

COMMERCIAL-SENSITIVE

Supply Issues Update for Primary and Secondary Care: January 2020

This report has been produced by the Department of Health and Social Care (DHSC) Medicine Supply Team. We aim to update this report monthly to provide an update on current primary and secondary care medicine supply issues that we are working on. This information is confidential to the NHS; please do not upload to websites in the public domain. Please do share with relevant colleagues and networks.

Where it has been stated 'a clinical memo from UKMI will be published on the SPS website', this will be found at the following URL: <https://www.sps.nhs.uk/category/shortages-discontinuations-and-expiries/>

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Information provided w/c 20 January 2020

New Issues

Injectables

Calcium Chloride 10mmol/10ml and 5mmol/5ml injection

- Calcium chloride 10mmol/10ml and 5mmol/5ml injection are currently out of stock until late March and early April 2020, respectively.
- Supplies of calcium chloride 10% (6.8mmol in 10ml) pre-filled syringes are very limited until end March; Martindale are working to expedite next deliveries.
- A medicine supply notification with further information will be shared with the NHS shortly.

Epirubicin 10mg/50mg/100mg solution for injection

- Epirubicin solution for injection (10mg, 50mg and 100mg) will be out of stock from 15 January 2020 until 3 February 2020.
- From 3 February 2020, there may be additional intermittent short-term supply issues until 01 April 2020.
- A medicine supply notification has been shared with the NHS on 14 January (attached) which provides further information.

Somatropin (Genotropin) 12mg refill cartridges

- Pfizer are out of stock until early March 2020.
- See information on somatropin (Genotropin) 5.3mg GoQuick below.
- A copy of the DHCP letter can be found attached.

Vecuronium 10mg powder for solution for injection

- Vecuronium 10mg injection will be out of stock until 3 February 2020.
- Supplies of rocuronium 50mg ampoules and atracurium 50mg ampoules remain available.

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- A medicine supply notification has been shared with the NHS on 6 January (attached) which provides further information.

Verteporfin (Visudyne) 15mg powder for solution for infusion

- Visudyne 15mg injection is out of stock until 21 January 2020.
- Unlicensed imports are available; lead times vary.

Orals

Azathioprine 25mg tablets

- Azathioprine 25mg tablets are out of stock until w/c 27 January 2020.
- Azathioprine 50mg tablets and 50mg/5ml oral suspension remain available.
- A medicine supply notification has been shared with the NHS on 17 January (attached) which provides further information.

Histamine (H2) antagonists

- Famotidine 20mg tablets are out of stock until February 2020.
- Cimetidine 200mg tablets are out of stock until the end of January 2020.
- Nizatidine 150mg and 300mg tablets are out of stock until February 2020
- A medicine supply notification has been shared with the NHS on 20 December 2019 (attached) which provides further information.

Adcal D3 dissolve 1500mg/400IU effervescent tablets

- Kyowa Kirin are currently out of stock and unable to confirm a resupply date.
- Alternative calcium/colecalciferol preparations remain available.

Opicapone (Ongentys) 50mg capsules

- Ongentys 50mg capsules, manufactured by Bial Pharmaceutical are out of stock until mid-February 2020 due to a production incident affecting global supply of opicapone.
- Please see the below link to the Supply Disruption Alert issued on 25 October 2019:
<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102911>

Phenytoin 100mg capsules

- Accord are expected to be out of stock of phenytoin 100mg capsules until early May 2020 due to a regulatory change at their manufacturing site.
- Flynn Pharma can support the full market during this time.
- As phenytoin is classed as a Category 1 anti-epileptic drug by the MHRA, switching to an alternative formulation requires monitoring and may also require specialist support, advice or referral.
- Please see the below link to the recent Supply Disruption Alert (SDA) issued on 10 January:
<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102954>

Prazosin (Hypovase) 500mcg tablets

- Pfizer, sole supplier is out of stock until 14 February 2020.
- See below for information on Hypovase 1mg tablets and clinical management.

