



Department
of Health &
Social Care

NHS

DHSC and NHS England

Mitigating and managing medicine shortages

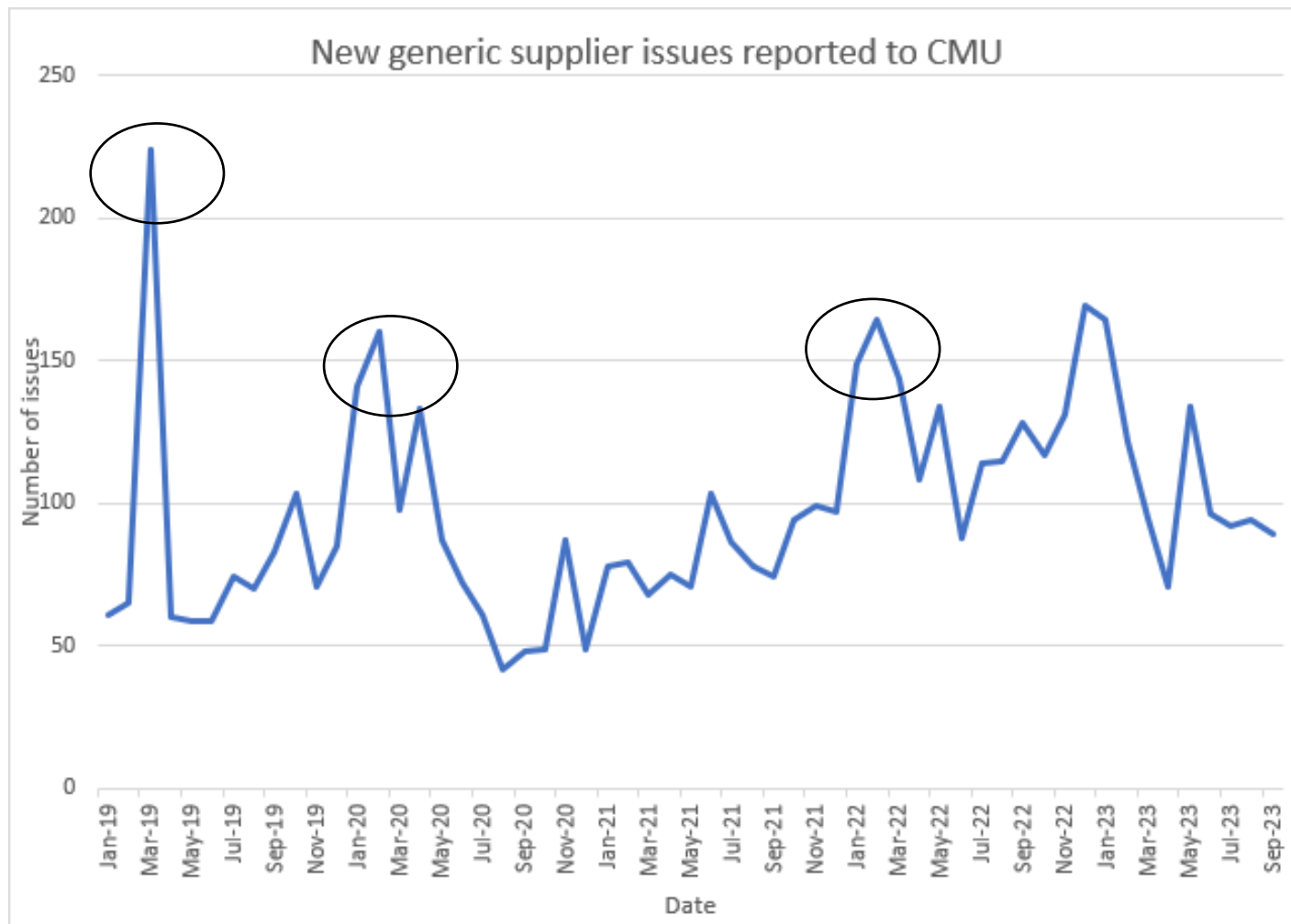
Current strategies and case studies

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November 2023

CMU generic supply issue notifications



March 2019

- 224 supply issues reported (EU exit)

