

## Supply issues update for primary care April / May 2018

### New issues

#### **Lofexidine tablets:**

- Britannia have advised us of a temporary issue affecting the supply of Britlofex (lofexidine) tablets. Currently Britannia still have good supplies available, but this stock is short dated (expires at the end of May).
- This stock is now only available to order directly from Britannia (telephone number: 01189209500). This short dated stock will no longer be distributed through wholesalers.
- Britannia do not yet know the resupply date for the next delivery of Britlofex tablets, so there is a potential supply issue from June onwards. This is due to the transfer of the product to a new manufacturer. Britannia are currently exploring several options for continued supply.
- We are in discussion with importers about whether unlicensed supplies from abroad are an option.

#### **Rifampicin 150mg tablets:**

- Sanofi are out of stock of Rifadin 150mg capsules. Estimated resupply in late June 2018.
- Sanofi continue to have good stock available of Rifadin 300mg capsules.
- Mylan have stock of generic Rifampicin 150mg capsule.

### Ongoing issues

#### **EpiPen 0.3mg:**

- 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, pharmacies are allocated stock on a prescription-only basis and can place orders for up to a maximum of two 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 a statement, which is available on their website [www.epipen.co.uk](http://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.
- We are aware of two alternative adrenaline auto-injector devices, Jext and Emerade. We have been in contact with the suppliers to these products.
- We understand that there are supplies available of both of these products in various strengths although they may be limited. However, further deliveries are expected in the coming weeks for both products.

#### **Xylocaine 10% spray:**

- Aspen who are the sole supplier of this product are currently out of stock due to capacity issues at their manufacturing site, they are now out of stock.
- Aspen are expecting further stock to be made available at the end of May.
- In the interim period, UKMI have published the guidance, which can be found [here](#). This advises that:
  - Existing stock should be prioritised for use in areas most in need of this product and that usage should be rationalised where possible
  - An unlicensed import (Astra Zeneca product) is available from Europe but there is a 7 to 10 day lead time. Please contact the specialist importer companies directly. Importers have been advised about the further delay to supply and are obtaining further stock from Europe
  - The memo also advises on the potential 'off label' use of other lidocaine products including a lidocaine (5%)/phenylephrine hydrochloride 0.5% w/c product from Martindale Pharma. Martindale have just released new stocks of this product, so it should now be available again (as of 30<sup>th</sup> April)

- Another product called Xylonor spray from Septodont is also a possible option. Please note Xylonor is a dental product but is available to order from Arcadia Pharma Limited. Arcadia have also recently supplies Oxford Pharmacy stores so they may also have supplies available
- The following PGD from NHS Grampian may be useful, available [here](#).

#### Menadiol tablets:

- 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 form Alcura



Menadiol  
Diphosphate Informal

- Other specialist importers are also able to source unlicensed supplies.
- UKMI have drafted a shortages memo, which will provide advice on alternatives, this is available on the SPS website: [www.sps.nhs.uk/articles/shortage-of-menadiol-diphosphate-tablets-10mg/](http://www.sps.nhs.uk/articles/shortage-of-menadiol-diphosphate-tablets-10mg/)
- Please do pass on information about this shortage to relevant clinical specialities including paediatrics.

#### Bactroban nasal ointment:

- GSK have a manufacturing issue and are out of stock.
- GSK are expecting new stock to be available mid-May which should resolve the overall supply situation.
- UKMI have published a shortages memo, which provides advice on clinical alternatives. This is available at the following link: [www.sps.nhs.uk/articles/shortage-of-bactroban-mupirocin-nasal-ointment/](http://www.sps.nhs.uk/articles/shortage-of-bactroban-mupirocin-nasal-ointment/)
- We have been in discussion with the suppliers of the alternatives, who are aware of GSK's latest updates and are working with their supply chains to bring in additional stock:
  - Naseptin Nasal Cream- Alliance Pharmaceuticals available via the wholesalers: AAH, Alliance Healthcare and Well Pharmacy.
  - ProntoDerm – B.Braun have advised limited supplies are available via NHS supply Chain and wholesalers: AAH and Alliance.
  - Octensian Nasal gel – Schülke & Mayr UK Ltd have supplies available.

