

Supply issues update for primary care July 2018

This report has been produced by the Department of Health and Social Care (DHSC) Medicine Supply team. We aim to update this report on a monthly basis for the PRESCQIPP network to provide an update on current primary care medicine supplies issues that we are working on. Please share with all relevant colleagues and networks in primary care.

Information provided w/c 16 July

New issues

Imigran (sumatriptan) injection

- We have been made aware of a manufacturing issue affecting supplies of GSK's branded sumatriptan injection, Imigran.
- Limited supplies of both Imigran injection initiation packs and Imigran injection refill packs are currently available, but it is estimated that supplies will be exhausted mid-August 2018
- Resupply is not expected until Q1 2019 (January-March 2019)
- Generic supplies of sumatriptan injection in both initiation and refill packs are available from Sun Pharma/Ranbaxy – (this product is 'sumatriptan 6 mg/0.5 ml solution for injection')
- Sun Pharma/Ranbaxy have confirmed that they are able to support the additional demand during this time.

Priadel oral solution – Lithium Carbonate oral solution 520mg in 5ml.

- Sanofi have confirmed that there is very limited stock available currently of Priadel oral solution – Lithium Carbonate oral solution 520mg in 5ml.
- Priadel 200mg and 400mg tablets remain available and stock is available to order via AAH.
- Next delivery scheduled for Priadel liquid is the 3rd August 2018
- Rosemont have confirmed the oral liquid of lithium citrate tetrahydrate remains available in both strengths:
 - 509mg/5ml of lithium citrate tetrahydrate equivalent to 200mg of lithium carbonate solution per 5ml
 - 520mg/5ml of lithium citrate tetrahydrate equivalent to 204mg of lithium carbonate solution per 5ml
- We are seeking further clinical advice about this and working with Sanofi to expedite the resupply date

Ongoing issues

Diamorphine injection - ongoing

- The DHSC and NHS England have been made aware of a manufacturing issue from one of our suppliers of Diamorphine 5mg and 10mg injection.
- There are currently two suppliers of Diamorphine injection in the UK; Accord and Wockhardt. Recently Accord's plant in Germany has experienced quality issues and we are working closely with Accord, regulators, and others in the resolution of these issues.
- We are working closely with Wockhardt to secure further supplies for the UK market from July and August. We also continue to work with Accord to resolve the manufacturing issue as soon as possible.
- There is currently stock available to order, please follow recommended actions below.

Recommended Local Action- Primary care and drug misuse centres

- Primary care and drug misuse centres will be able to access diamorphine as per historical demand
- We would encourage prescribers to be aware of the supply issues and reduce prescribing where appropriate
- Please order responsibly during this time, in line with historical demand and do not stock pile to avoid lengthening the stock out period.
- In the case that diamorphine cannot be accessed, please refer to the clinical guidance issued by UKMI which provides more information on suggested alternatives to diamorphine: www.sps.nhs.uk/articles/shortage-of-diamorphine-5mg-10mg/. The first-choice is morphine which is given in detail in this link. If you require clinical guidance locally – please liaise with secondary care prescribing partners in substance misuse services or pain specialist services
- Further information which you may wish to review include the Patient Safety Alert on high dose morphine and diamorphine www.nrls.npsa.nhs.uk/resources/?entryid45=59803

Distribution Arrangements for community pharmacy (From w/c 2nd July)

- Diamorphine 5 and 10mg will only be available to order from Alliance. No minimum surcharges will be levied
- Morphine 10mg injection (Martindale) available to order from AAH only.
- Diamorphine 30mg injection (Wockhardt), diamorphine 100mg (Accord) and diamorphine 500mg (Accord and Wockhardt) – usual wholesalers.

Diazepam 5mg/ml Emulsion for injection (Diazemuls) - ongoing

- Accord, the sole supplier of diazepam emulsion for injection, has informed us that, due to an issue with the raw material, they will be out of stock of this product until mid-August 2018.
- UKMI have prepared the following advice on alternatives, which can be found [here](#), which suggests the following products as possible alternatives and we have been in a contact with all the suppliers to make them aware of the issue:
 - Ativan (lorazepam 4mg/ml)- Pfizer in stock
 - Buccolam (Midazolam buccal)- Shire are in stock of all strengths
 - Diazepam rectal tubes- see information below

Diazepam Rectal tubes – ongoing

- Wockhardt, the sole supplier of diazepam 2.5mg rectal tubes is currently out of stock until late July.
- Wockhardt are also out of stock of the 5mg and 10mg.
- Diazepam 5mg and 10mg rectal tubes continue to be available from Accord and Desitin.