February 2020

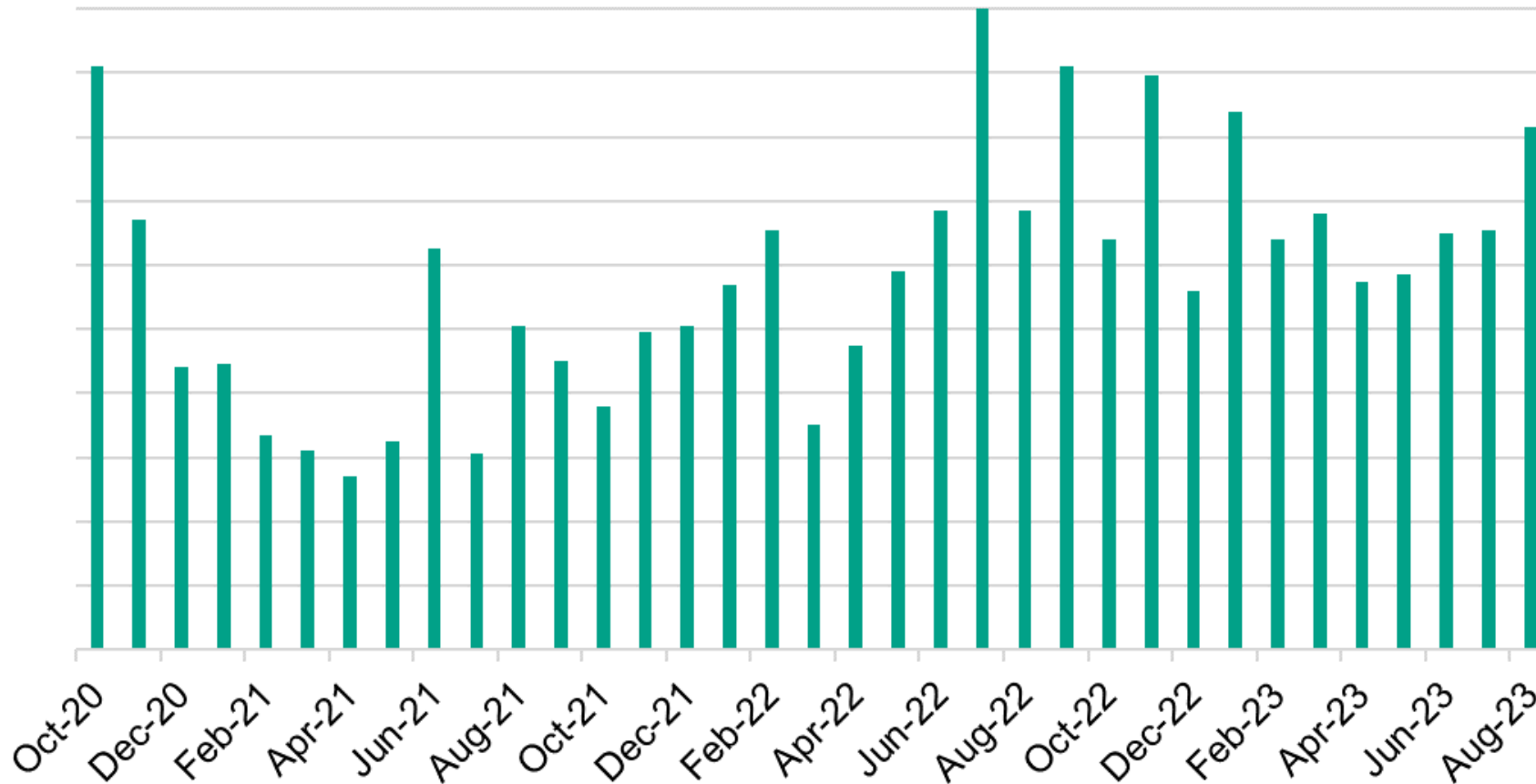
- 160 supply issues reported

December 2022

- Post covid peak 169 supply issues

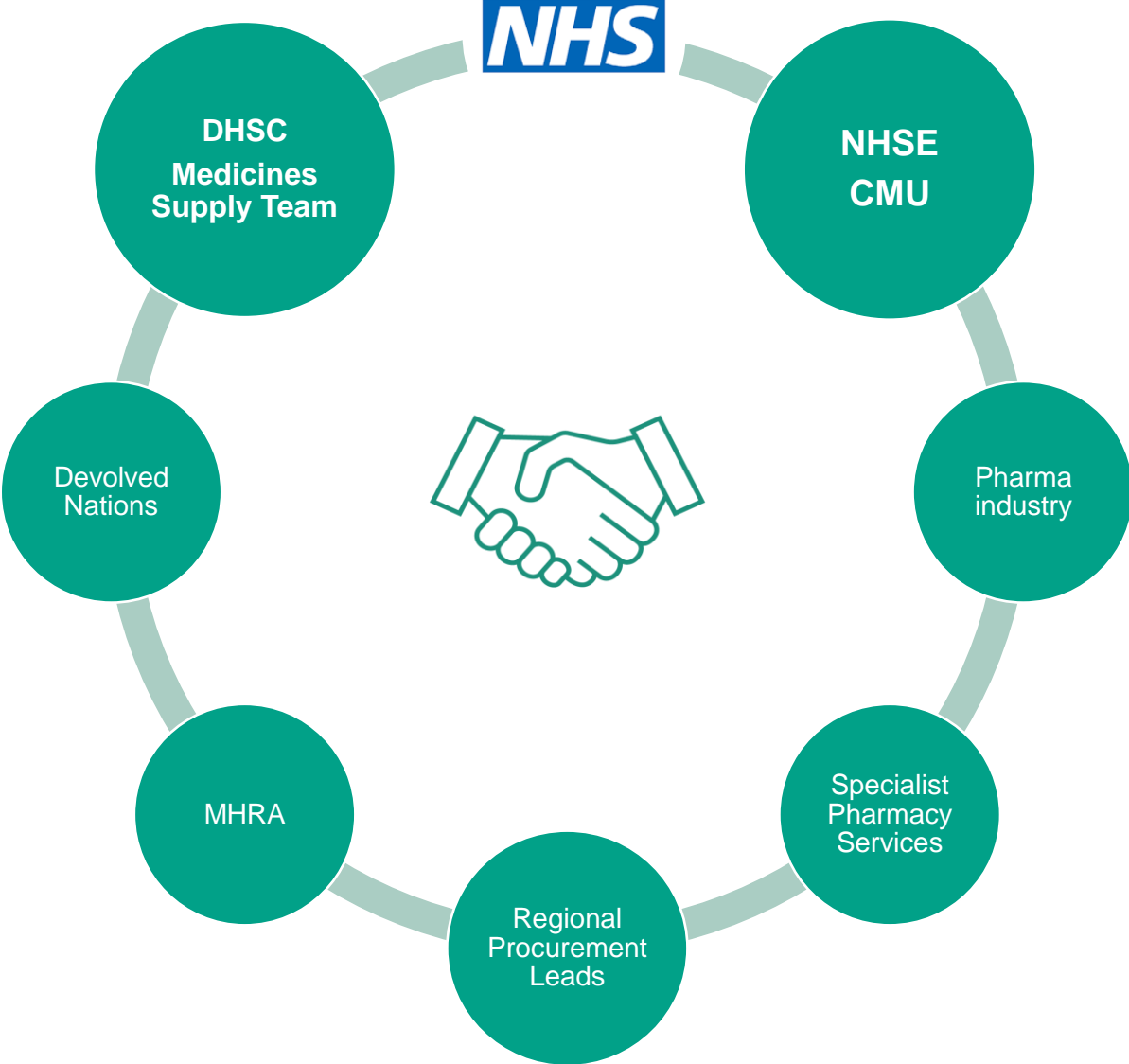
Medicine shortage notifications over time

