



ISSUES

There are many factors which can have an impact on the availability of drugs. These can occur at different points in the supply chain as follows:

DURING MANUFACTURE



Active Pharmaceutical Ingredient (API) shortages

Medicines availability can be affected by sudden increases in demand or quality and raw material (API) problems prior to manufacturing



Unforecasted demand

The UK (and non-UK) demand for a specific drug can increase beyond expectation or production capacity – for example if production of a medicine from one manufacturer fails and another has to suddenly pick up the unforeseen demand



Good Manufacturing Practice (GMP) licences

Businesses must hold a licence to manufacture pharmaceutical drugs – this licence can be revoked or suspended by the regulator



Batch release failures

If a batch of drugs fails to be released against their approved product specification, this can lead to an unexpected and sudden reduction in the supply of that product

FROM FACTORY TO DISTRIBUTOR



Competitor products out of stock

If a product suddenly goes out of stock this can place additional pressure on the demand for substitutes



Manufacturer return on investment

If the price achieved for a medicine falls too low, a manufacturer may decide to pull out of the UK market



Import / Export problems

Strikes, or delays at entry points into the UK, can disrupt deliveries to the distributor



Exchange rate changes

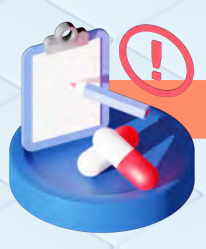
Medicines may be exported for sale abroad to take advantage of exchange rates, reducing UK available stock
Imported medicines can become more expensive, causing cost pressures which can affect availability



Global consolidation

Medicines manufacture has consolidated into fewer global production sites. If one of these sites had a supply issue, it is difficult to switch supply

AT THE DISPENSING POINT



Licensing changes

If a drug is reclassified as a controlled drug, the increased regulations that accompany the reclassification could cause availability issues in the short term



Tendering

Tenders for the supply of medicines can cause issues in some cases, as competitors are locked out of that particular market for the period of the tender



Stock management

Irregular ordering, last-minute surges in demand, or prescribing, can lead to availability issues



Change in patient population

A sudden change in patient demographic can cause an availability issue for particular medicines

OVERARCHING ISSUES



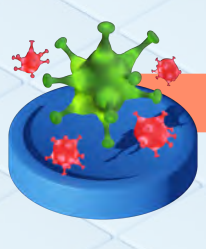
Stockpiling / speculation

Medicines stockpiling or hoarding, at any point in the medicines supply chain, can contribute to availability pressures



Diverting stock to other countries

Some supply chain players may consider diverting medicines to other markets which offer an increased margin compared to the UK



Disease pandemics

If there is an unexpected pandemic, the demand for medications to treat this, and related symptoms, will increase exponentially



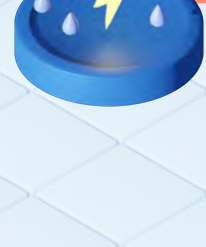
Weather

Bad weather can impact the most efficient of supply chains, often on a localised basis



IT failures

Everything is digitalised, IT failures can cause huge disruption in stock ordering, monitoring and controls at all points in the supply chain



'Acts of God'

Floods and fire can affect supply chain facilities, temporarily reducing the number of medicines available in the supply chain



Regulatory changes

Alterations to supply chain regulations can temporarily reduce the availability of medicines

INITIATIVES

The HDA and its members work closely with supply chain partners to mitigate supply challenges and reduce the number of drug availability incidents:



Working with regulators

The HDA works with regulators to reduce the risk of availability issues arising from regulatory issues and by ensuring the most efficient and cost-effective supply chain system is in place



Collaborating in extreme cases

In the event of cases where a medicine is in extreme shortage, HDA members can work together, with Governments and the NHS, to manage stock



Multi-sourcing

Sourcing medicines from multiple suppliers helps maintain continuity of supply



24/7 service

All HDA members offer an 'out-of-hours' service for all their customers



Emergencies

If a medicine is in critical demand, distributors can 'blue-light' (police escort) the treatment to ensure its speedy delivery; emergency supply can also be organised in collaboration with a manufacturer, when a medicine is in short supply



2x day delivery

For products in high demand, a more frequent delivery system assists with availability issues at the dispensing point and reduces the need to stockpile at the dispensing level, smoothing demand and helping cashflow



Cascading

If clinically appropriate, replacing a medicine in short supply with a series of alternatives



Managing stock

Managing the supply of stock helps to ensure that medicines can be equitably supplied across the customer base



Prescription validation

In isolated instances, a distributor will validate a prescription from a dispenser in order to release a medicine in very short supply



Seasonal stock-build

Anticipating an increase in demand over the Christmas seasonal period, distributors will increase their supply in advance



Investing in stock

Distributors will invest in additional stock based on the forecasting of future demand and move it around the country to the areas where it is in most demand



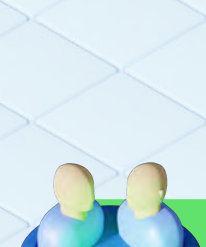
Generous returns regime

Making the returns system easy and fast enables the efficient turnaround of products that have been ordered in error or excess



Fast-tracking

Medicines in danger of going short will be fast-tracked through the distribution supply chain system



Forecasting & monitoring sales

Creating weekly and monthly demand forecasts which help analyse the need to obtain more (or less) of specific medicines



Building buffer stocks

Based on market intelligence, distributors may order more of an 'at-risk' medicine than the forecasted demand



Supply chain communications

Working with manufacturers to share information about drugs availability issues early and move stock around
Distributors provide weekly bulletins on the availability of medicines
Distributors are working with IT service providers to provide improved 'out of stock' codings