Colestyramine (Questran)

- Teva have discontinued their product colestyramine 4g oral suspension powder sachets
- BMS are currently the sole supplier of colestyramine.
- Due to recent manufacturing issues, BMS are out of stock of Questran Powder for Oral suspension 4g. Supplies are now expected towards the end of August.
- Questran Light is now back in stock and have advised that good supplies are available
- Due to recent issues with Questran / Questran Light, UKMi have prepared [a memo](#) to advise on alternatives
- We have also made importers aware of the issue and they have confirmed that supplies can be sourced from abroad although lead time will vary.

Adalat LA20- ongoing

- Bayer are out of stock of Adalat LA 20 tablets. Estimated resupply date Mid July 2018.
- Other brands of Nifedipine in a 20mg modified/prolonged release formation remain available including;
 - Adipine (Chiesi), Coracten (UCB), Nifedipress (Dexcel), Tensipine (Genus)

Epipen – ongoing

- Mylan have informed us that due to manufacturing delays from our contract manufacturer, Meridian Medical Technologies, a Pfizer company, there are intermittent supply constraints of EpiPen® 0.3mg Adrenaline Auto-Injector in the UK.
- Alliance Healthcare has recently received additional stock of EpiPen® 0.3mg Adrenaline Auto-Injector from Pfizer and they will be working with pharmacies to fulfil prescriptions.
- To further assist in the stock management of EpiPen® 0.3mg, pharmacies are allocated stock on a prescription-only basis and can place orders for up to max 2 EpiPen® 0.3mg Auto-Injectors per prescription.
- At this time, there are no supply constraints of EpiPen® Jr 0.15mg Adrenaline Auto-Injectors.
- Mylan have shared the attached statement, which is also available on their website www.epipen.co.uk.
- Mylan is working closely with Pfizer to manage supply carefully to avoid long-term supply shortages. Pfizer anticipates that production rates will increase over the coming months; however, at this time, cannot commit to a specific time for when the supply constraint will be fully resolved.
- There are two alternative adrenaline auto-injector products available in the UK, Emerade and Jext.
- Currently supplies are available in various strengths of both of these alternative devices.
- We are in contact with the manufacturers of these alternative devices to keep them updated on the situation. They both have additional deliveries arriving over the coming weeks and they are working to expedite future deliveries and bring additional stock to the UK where possible.

Lofexidine – ongoing

- Britannia are no longer supplying Britlofex (lofexidine) tablets due to manufacturing problems.
- Britannia is the sole supplier of this product to the UK.
- Britannia does not yet know the resupply date for the next delivery of Britlofex tablets, but the out of stock period is likely to last several months. This is due to the transfer of the product to a new manufacturer. We have been in discussion with the specialist importer companies about this and they have been unable to source supplies from abroad, as this product is not used in many other countries.
- UKMI have prepared the following shortages memo, which has now been published on the [SPS website](#)



Britlofex Temporary
Discontinuation Notifi

Menadiol tablets – ongoing

- Alliance, the sole supplier is out of stock from mid-January until approximately October 2018.
- They are now supplying an unlicensed special which is the same formulation as the licensed product. Please find attached information sheet which was drawn up about the special product. This product is available to order from Alcura



Menadiol
Diphosphate Informa

- Other specialist importers are also able to source unlicensed supplies.
- UKMI have drafted a shortages memo, providing advice on alternatives, available on the [SPS website](#)
- Please do pass on information about this shortage to relevant clinical specialities including paediatrics.

Acetazolamide MR - ongoing

- Diamox MR – Concordia have advised resupply not due until Q3 (July-Sep 2018).
- Eytazox Cap 250mg M/R- Teva have advised resupply not due until late July 2018.
- Immediate release acetazolamide 250mg tables are available from both Teva and Concordia.

Venlafaxine 37.5mg and 75mg tablets - ongoing

- There have been recent generic supply issues with venlafaxine 37.5mg and 75mg immediate release tablets.
- Stocks of both strengths are currently available from wholesalers.
- Further supplies have recently been released.

Trimovate cream - ongoing

- Product has recently divested from GSK to Ennogen, but Ennogen will not be in stock until late in 2018.
- Ennogen have imported in Trimovate cream as an unlicensed product and are now distributing this product.
- A copy of the communication letter with ordering details is attached.