Shortage Notifications by date added to DaSH, monthly

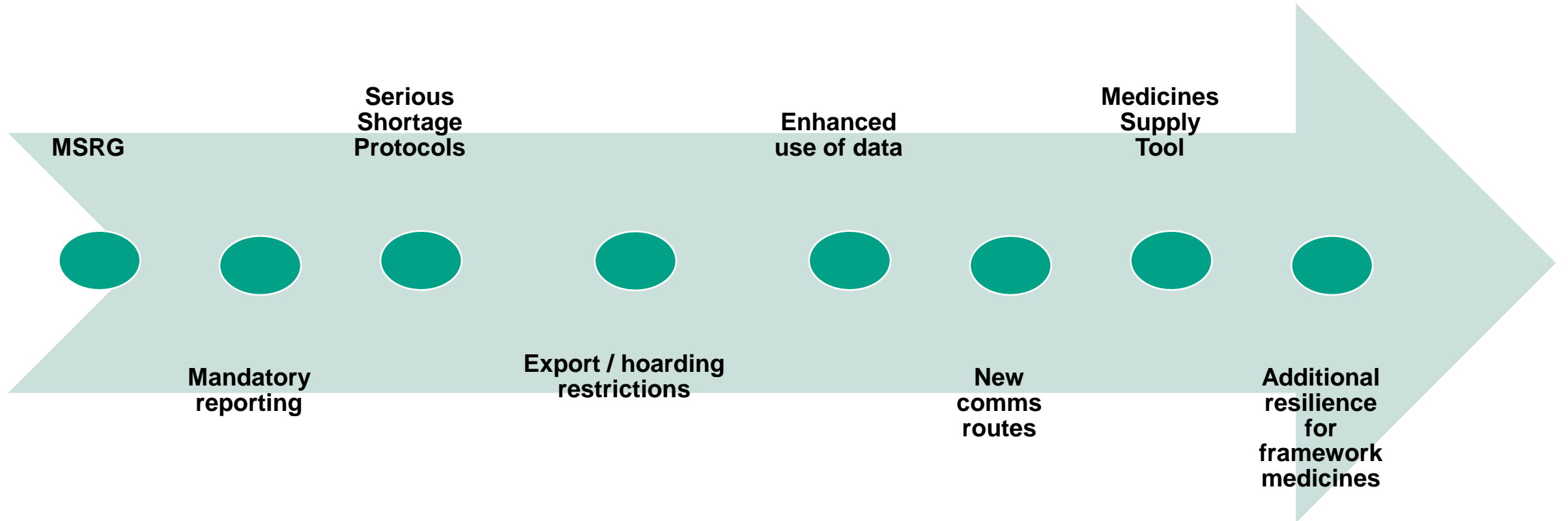


National Management of Supply Issues

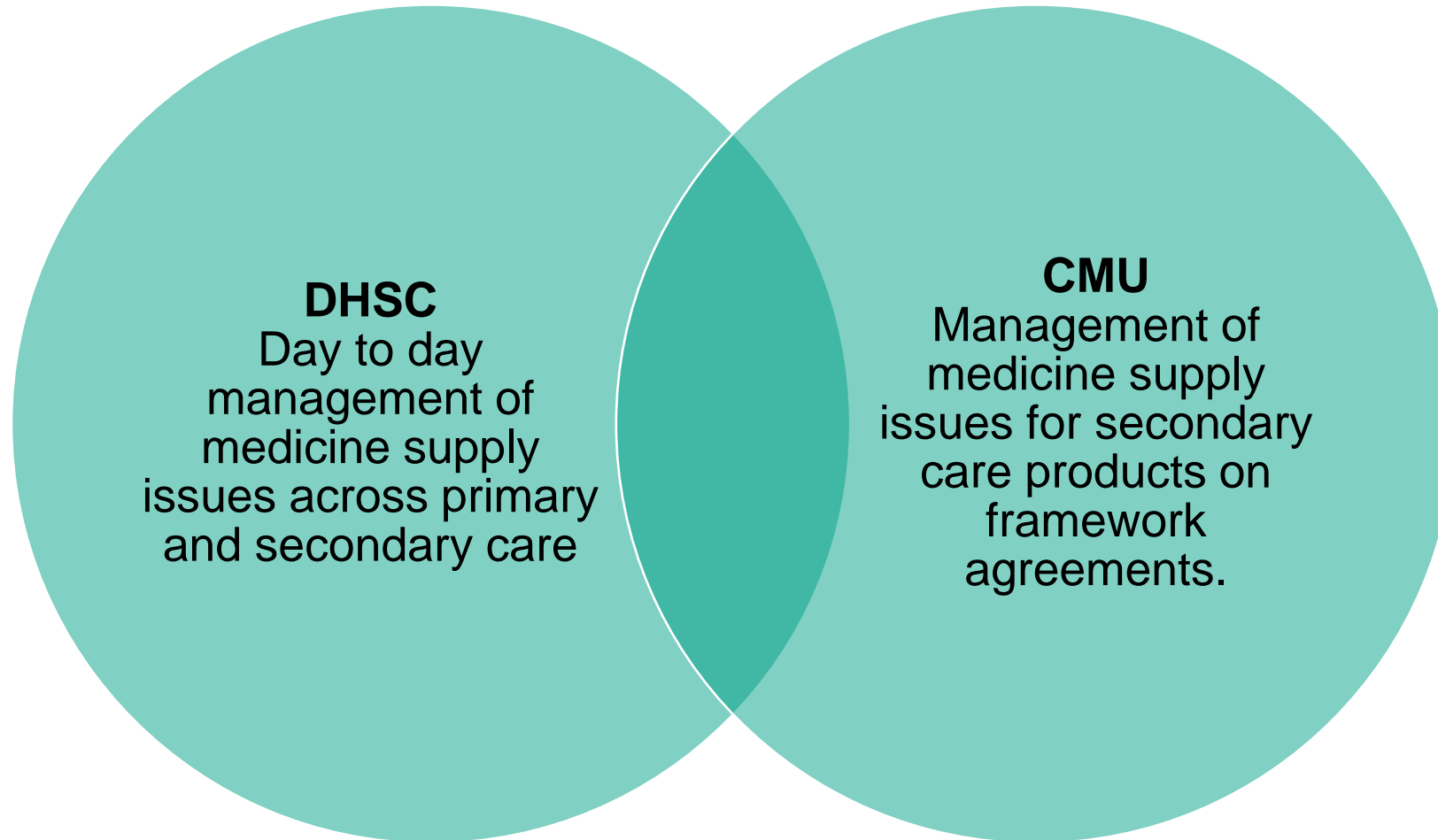
Cross functional collaborative system



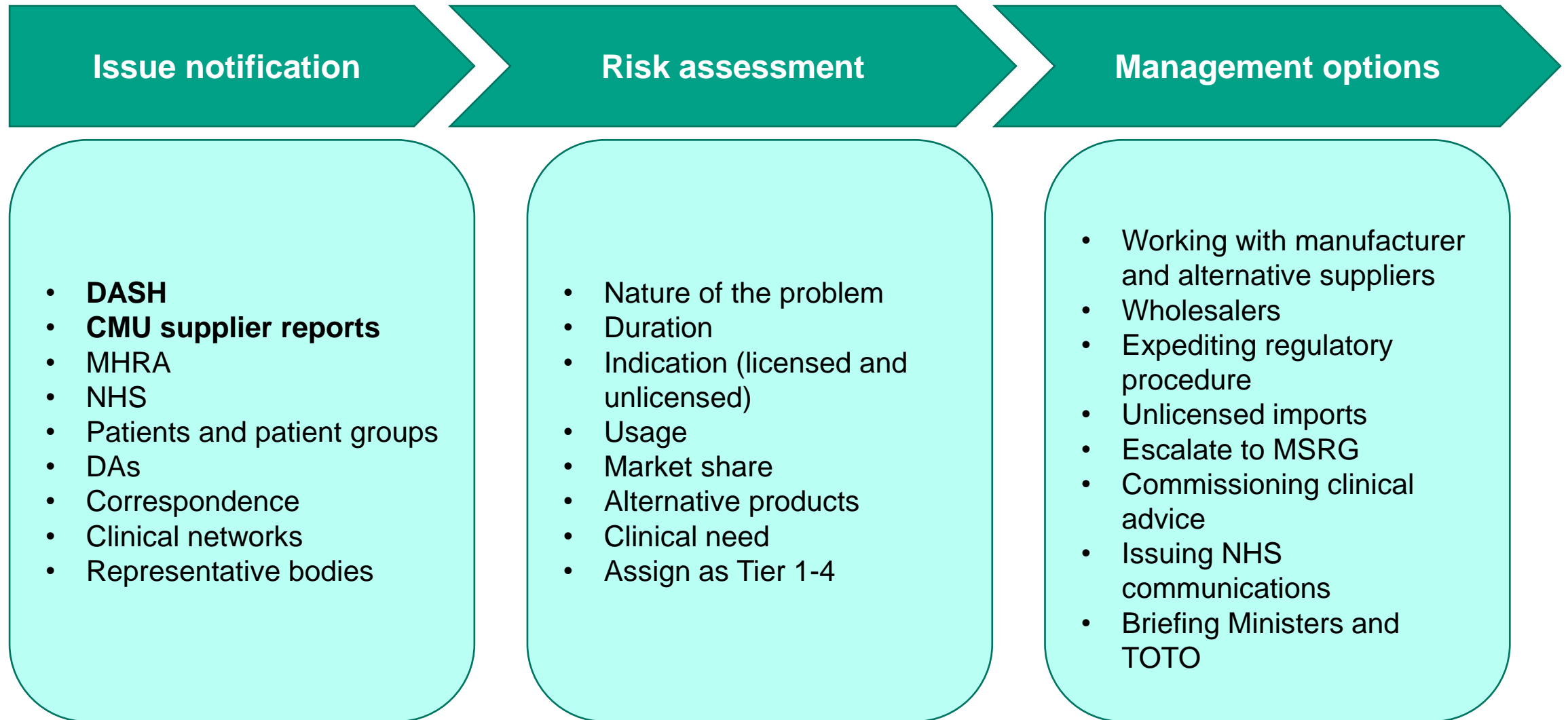
Since we last spoke at PDIG.....



Our roles



Process for managing a supply issue



Regulatory control

Part 6 of the Health Service Products (Provision and Disclosure of Information) Regulations 2018

- **On 1 January 2019 new regulations, replacing voluntary guidance, came into force mandating Marketing Authorisation Holders (MAHs) to provide DHSC with medicine supply information within certain timeframes under threat of financial penalty.**

Two regulations in Part 6 are of particular relevance:

- **Regulation 28:** Provision of information about availability of health service medicines and regulation
- **Regulation 29:** Requirement to provide information about discontinuation or anticipated supply shortage of certain health service medicines.

Guidance is available to provide information on reporting requirements for both shortages and discontinuations it can be found here: www.gov.uk/government/publications/reporting-requirements-for-medicine-shortages-and-discontinuations



DaSH portal

Aware of shortage date

Contacts

Affected product

Reason for shortage

Quantities

Stock exhaustion date

Estimated resupply date

Supplied under an NHS framework?

Are there non-human uses?

Are there any linked shortages?

Are there any alternative products?

