

The supply of medicines

Following concerns raised with us about medicine shortages in the UK, the CMA has sought information on the extent to which there are shortages of medicines, and their likely causes.

The CMA recognises that any shortage of medicine can potentially be harmful or distressing for the patient concerned. However, the CMA did not find persuasive evidence that the extent of shortages in the UK justified further investigation. Moreover, it did not find reason to believe that a significant proportion of any shortages that do exist could be attributed to causes originating in the UK, nor that the CMA would be the best placed organisation to investigate or address any that were.¹ The CMA has therefore decided not to look further into the issue of medicines shortages at this time on the grounds of its administrative priorities. This does not preclude the CMA from carrying out further work in the future should our assessment of priority change, or if information comes to light to prompt a re-assessment.

The CMA looked at a number of possible causes of reported shortages in the UK:

- The CMA saw little evidence to suggest that distribution arrangements - including the Direct to Pharmacy distribution model - were contributing significantly to shortages.
- While we have no estimates as to how much medicine is currently exported from the UK, we consider that parallel exporting is currently less likely to lead to significant shortages than has been the case in the past, possibly due to changes in the exchange rate between the Pound and the Euro and the impact of quotas introduced by manufacturers.
- If applied inflexibly, or set at the wrong level, quotas introduced by manufacturers – where manufacturers choose to limit the amount of a particular medicine that can be ordered – may contribute to shortages or

¹ At national level, the lead for medicines supply lies with the Department of Health (DH). There is a DH team which works closely with the Medicines and Healthcare products Regulatory Agency (MHRA), the pharmaceutical industry, NHS England and others operating in the supply chain to help prevent shortages and to ensure that the risks to patients are minimised when they do arise. The work is underpinned by joint DH/pharmaceutical industry best practice guidelines which give advice to companies on what to do in the event of a shortage. The MHRA is the government body responsible for the safety and licensing of medicines in the UK. As part of that role the MHRA enforces the licensing requirements under the Human Medicines Regulations 2012.

impact the ability of pharmacists to receive medicines on a timely basis. However, we understand that where shortages are considered to be caused by parallel trade or quotas, there is generally stock available somewhere in the UK market, and that shortages caused by parallel exporting or quotas may be short-term in nature and relatively easily addressable.

- Furthermore, we have seen data that indicates that a potentially significant proportion of shortages in the UK are likely to have causes originating outside the UK, due to the international nature of medicine manufacturing. These include difficulties faced by manufacturers in sourcing raw materials; problems with the manufacturing process; and regulatory interventions in the country of manufacture.