#### Hydrocortisone sodium phosphate 100mg injection:

- Concordia are out of stock of hydrocortisone sodium phosphate injection 100mg/ml (formerly marketed as Efcortisol) due to an API issue. We do not currently have an estimate for resupply.
- Solu-Cortef (hydrocortisone sodium succinate) 100mg, manufactured by Pfizer, is considered an acceptable alternative during this time. Solu-Cortef is currently available and we have made Pfizer aware of the supply issues with Concordia's hydrocortisone injection.
- There are differences in the formulation and administration between these two products, the following guidance provides further information about the administration of Solu-Cortef: [www.sps.nhs.uk/articles/shortage-of-hydrocortisone-100-mgml-or-500mg5ml-injection/](http://www.sps.nhs.uk/articles/shortage-of-hydrocortisone-100-mgml-or-500mg5ml-injection/)
- Additional information on the use of Solu-Cortef injection can also be found on these sites:
  - Injection video demonstrating the preparation technique for Solu-Cortef with a standard syringe: [www.addisons.org.uk/videos/view-10-34-solu-cortef-standard-syringe-emergency-injection/](http://www.addisons.org.uk/videos/view-10-34-solu-cortef-standard-syringe-emergency-injection/)
  - Solu-Cortef with a safety syringe: [www.addisons.org.uk/videos/view-9-33-solu-cortef-safety-syringe-emergency-injection/](http://www.addisons.org.uk/videos/view-9-33-solu-cortef-safety-syringe-emergency-injection/)
  - The AD SHG photo instructions for preparing Solu-Cortef with a safety needle: <http://www.addisons.org.uk/articles.html/articles-for/emergencies/how-to-give-an-emergency-injection-r33/?pagecommentundefined=3>

#### Acetazolamide MR:

- 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.
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### **Venlafaxine 37.5mg and 75mg tablets:**

- 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:**

- Product has recently divested from GSK to Ennogen, but Ennogen will not be in stock until late in 2018.
- Ennogen have now 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 Trimo

### **Lacidipine 2mg and 4mg:**

- 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 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.
- [www.sps.nhs.uk/articles/shortage-of-tranexamic-acid-tablets-500mg-all-brands/](http://www.sps.nhs.uk/articles/shortage-of-tranexamic-acid-tablets-500mg-all-brands/)

### **Trifluoperazine tablets:**

- 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 they 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):**

- 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

## Eye drops/ treatments:

### Novartis

- **Iopidine (apraclonidine) 5mg/ml eye drops x 5ml.** – new supplies released recently
- **Maxidex (dexamethasone) 0.1% eye drops x 5ml.** Limited stock but the company is chasing for delivery.
- **Icaps (lutein & zeaxanthin) tablets x 30.** There is limited stock available, the company is chasing for delivery.
- **Azarga (brinzolamide & timolol) eye drops x 5ml.** There have been recent shortages due to a significant increase demand; the company is responding to the increase and is waiting for the next batch from QA.
- **Simbrinza (brinzolamide & brimonidine) eye drops x 5ml.** Limited stock but company is chasing for delivery.
- **Duotrav (timolol & travoprost) eye drops x 2.5ml.** Limited stock but the company is chasing for delivery.

### Allergan

- **Carmellose 1% eye drops x 30 unit dose.** There is a current shortage with the 30 unit dose which is expected to be resolved by mid-March. In the meantime, there is a good supply of the 60-unit dose pack.

### Lacri lube eye ointment:

- Allergan are out of stock with no resupply date due to a manufacturing issue.
- The Royal College of Ophthalmology is aware of the issue and is recommending Xailin Night Ointment: [www.rcophth.ac.uk/standards-publications-research/quality-and-safety/medicines-safety/drugs-shortages/](http://www.rcophth.ac.uk/standards-publications-research/quality-and-safety/medicines-safety/drugs-shortages/)
- We are in discussion with the manufacturer of Xailin, Nicox, about their supply position.