DHSC Fields

MAH Fields

MAH Fields

Aware of shortage date	5 Jul 2021
Contacts	Supply Man (csstest.k9@gmail.com)
Affected product	Paracetamol 500mg tablets (30 TABLET)
Reason for shortage	Manufacturing
Quantities	Packs available for supply: 344 Monthly sales of Packs: 123 Estimated market share: Don't know
Stock exhaustion date	14 Jul 2021 Action taken: ss
Estimated resupply date	21 Jul 2021 Resupply comments:
Regions affected	• Scotland
Supplied under an NHS framework?	No
Are there non-human uses?	Yes
Are there any linked shortages?	Yes
Linked shortages	AJVT8U (Visudyne 15mg powder for solution for infusion vials) (1 VIAL)
Are there any alternative products?	No

[Edit MAH Values](#)

Create discontinuation from shortage

Delete Shortage

<https://report-discontinuations-shortages.service.dhsc.gov.uk>

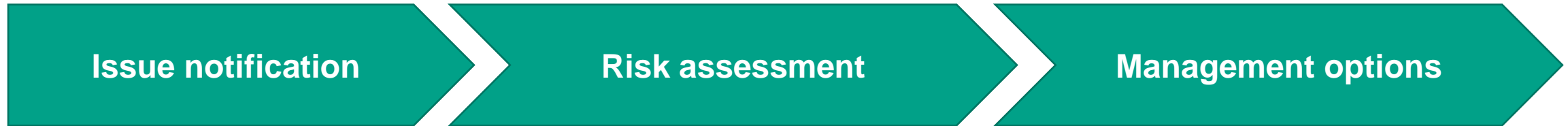


Medicines shortages tier system & management options

Tier	Definition
1: Low Impact	Likely to carry low risk. Management options should result in patients being maintained on the same licensed medicine.
2: Medium Impact	Require more intense management options which may carry a greater risk, but considered safe to be implemented locally without further escalation.
3: High Impact	Considered more critical than tier two issues, with potential patient safety implications that may require clinical advice to the system.
4: Critical Impact	Cannot be resolved as a level three shortage, and which requires additional support from outside the health system.



Medicines Shortages Response Group (MSRG)



A clinically chaired decision-making body to oversee and support both MST and CMU

Commissions expert advice from NCDs, GIRFT leads, CRG chairs and or Royal Colleges / other professional bodies.

A key role of MSRG is to determine and oversee escalation and de-escalation

Agrees the content and dissemination routes for communications to 'the system' and

Provides sign off for management plans


Representatives from patient safety, primary care, RPS, H&J, Comms, SPS, DAs, MHRA



National communication of medicine supply issues

Tier	Definition	Potential communication routes
1: Low Impact	Likely to carry low risk. Management options should result in patients being maintained on the same licensed medicine.	Medicines Supply Tool CMU supplier issues spreadsheet
2: Medium Impact	Require more intense management options which may carry a greater risk, but considered safe to be implemented locally without further escalation.	Medicines Supply Notification Serious Shortage Protocol Medicines Supply Tool CMU supplier issues spreadsheet
3: High Impact	Considered more critical than tier two issues, with potential patient safety implications that may require clinical advice to the system.	National Patient Safety Alert Medicines Supply Notification Serious Shortage Protocol Medicines Supply Tool CMU supplier issues spreadsheet
4: Critical Impact	Cannot be resolved as a level three shortage, and which requires additional support from outside the health system.	Bespoke communications to specific healthcare organisations / professionals, patient facing, National Patient Safety Alert Medicines Supply Notification Medicines Supply Tool CMU supplier issues spreadsheet



Communications



Shortage of GLP-1 receptor agonists

Date of issue:	18-Jul-23	Reference no:	NatPSA/2023/008/DHSC
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This alert is for action by: All organisations involved in prescribing and dispensing GLP-1 RA medicines

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in diabetes, GP practices, pharmacy services in all sectors, weight loss clinics, private healthcare providers, those working in the Health and Justice Sector.

<p>Explanation of identified safety issue:</p> <p>There are very limited, intermittent supplies of all glucagon-like peptide-1 receptor agonists (GLP-1 RAs) ^{NOTE A}.</p> <p>Supplies are not expected to stabilise to meet full market demand until at least mid-2024.</p> <p>The supply issues have been caused by an increase in demand for these products for licensed and off-label indications.</p> <p>The off-label use of these agents for the management of obesity is strongly discouraged. Existing stock must be conserved for use in patients with diabetes. These shortages have serious clinical implications in the management of patients with type 2 diabetes. The clinical implications include erratic blood glucose control, with the potential to increase diabetes-related complications, including the risk of future cardiovascular events and diabetic ketoacidosis.</p> <p>Patients established on GLP-1 RA products may not be able to access products which could result in treatment failure and/or a loss of blood glucose control. Some patients established on GLP-1 RA therapy for type 2 diabetes may need to be switched to alternative treatments including insulin. Initiating insulin therapy requires training and education alongside a potential need for enhanced glucose monitoring to ensure patients are aware of how to recognise and manage hypoglycaemic events.</p> <p>Saxenda (liraglutide), a GLP-1 RA licensed for weight loss is unavailable until mid-2024.</p>	<p>Actions required</p> <p>Actions to be completed as soon as possible, and not later than 18/10/2023</p> <p>Actions for clinicians and prescribers of GLP-1 RAs until supply issues have resolved.</p> <ol style="list-style-type: none"> Only prescribe GLP-1 RAs for their licensed indications. Do not initiate new patients on GLP-1 RAs for the duration of the shortage. Proactively identify patients established on affected GLP-1 RAs and consider prioritising for review based on the criteria set out in the clinical guidance and <ol style="list-style-type: none"> discuss stopping treatment with patients who have not achieved treatment targets as per NICE NG28 or NICE CG189 do not switch between brands of GLP-1 RAs, including between injectable and oral forms. do not double up a lower dose preparation where a higher dose preparation of GLP-1 RA is not available. do not prescribe excessive quantities; limit prescribing to minimise risk to the supply chain whilst acknowledging the needs of the patient. Use the principles of shared decision making where an alternative agent needs to be considered, as per NICE guidelines³ and in conjunction with the clinical guidance.^{2,4} Support patients to access structured education and weight management programmes where available. For type 2 diabetics; if switching a patient on to insulin, please ensure an insulin is chosen as per information on the SPS page on prescribing available insulins as not all suppliers are able to manage an uplift in demand.⁴
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For further detail, resources and supporting materials see: [Enter specific webpage provided by alert issuer](#)
For any enquiries about this alert contact: DHSCmedicinesupplyteam@dhsc.gov.uk

