**Medicine Supply – Factsheet**

There have always been intermittent medicines shortages, however the supply situation began to deteriorate sharply approximately eight years ago and remains highly unsatisfactory.

The priority of community pharmacies is to get medicines to patients who need them when they need them. Pharmacists and pharmacy staff are going to great lengths to ensure timely supply, often putting in extra work to source medicines.

The supply problems fall into four main categories

* Supply/demand problems o Quotas
	+ Branded Generic supplies
	+ Wholesale availability and supply directly from manufacturers
* Manufacturing problems
* Raw material problems
* Regulatory problems

# Supply/Demand Problems

**Quotas:**

EU law permits manufacturers to manage supplies in order to ensure a fair distribution.

**They do this by applying quotas.**

For example, NHS regulations require that all prescriptions presented to a pharmacy are dispensed, yet the law **does not oblige manufacturers and wholesalers to meet the orders.** Pharmacies must accept all NHS prescriptions presented to them. Pharmacies are required to supply items, even when there are difficulties in obtaining the product. The supply must be made with reasonable promptness.

**Some manufacturers ask pharmacies to provide evidence of patient demand before releasing stocks.** This is usually in the form of requesting anonymised copies of prescriptions. This places an administrative burden on pharmacies and presents confidentiality issues.

**Branded Generics:**

With responsibility for prescribing costs, some CCGs encourage the prescribing of, and switching patients to, specific branded medicines or ‘branded’ generics. Such a policy may deliver some cost savings to the primary care drugs bill, however on occasions the branded product, **subject to hugely increased demand will be out of stock with the manufacturer**. The more CCGs that encourage the use of the product the more likelihood of this happening.

**Wholesale availability and supply direct from manufacturers**

At the heart of the problem are changes in the European import and export market. A weak Pound and strong Euro has reduced the benefits from using parallel imported products; increasing the demand for UK medicines both from UK pharmacies and internationally.

This is a complex issue – there is no easy solution. It is not possible to prevent the export of UK medicines as this would be contrary to European trade laws.

## NCSO – No cheaper stock obtainable

This is a concession applied when the Department of Health agrees that a pharmacy contractor is unable to purchase a Part VIII generic drug at the price listed in Drug Tariff Part VIII. To claim NCSO, contractors should have firstly made all reasonable efforts to obtain the product at the appropriate price but haven't succeeded.

The Department of Health may decide to grant a concessionary price as an alternative to granting the NCSO concession. A price concession is a new, fixed price for the month, which is higher than that in the Drug Tariff.However, this is only agreed on a monthly basis, necessitating a reapplication the next or following months if appropriate. The number of concessions agreed each month has risen steeply

Concessionary lists are available at:

<http://psnc.org.uk/dispensing>[-supply/supplychain/generic-shortages/](http://psnc.org.uk/dispensing-supply/supply-chain/generic-shortages/)

## (see Appendix 1)

**Manufacturing Problems**

These are due to a number of different causes. Manufacturing failure; Closure/planned maintenance of the manufacturing site; Quality defect (product, packaging); Raw material unavailability; GMP non-compliance at a manufacturing site; Contamination; Unexpected increase in demand in clinical practise due to a supply shortage of a different medicinal product; Drug recall, discontinuation; Natural disaster, fire…

# Raw Material Problems

Raw material issues including shortages account for 9% of medicines shortages. With an increase in globalisation of medicines. Many molecules are now manufactured by only one supplier internationally, this can cause international shortages if the supply chain fails in any way, which could be due to factory issues, quality control failure or increased demand without increased production.

**(see Appendix 2)**

# Regulatory Problems

The role of the MHRA is to protect and promote public health in everyday practice and it has an obligation to protect patients against ineffective or harmful drugs. This results in a gatekeeper function and obliges the MHRA to apply stringent standards of assessment and to deny marketing authorisation where deemed necessary. Failure to meet these standards can cause withdrawal of a medicine hence causing shortages.

When a product is suspected or known to be faulty, the MHRA immediately works with manufacturers and wholesalers on the most appropriate and timely action to take. Sometimes this means a product has to be recalled and taken out of the supply chain.

**Appendix 1**

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The list of concessionary items is listed each month and extends to both doctors and pharmacies. The list is usually only released at the end of the month. Contractors do not know what will be included in the list and may be disadvantaged if an item is not listed, but the price had increased above the Drug Tariff price and will be dispensing at a loss.

## Appendix 2

**Raw and Bulk Material** **Unavailability**

This is a problem when multiple manufacturers make a drug product with material available from only one source (that discontinues production).

Availability problems arise when raw materials come from undeveloped parts of the world or where there are hostilities, animal diseases contaminate tissue used to extract raw material, climatic and other environmental changes depress the growth of plants used to extract raw material.

Raw materials are degraded or contaminated during harvesting, storage, or transport. Voluntary recalls can cause shortages, especially when a sole manufacturer’s drug product dominates the market supply.

Manufacturing production decisions – In many cases raw materials for pharmaceuticals are only a small portion of the total amount of raw material being produced. Decisions to cut back on production can compromise raw material supply.

Manufacturer mergers often result in decisions to narrow the focus of product lines, resulting in the discontinuation of a key raw material.

Occasionally, an unexpected increase in demand for a drug product exceeds production capacity.

Natural disasters cause raw material shortages when they affect manufacturing facilities, particularly those manufacturers that are the sole source for a raw material.

February 2018