribe to them and routinely monitor
- Setup a protocol with them in the event a therapy shortage materializes

**For “Must Have” drugs, communicate with manufacturers directly**

- Regularly inquire about specific key therapies you purchase from them and potential issues
- Determine how they allocate products to better position your organization
- If they provide email updates on urgent product availability issues, subscribe to them and routinely monitor
- Setup a protocol with them in the event a therapy shortage materializes

**Contact primary distributors and wholesalers frequently**

- Engage the business and professional entities your organization is a member of
- Determine their interpretation of the issues and assess the position you are in
- What actions have they taken to work through drug shortages on behalf of their members?
- How else may they assist you and what can they do to influence the drug shortage events you are experiencing?

**Connect with your buying groups, GPOs and associations**



- How are they sourcing product?
- What is their version of a DSMP?
- Share best practices
- Identify other ways to collaborate

**Network with peer organizations**



- Reasons behind product shortages
- Drugs currently or about to be in short supply
- Potential substitute therapies and alternative sources
- Expected return to normal availability

**Use global and government healthcare information resources**

- Central Drugs Standard Control Organization (CDSCO)-India: [www.cdsc.nic.in](http://www.cdsc.nic.in)
- European Medicines Agency (EMA)-Europe: [www.ema.europa.eu](http://www.ema.europa.eu)
- Food & Drug Administration (FDA)-United States: [www.fda.gov](http://www.fda.gov)
- Medicines and Healthcare products Regulatory Agency-(MHRA), UK: [www.mhra.gov.uk](http://www.mhra.gov.uk)
- National Health Surveillance Agency (ANVISA)-Brazil: [www.anvisa.gov](http://www.anvisa.gov)
- Pharmaceuticals and Medical Devices Agency (PMDA)-Japan: [www.pmda.go.jp](http://www.pmda.go.jp)
- Saudi Food and Drug Authority (SFDA)-Saudi Arabia: [www.sfda.gov.sa](http://www.sfda.gov.sa)
- Therapeutic Goods Administration (TGA)-Australia: [www.tga.gov.au](http://www.tga.gov.au)
- World Health Organization (WHO)-Global: [www.who.int](http://www.who.int)

## **Global and government healthcare websites**

- Use a variety of resources, stay informed
- Closely manage key therapies with inconsistent availability
- Establish a formal DSMP in advance
- Build collaboration with clinical and procurement staff in your organization
- Identify and manage your options moving forward



**Summary**

**For ongoing business and clinical healthcare industry resources, please go to:**

**[www.HealthcareMedicalPharmaceuticalDirectory.com](http://www.HealthcareMedicalPharmaceuticalDirectory.com)**

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