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

Medicine Supply Notification

MSN/2023/008

Generic drug name (brand name*) strength formulation
Tier 2 – medium impact*
Date of issue: dd/mm/yyyy
Link: [Medicines Supply Tool](#)

Summary (add/delete as appropriate)

- Name (brand name*) strength form is out of stock until date month year.
- Alternate strengths of name (strength) form remain available and will be able to support increased demand.
- Alternate brand(s)/another formulation remains available. Where these are not suitable, unlicensed supplies may be sourced, lead times vary. ~~Delete if not appropriate.~~

Actions Required (adapt/delete as appropriate)

Where patients have insufficient supplies to last until the re-supply date, clinicians/prescribers should:

- review patients to determine if this is still the most suitable therapy;
- work with local pharmacy teams to understand availability of alternative strengths and issue a prescription to make up the required dose of drug name;
- consider prescribing xxx which is able to support the market during this time, ensuring that the patient is not intolerant to any of the excipients and is counselled on the appropriate dose and volume required (see supporting information below);
- consider prescribing unlicensed products only where licensed alternatives are not appropriate. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see supporting information below); and
- if the above options are not considered appropriate, advice should be sought from specialists on management options.

If the patient is deemed ineligible or does not consent to receive an alternative product via the SSP, clinicians can consider prescribing:

- xxx drug; or
- a suitable alternative medicine.



Supporting information (add/delete as appropriate)

[Clinical Information](#)

- Include SPS MI advice if provided

*Classification of Tiers can be found at the following link:
<https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/>

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SERIOUS SHORTAGE PROTOCOL (SSP)

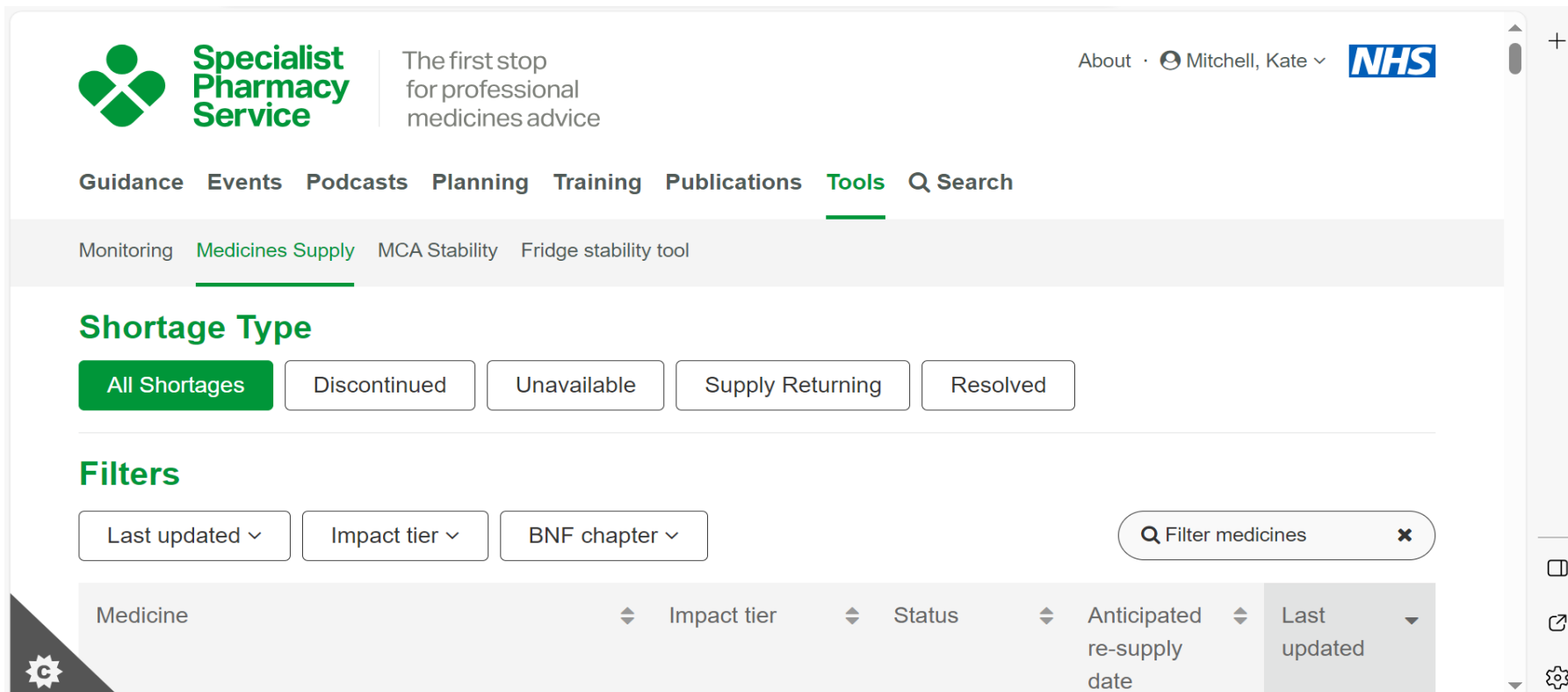
Reference Number: SSP057

This SSP applies to the following medicine:

Name of medicine (including strength and formulation)	Estradot® (Estradiol (as hemihydrate)) 100 microgram patch
Legal category	POM

1. Details of medication to be supplied under this SSP

Name of medicine (including formulation and strength) to be supplied	Evorel® 100 microgram patch OR Estraderm MX® 100 microgram patch
Quantity of this formulation (if applicable)	Total quantity supplied under this protocol to be equivalent to the number of days supplied on the original prescription. For every Estradot® 100 microgram patch, the following quantity must be supplied in accordance with this protocol: 1 x Evorel® 100 microgram patch