### 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 Betamethasone Eye Ointment 0.1% w/w x 3g and are currently expecting stock in early June.

## Resolved

**Adalat Retard 10mg modified release tablets:** Bayer are now back in stock of this product

**Mianserin 10mg tablets:** Mylan are back in stock of Mianserin 10mg tablets and continue to have good supplies of Mianserin 30mg tablets

**Glipizide 5mg tablets:** Mylan have confirmed that they are back in stock of their product.

## Vaccines:

For updates on vaccine supply positions, please refer to [PHE's Vaccine Update Bulletin](#)

### Pneumococcal Polysaccharide Vaccine (PPV23):

- MSD are the sole UK supplier of this vaccine
- Stocks have been recently been made available with further supplies are expected in late July
- Supply may be intermittent throughout 2018
- PHE have previously issued guidance to GPs on how to manage patients if unable to obtain PPV vaccine.



PPV vaccine shortage PHE letter t

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



Vaccine updates...

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

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

### **Hepatitis B Vaccines**

- PHE previously developed temporary recommendations on hepatitis B vaccine including risk-based prioritisation of vaccine, dose-sparing and deferral of boosters
- Supply of Hepatitis B vaccines has improved, however will remain constrained and 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
- However, a recovery plan for 2018 was published by PHE on 26<sup>th</sup> February 2018 and vaccine ordering will be 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: [www.gov.uk/government/publications/hepatitis-b-vaccine-recommendations-during-supply-constraints](http://www.gov.uk/government/publications/hepatitis-b-vaccine-recommendations-during-supply-constraints)
- PHE have issued a letter to GPs (see attached document) outlining the implication for GPs



gp hepB vaccine  
recovery plan signed

- PHE have also issued a letter to NHS and non-NHS occupational health service providers (see attached document) outlining the implication for OH



OH letter necessary  
plan 2018...

- A mechanism remains in place for both suppliers to allow for exceptional orders if there is an urgent and immediate need.

## **Discontinuations**

### **Cardene SR (nicardipine) (Astellas):**

- Cardene SR is being discontinued in January 2018. Nicardipine immediate release remains available & a number of other therapeutic alternatives.

### **Isotrex (isotretinoin) gel (GSK):**

- GSK discontinued Isotrex gel in February 2017 but have informed us that it is now out of stock. Alternate products remain available.

### **Izinova (sodium sulfate, anhydrous, magnesium sulfate heptahydrate & potassium sulfate) concentrate for oral solution (Ipsen):**

- Izinova is being discontinued at the end December 2017 due to problems with a third-party manufacturer. Therapeutic alternatives remain available.

### **Daklinza (daclatasvir) 90mg tablets (BMS):**

- BMS is discontinuing Daklinza (daclatasvir) 90mg tablets from the EU market in December 2017 as part of a portfolio rationalisation process. The company has confirmed that the 30mg & 60mg presentations will remain available. Daklinza is indicated for the treatment of chronic Hepatitis C and the recommended dose is 60mg (alternate dosage regimens can be managed by the remaining strengths).

**Fosamax (alendronic acid) 10mg tablets (MSD):**

- MSD plans to discontinue Fosamax (alendronic acid) 10mg tablets with immediate effect from the UK market as part of a portfolio rationalisation process. Fosamax Once Weekly and generic alendronic acid 10mg tablets remain available.

**Nizatidine 150mg capsules (Flynn):**

- Flynn plans to discontinue Nizatidine 150mg capsules with immediate effect from the UK market. Generic Nizatidine 150mg capsules remain available from other suppliers.

**Chlordiazepoxide tablets:**

- Dr Reddy's, the sole supplier of chlordiazepoxide tablets has discontinued this product in both the 5mg and 10mg strengths.
- Supplies of generic chlordiazepoxide capsules in 5mg and 10mg strengths are available from Crescent, Athlone and Kent. Supplies of the brand Librium are also available from Mylan.

**Modecate**

- As per previous notifications from the company, Sanofi are discontinuing Modecate in the second half of 2018 -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
- We are in discussion with the importers about the availability of unlicensed fluphenazine depot injection and will share further info when it is available.



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