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Valproic acid (Convulex) 150mg/300mg/500mg capsules

- Pfizer have limited supplies of Convulex capsules remaining due to manufacturing delays.
- Convulex 150mg and 500mg capsules are currently out of stock until April 2020.
- Convulex 300mg capsules are expected to be out of stock from early February until April 2020.
- Please see the below link to the recent Supply Disruption Alert (SDA) issued on 23 December 2019:

<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102953>

Venlafaxine XL (Efexor) 75mg/150mg capsules

- Pfizer are out of stock of Efexor 75mg XL capsules from late January until 6 March 2020.
- Efexor 150mg XL capsules will also be out of stock from late January until 14 February 2020.
- Limited parallel imports of Efexor XL 150mg capsules are available for direct orders from the following companies:
 - CST Pharma – contact the sales department on 01477 549310
 - DrugsRUs - 020 3637 4844 | F: 020 3637 3446 E: nhs@drugrus.co.uk
- Alternative branded generics remain available.

Others

Sofradex ear/eye drops

- Sanofi are out of stock until early February 2020.
- Alternative preparations for use in the ear/eye remain available.

Ongoing Issues

Injectables

Adrenaline Auto-Injectors (AAIs)

- Recent supply issues affecting some brands of AAIs has impacted on all manufacturers, however, there are currently sufficient supplies overall to meet normal UK demand.

Emerade (Bausch & Lomb UK Ltd)

- On 28 November, the MHRA issued a Class 2 pharmacy level recall for all strengths of Emerade devices following reports from the manufacturer, Bausch & Lomb UK Limited, of Emerade devices that have failed to activate. See link:
<https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-emerade-150-300-and-500-microgram-solution-for-injection-in-pre-filled-syringe-mdr-57-08-19>
- On 29 November, DHSC issued a Supply Disruption Alert (SDA) with advice on how to manage patients affected. See link:
<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102938>
- The MHRA can confirm, following discussion with DHSC that Emerade stock held by pharmacies that has been designated for the flu vaccination/emergency use, should not be subject to the recall.
- This stock should have been in accordance with the recommended storage conditions and therefore should not be impacted by the temperature issues that have been highlighted in the alert.
- When renewing the adrenaline in your anaphylaxis kits (once Emerade/AAI devices have expired/been used), all staff are alerted to please stock ampoules (see adrenaline 1:1000 ampoules below).

Jext (ALK-Abello Ltd)

- Jext 150 microgram and 300mcg devices are currently available.
- Specific batches of UK licensed Jext 150 micrograms and 300 micrograms have received MHRA approval for extended use by four months beyond the labelled expiry date.
- Clinicians should check with patients requesting new Jext 150 micrograms and 300 micrograms to establish if they currently hold one of the batches that can be used beyond the listed expiry. If one of the listed batches is held, further supplies should be delayed until the extended expiry date, counselling the patient on the extended expiry.
- Please see the link for further information: <https://jext.co.uk/>

EpiPen/EpiPen Junior (Mylan)

- Supplies of both EpiPen and EpiPen Junior are currently available via a prescription validation process.
- Community Pharmacies can place orders for up to a maximum of two EpiPen's per prescription. Trusts place orders via Mylan's customer service team.
- Hospitals should request EpiPen's from the Mylan customer services team (mguk_customer.services@mylan.co.uk; +44 (0) 1707 853 100) with information including the number of the pens required, the reason for need and their Alliance Healthcare account number.
- Specific batches of EpiPen 300 micrograms have received MHRA approval for extended use by four months beyond the labelled expiry date.
- Clinicians should check with patients requesting new EpiPen 300 micrograms to establish if they currently hold one of the batches that can be used beyond the listed expiry. If one of the listed batches is held, further supplies should be delayed until the extended expiry date, counselling the patient on the extended expiry.
- Please see the link for further information: <http://www.epipen.co.uk/>