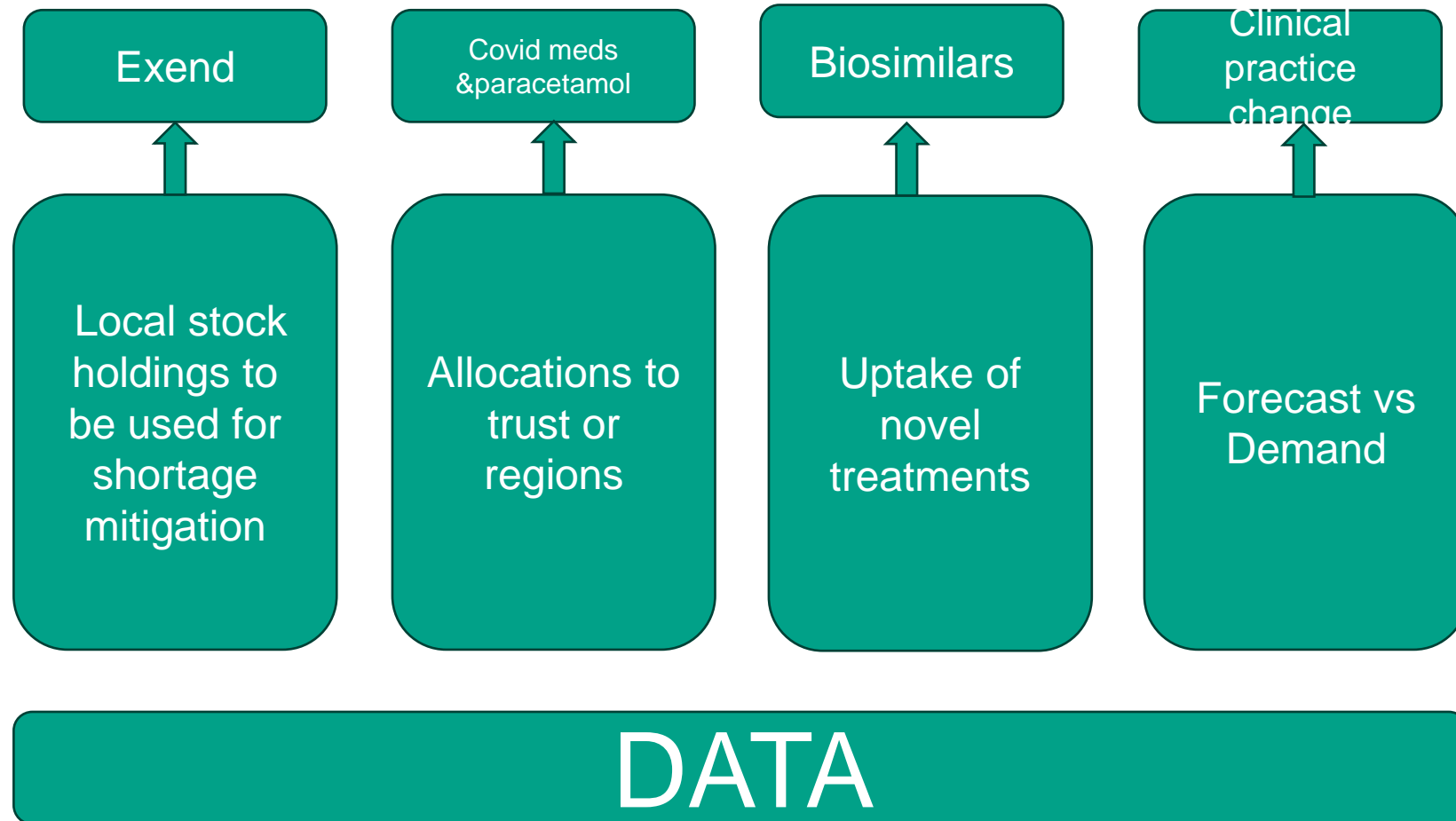
The screenshot shows the web interface for the Medicines Supply Tool. At the top left is the Specialist Pharmacy Service logo and tagline: "The first stop for professional medicines advice". To the right, there are links for "About", a user profile for "Mitchell, Kate", and the NHS logo. A navigation menu includes "Guidance", "Events", "Podcasts", "Planning", "Training", "Publications", "Tools" (which is highlighted), and "Search". Below this, a sub-menu shows "Monitoring", "Medicines Supply" (highlighted), "MCA Stability", and "Fridge stability tool".

The main content area is titled "Shortage Type" and features five filter buttons: "All Shortages" (active), "Discontinued", "Unavailable", "Supply Returning", and "Resolved". Below this is a "Filters" section with three dropdown menus: "Last updated", "Impact tier", and "BNF chapter". To the right of these is a search box labeled "Filter medicines".

At the bottom, a table header is visible with columns: "Medicine", "Impact tier", "Status", "Anticipated re-supply date", and "Last updated". A gear icon for settings is located in the bottom-left corner of the interface.

<https://www.sps.nhs.uk/home/tools/medicines-supply-tool/>

Enhanced use of data

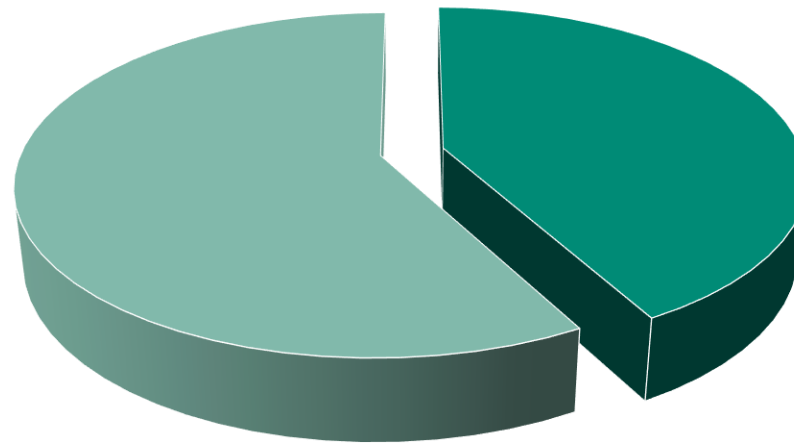


Improving resilience- buffer stocks

CMU mandated 8 week buffer stock holding introduced late 2021

e.g. weekly sales of 100 packs: $100 \times 8 = 800$ packs stock holding additional to required volume to meet expected demand