Letter to Pharmacists
Prof Groups RE Trim

Lacidipine 2mg and 4mg - ongoing

- Due to a combination of manufacturing and regulatory issues, there are currently some generic supply issues with this product.
- Teva are in stock of both strengths of generic lacidipine (2mg and 4mg).
- GSK have good supplies of the brand, Motens in both 2mg and 4mg strength.

Tranexamic acid 500mg tablets – ongoing

- Ongoing supply issues due to difficulty in obtaining raw material.
- Currently Teva and Tillomed have supplies available of generic.
- Mylan have supplies of the brand Cyklokapron.
- Supplies are therefore available but may be limited.
- UKMI have provided the following shortage memo which advises on alternatives, available [here](#).

Trifluoperazine tablets - ongoing

- There have been ongoing supply issues affecting trifluoperazine 1mg and 5mg tablets.
- Supplies will not improve until some point in 2019 due to manufacturing issues with the active ingredient, therefore long term issues affecting the tablets.
- Concordia and Rosemont have trifluoperazine available in liquid formulations and have good supplies.
- We are also aware that unlicensed supplies of both the 1mg and 5mg tablet are available from both Ennogen and a number of specialist importer companies. Under the medicines legislation, doctors can prescribe unlicensed products for their patients if they think it appropriate, but do so entirely on their own responsibility. Pharmacies can obtain unlicensed supplies via these specialist companies or Ennogen.

Zaditen 300ml (1.38mg in 5 ml oral solution)- ongoing

- CD Pharma currently out of stock of Zaditen oral solution 300ml (no date available for resupply).
- In the interim, they can provide an alternative 100 ml packs for Zaditen Syrup (Origin Polish market), which is now available at our Alloga
- The MHRA has approved a variation for CD Pharma to supply this product, so it is considered licensed.
- Please find attached the information letter for further info.
- Zaditen 1mg tablets are not affected by this issue and remain readily available.



Final letter to distributors for Zadite

Phenobarbital injection - ongoing

- Martindale are the sole supplier of phenobarbital injection and they are currently out of stock of the 30mg and 60mg presentations.
- This issue is due to regulatory changes with the British Pharmacopoeia monograph for phenobarbital
- We have been working with both Martindale and the MHRA to resolve this issue and can now confirm that the 200mg batch has been released. Supplies should now be available via AAH.
- The timescales for further supplies of the remaining strengths are not yet confirmed but we are continuing to work towards making these available as soon as possible.
- UKMI have prepared the following shortages memo, which has now been published on the [SPS website](#)
- This provides advice on possible alternatives and they have also provided information on using the 200mg product in place of the lower strengths if needed.

Eye drops/ treatments:

Allergan –

- **Lacri-lube supplies-** out of stock for the rest of the year due to a manufacturing issue.
- [Royal College of Ophthalmology](#) is aware of the shortage and is recommending Xailin Night Ointment.

Bausch & Lomb –

- **Minims Pilocarpine 2%** stock will be released into the market end of July.
- **Prednisolone and Phenylephrine 2.5%** transient back orders but there is still stock in wholesale which should cover the market for a few weeks.

Novartis –

- **Azopt 5ml eye drops** – currently out of stock due to PI shortage and delay at plant, there is likely to be intermittent shortages over the next few months.

RPH Pharmaceuticals AB - Betnesol Eye Ointment 0.1% w/w x 3g

- RPH Pharmaceuticals AB (marketing authorisation holder) who distribute the product through Focus Pharmaceuticals have advised about the discontinuation of Betnesol Eye Ointment 0.1% w/w x 3g towards the end of March
- RPH Pharmaceuticals will be launching a generic Betamethasone Eye Ointment 0.1% w/w x 3g and are currently expecting stock mid-July.

Resolved

Hydrocortisone sodium phosphate 100mg injection- Pfizer has advised that new supplies available mid/late July and that the manufacturing issues have now been resolved.