Adrenaline 1:1000 ampoules for anaphylaxis kits

- Adrenaline 1:1000 ampoules are currently available in sufficient quantities to meet normal demand.
- Some healthcare professionals may be holding an AAI in preference to adrenaline ampoules, to treat anaphylactic reactions; this should not be necessary.
- All healthcare professionals providing services where anaphylaxis treatment may be required, including but not exclusive to flu vaccination services, should have the competency to draw up and administer intramuscular adrenaline from ampoules with a normal syringe and needle.
- During the current shortage, please use ampoules and not auto-injectors to replenish anaphylaxis kits. Remember to include the relevant dosing charts, syringes and needles.
- The [Green Book](#) and [Resuscitation Council](#) guidance provides additional advice to healthcare professionals on the use of adrenaline in response to anaphylaxis. Pharmacists providing vaccination services may also wish to refer to [PSNC FAQs](#). There is an expectation that healthcare professionals should use adrenaline ampoules in preference to Emerade or other AAIs.

Amikacin 100mg/2ml injection

- Vianex SA are out of stock until w/c 17 February 2020 due to manufacturing delays.
- Amikacin 500mg/2ml injection remains available.
- Review local protocols, ensuring that all those affected are aware of this issue and that consideration is given to mitigating the risks associated with switching to a different strength of amikacin injection.
- A medicine supply notification has been shared with the NHS on 19 December (attached) which provides further information.

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Botulinum toxin type A (Azzalure) 125unit injection

- Galderma Ltd will have intermittent supplies until February 2020 due to supply challenges and increased demand.
- If Azzalure (which is only indicated for cosmetic use) is not available, *Botox* 50, 100 and 200unit and *Bocouture* 50 and 100unit can be used and are currently in stock but are not exact equivalents.
- Clinicians should refer to the SPCs for dosing.
- Galderma Ltd have supplied the following email for availability enquiries:
MedinfoUK@galderma.com

Crisantaspase (Erwinase) injection

- Porton Biopharma, the manufacturer of Erwinase, have had ongoing manufacturing issues affecting this product for the past 1-2 years with intermittent supply issues expected until mid-2020.
- Jazz Pharmaceuticals distributes Erwinase and supplies are currently available.
- Jazz Pharmaceuticals works closely with the clinical networks and supplies are prioritised on a patient need basis in conjunction with the treating clinicians.

Diamorphine 5mg and 10mg injection

- Accord are out of stock until March 2020 due to ongoing issues at their manufacturing plant in Europe.
- Wockhardt have insufficient stock to cover full forecasted demand in both primary and secondary care.
- There are insufficient volumes of other strength diamorphine injections to cover any shortfall.
- Primary care, private hospitals, hospices and substance misuse treatment centres can continue to order diamorphine, unrestricted, from usual wholesalers.
- **Secondary care should:**
 - reduce orders of diamorphine 5mg injection to 25% of historical demand;
 - order diamorphine 10mg injection up to 60% of historical demand;
 - discuss this supply issue with clinical colleagues and consider local prioritisation of available diamorphine 5mg and 10mg stock;
 - continue to order morphine 10mg injection from Martindale in line with historic demand. Martindale CANNOT support increased orders;
 - order additional morphine 10mg injection from Hameln, who can support this supply issue;
 - consider how you will manage having two morphine 10mg injection presentations in your departments;
 - let your regional procurement specialist know of any local issues or if you are considering using an alternative other than morphine and;
 - cascade onto any relevant networks, who may find this information useful.
- For any concerns around patient safety, please contact your local Medication Safety Officer who will escalate to Nicola Wake (Medication Safety Lead, Specialist Pharmacy Service).
- UKMi guidance to support the management of this supply issue can be found at:
<https://www.sps.nhs.uk/articles/shortage-of-diamorphine-5-and-10mg/>
- A medicine supply notification has been shared with the NHS on 28 November (attached) which provides further information.