Proportion of supplier issues attributed to poor performing suppliers

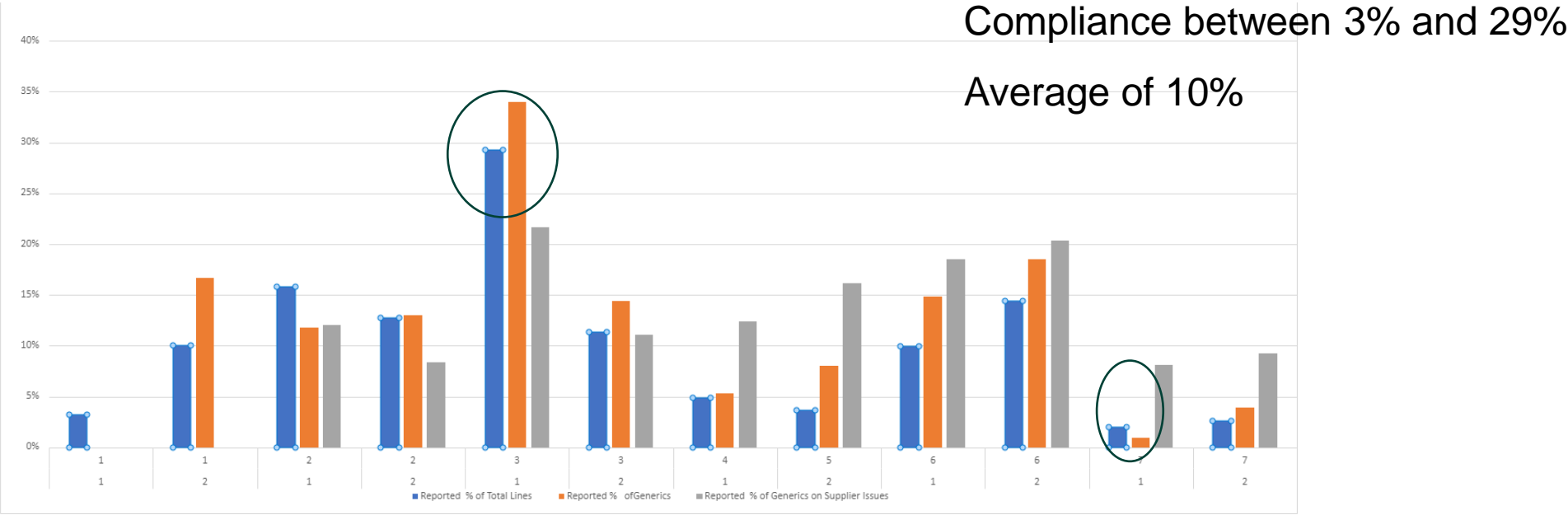


■ 10 worst performing suppliers ■ All other suppliers

Improving resilience- buffer stocks

Feb 2023 voluntary pilot launched to monitor buffer stocks held and compliance to CMU contractual ask

September 2023 pilot phase completed with clear correlation between reported out of stocks and lack of buffer stocks in place



Future NHSE Resilience roadmap

- Direction of travel is to move away from reactive medicines shortage mitigation and move to proactive management of supply chain
- Use the data available and build data modelling capability for medicines supply chains
- Nurture a dynamic supply response ecosystem with integration of regulator and supplier info
- Supply response ecosystem



Case study – IV Fluids

Background

- Spirit medical were the sale distributor for Carelide UK a subsidiary of a large French based Iv Fluids manufacturer.
- Notified in June 2023 key products had not been shipped to the UK with no immediate information on the cause or resolution date.
- Commercial acquisition of Carelide France led to contractual review of all business units including sole distributor rights for the UK
- Potentially a proportion of English hospitals had no access to critical IV fluids within 48 hours of notification

Engagement

- Clinical colleagues across secondary care
- Full market Usage information and hospital stock holding scrutinised
- All other suppliers stood up to give emergency support
- DHSC / UKHSA held stockpiles were assessed for emergency release



IV fluids – Management plan

Management plan

- All 3 alternative suppliers expedited stock releases and made available product to none contract customer
- DHSC Stockpile mobilised within 24 hours for large volume fluids for immediate call upon
- Emergency drops of pallets of small volume fluids arranged into wholesaler depositions
- Urgent review on title of remaining Carelide stock enabling rapid mobilisation

Monitoring and contractual review

- Daily monitoring and allocation of orders for Carelide customer for 4 weeks to then weekly review
- Monthly review of position including winter planning assumptions
- Review of CMU Framework and novation of contract to Agguetant Ltd



HRT – Management

Management plan

- *HRT taskforce*
- *Extensive engagement with suppliers, wholesalers, primary care organisations and trade associations.*
- *Cross organisation collaboration to help provide data on dispensing and predict future demand*
- *Analysis provided to industry and extensive engagement with individual suppliers to improve future forecasts.*
- *SSPs integral part of management – 23 in total used to date with only 1 remaining.*
- *Export restrictions*
- *Quarterly roundtables - ongoing*



National Management of Supply Issues

Take-home messages

NHS:

- Use the Medicines Supply Tool.
- Know your local processes and escalation routes.

Industry:

- Early notification is essential and if unsure whether to report get in touch
- If you are seeing unusual demand patterns, get in touch
- Ensure contracted volumes are in place.

DHSCmedicinesupplyteam@dhsc.gov.uk
England.cmupharmacyteam@nhs.net