Sustanon injection – back in stock

Rifater – back in stock

Vaccines:

For updates on other vaccine supply position, please refer to PHE's Vaccine Update Bulletin found at the following address: www.gov.uk/government/collections/vaccine-update#2018

Hepatitis B Vaccines

- Supplies of GSK vaccines have improved.
- MSD allocations remain set as they are.
- A mechanism remains in place for both suppliers to allow for exceptional orders if there is an urgent and immediate need.
- PHE previously developed temporary recommendations on hepatitis B vaccine including risk-based prioritisation of vaccine, dose-sparing and deferral of boosters
- Although, supply of Hepatitis B vaccines has improved, controlled stock management and ordering restrictions will continue to allow for the backlog of patients/staff who had vaccination deferred last year and because manufacturers have not got their usual full UK allocation
- A recovery plan for 2018 was published by PHE on 26th February 2018 and vaccine ordering was opened out in a phased approach over 2018 to lower priority group (4) patients, from March. Priority group 1-3 patients/staff will continue to have access to vaccine.
- Information on the temporary recommendations and recovery plan can be found at the following [link](#)
- PHE have issued a letter to NHS and non-NHS occupational health service providers (see attached) outlining the implication for OH



OH letter necessary
plan 2018 s...

Pneumococcal Polysaccharide Vaccine (PPV23):

- MSD are the sole UK supplier of this vaccine and limited supplies are currently available
- Further supplies are expected in July
- Supply may be intermittent throughout 2018
- PHE have previously issued guidance to GPs (see attached) on how to manage patients if unable to obtain PPV vaccine.



PPV vaccine
shortage PHE letter to

- Updates on recommendations are now available in February edition of PHE's Vaccine Update Bulletin (p7)



Vaccine update...

Menveo (meningitis A,C,W,Y):

- GSK are out of stock of Menveo until late 2018 (date has not yet been confirmed)
- Pfizer have confirmed they are in stock of Nimenrix and currently able to support increased demand

Discontinuations

Modecate

- As per previous notifications, Sanofi are discontinuing Modecate and -see attached letter
- Sanofi have further advised that UK supplies will longer be available from the end of Q3
- No new patients should be commenced on this treatment
- Importers have confirmed they can source unlicensed supplies from abroad that are not connected to the Sanofi supply chain. We will share further info with regional leads as more information becomes available.



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DHCP_Letter_Modeca

Ciproxin (ciprofloxacin) 750mg tablets (Bayer): Stock now exhausted. Alternatives available from other suppliers.

Testim (testosterone) gel (Ferring): Stock now exhausted. Alternatives remain available for other suppliers.

Hypurin Bovine insulin (Wockhardt): Update

- Bovine Isophane Vial x 10ml will deplete in July 2018 (earlier than previous predictions). This is a significant withdrawal for the market as it means Bovine Isophane insulin will no longer be available in any form. All the latest information can be found on the [Wockhardt website](#)

Olysio (simprevir) (Janssen-Cilag)

- Being discontinued in June 2018 as a result of sales dropping due to other newer products entering market

Duavive (conjugated oestrogens & bazedoxifene) (Pfizer)

- Being discontinued in December 2019 due to commercial reasons

Asacol (mesalazine) 250mg & 500mg suppositories (Allergan)

- Discontinued with immediate effect stocks now exhausted. Alternatives available from other suppliers.

Magnesium hydroxide mixture (Artyon Saunders)

- Being discontinued in September 2018 available from alternate suppliers.

Coro-Nitrate (glyceryl trinitrate) spray (Aryton Saunders)

- Discontinued with immediate effect. Stocks exhausted. GTN spray remains available from a number of alternate suppliers.

Desloratadine 2.5mg in 5ml oral solution (Rosemont)

- The company has discontinued with immediate effect due to low volume sales and all remaining stock has expired. Alternatives remain available from other suppliers.

Rewisca (pregabalin) capsules (Consilient) - discontinued July 2018. Alternatives available from other suppliers.

Torbay are planning to discontinue the following unlicensed special products:

Product	Alternative supplier	Expiry date of current batch
Acetic Acid 3%	Tayside, Preston & Huddersfield	Out of stock
Cocaine Hydrochloride 4%w/v p/f eye drops 4ml sol	Huddersfield 2ml	available until 30/9/2018
Glucose 30% Oral Solution	Other preparations available	Out of stock
Mannitol 20% in 100ml	Licensed Baxter Healthcare 500ml	Out of stock
Papaverine Solution for Injection 80mg in 2ml	Huddersfield 1ml	Out of stock
Povidone Iodine 5%w/v Cutaneous Solution	Huddersfield 30 & 100ml	available until 31/08/2018
Zinc Sulfate 57.5 mcg in 10ml	Contract manufacture not purchased	available until 31/5/2018