Human C1-esterase inhibitor (Berinert) 500IU powder for reconstitution and injection

- CSL Behring, the sole manufacturer of the Berinert brand, continue to manage current stocks in accordance to agreed quantities supplied by the Commercial Medicines Unit.

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- There is sufficient stock available to maintain supply to all existing patients on continuous home treatment.
- There is insufficient stock available to replenish stock for inpatient and A&E use until 14 February 2020.

Medroxyprogesterone acetate (Sayana Press) 104mg injection

- Pfizer are out of stock of Sayana Press injection due to manufacturing delays.
- Resupply is to be confirmed but is expected to be during Q1 2020.
- See the attached letter from Pfizer for further information.
- On 23 October, the MHRA issued a class 2 medicines recall for Sayana Press injection. See the link below for further details:
<https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-sayana-press-104mg-0-65ml-mdr-055-06-19>

Midazolam 50mg/10ml solution for injection ampoules

- Hameln and Accord are out of stock until 31 January 2020.
- Midazolam 10mg in 2ml ampoules remain available from Hameln and Accord.
- Review local protocols, ensure that all those affected are aware of this issue and that consideration is given to mitigating the risks associated with switching to a different volume of midazolam (5mg/ml) ampoule presentation.
- A medicine supply notification has been shared with the NHS on 5 December (attached) which provides further information.

Mitomycin 2mg/10mg/20mg injection and mitomycin 40mg intravesical solution (Mitomycin-C)

- Kyowa Kirin are out of stock due to quality control release and manufacturing delays with no date for resupply.
- No alternative supplies of UK licensed mitomycin are currently available in sufficient quantities to support this gap in supply.
- Please see the below links to the recent Supply Disruption Alerts (SDA) and an MHRA Class 2 recall for all unexpired Kyowa Kirin LTD Mitomycin-C products for further information:
Latest update:
<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102921>
MHRA Class 2 recall:
<https://www.cas.mhra.gov.uk/ViewAndAcknowledgment/viewAlert.aspx?AlertID=102920>
- Supplies of Medac mitomycin 40mg intravesical kits are available with more stock expected to be available in the coming months.
- Unlicensed imports are also available; lead times vary.

Oily Phenol 5% (almond oil) injection

- Martindale, sole suppliers are out of stock due to packaging delays until late February 2020.

Procyclidine 10mg/2ml injection

- Accord, sole supplier, are out of stock until March 2020.
- Consider sharing remaining stock locally with the support of your regional procurement lead.
- Unlicensed imports of procyclidine are not available.
- An alternative injectable anticholinergic agent, benztropine mesilate (unlicensed), is available from pharmaceutical importers.

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- A medicine supply notification has been shared with the NHS on 5 November (attached) which provides further information.

Sodium thiosulfate 12.5g/50ml solution for injection vials

- Hope Pharmaceuticals, sole supplier, are currently experiencing a long term out of stock.
- UK licensed *Nithiodote*, also by Hope Pharmaceuticals, contains 1 vial of sodium thiosulfate 12.5g/50ml and 1 vial of sodium nitrite 300mg/10ml and is available to order at no extra cost.
- Unlicensed imports are also available; lead times vary.

Somatropin (Genotropin) 5.3mg GoQuick

- Pfizer are out of stock until at least late January 2020.
- See information on somatropin (Genotropin) 12mg refill cartridges above.
- A copy of the DHCP letter can be found attached.

Tetracosactide 1mg depot injection

- Mallinckrodt, sole suppliers will be out of stock until the second half of 2020.
- Unlicensed imports are available; lead times vary.

Tobramycin 80mg/2ml injection

- Pfizer are out of stock until early February 2020.
- Tobramycin 240mg/6ml is currently available.
- There is sufficient 80mg/2ml available from Flynn (via Alloga) to cover full usage.

Urokinase (Syner-KINASE) injection

- Syner-Med are currently in stock of all strengths of Syner-KINASE injection.
- Supply restrictions will likely remain in place until mid-2020.
- Details of suggested alternative products, if required, can be found in the UKMi memo below: <https://www.sps.nhs.uk/articles/shortage-of-urokinase-injection-syner-kinase-10000-iu-25000-iu-and-100000-iu-powder-for-solution-for-injection-or-infusion/>
- Additional information for the product Taurolock is attached. To place orders for this product, contact customerservice@kimal.co.uk and copy louise.kelly@kimal.co.uk

Orals

Carbamazepine (Carbagen) various preparations

- Carbamazepine is considered a Category 1 anti-epileptic drug and patients should normally be maintained on the same brand, however Mylan (manufacturers of Carbagen) will be out of stock of the below products and Mylan are currently unable to advise a resupply date:
 - Carbagen 200mg and 400mg immediate release tablets
 - Carbagen 200mg and 400mg modified release tablets
- Patients currently prescribed Carbagen tablets will need to be switched to an alternative brand of carbamazepine tablets during this time.
- Novartis, the manufacturer of Tegretol tablets, the alternative brand of carbamazepine, have confirmed that all presentations are currently available that they are able to support additional demand during this time for all affected strengths and formulations.
- DHSC have worked with NHSE/I and UKMi to develop a clinical memo, which has been produced to support clinicians in prioritising and switching patients: <https://www.sps.nhs.uk/articles/shortage-of-carbagen-carbamazepine-tablets/>

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Clonidine 25microgram tablets

- Accord are out of stock and unable to advise a resupply date.
- Limited supplies are available until mid-February 2020.
- A clinical memo from UK Medicines Information (UKMi) has been published on the SPS website.
- A medicine supply notification has been shared with the NHS on 20 December (attached) which provides further information.

Co-careldopa 25mg/100mg tablets

- Teva, a generic supplier is out of stock and is currently unable to provide a resupply date.
- MSD, the supplier of the brand *Sinemet Plus* can cover supply for the whole market during this time.

Co-fluampicil 250mg/250mg capsules

- Crescent are out of stock until late January 2020.
- Clinicians are advised to prescribe flucloxacillin and ampicillin capsules as separate preparations, considering patients' ability to swallow an increased number of capsules.
- Ampicillin 250mg and 500mg capsules are available from Crescent and Chemidex.
- Ampicillin oral suspensions (125mg/5ml and 250mg/5ml) are also available from Chemidex.

Colestipol (Colestid) 5g granules

- Colestid plain sachets are out of stock until mid-March 2020.
- Limited supplies of Colestid orange sachets currently remain available.

Colestyramine (Questran) Powder for Oral Suspension

- Cheplapharm are out of stock of Questran Powder 4g sachets until 2021.
- Unlicensed imports are available from importers; lead times vary.
- Limited supplies of Questran Light are currently available through Alliance Healthcare.
- Mylan have recently launched a generic colestyramine 4g light sachet which is available in wholesalers.

Diazepam 2mg/5ml oral solution

- Sandoz, sole supplier is out of stock until the end of February 2020.
- Diazepam 2mg/5ml (sugar-free) oral solution is available from alternative suppliers.

Disopyramide 150mg capsules

- Mylan, sole supplier is out of stock until March 2020.
- Unlicensed imports are available from importers; lead times vary.
- Disopyramide 100mg capsules (*Rythmodan*) are available from Sanofi.
- See link below for the Supply Disruption Alert issued 14 June 2019:
<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102869>
- A medicine supply notification has been shared with the NHS on 15 November (attached) which provides further information.

Eletriptan (Relpax) 20mg tablets

- Pfizer, sole supplier is out of stock until early February 2020.
- Unlicensed imports are available; lead times vary.
- Where unlicensed supplies are deemed inappropriate UK Medicine Information have advised:

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- The licensed initial dose of eletriptan is 40 mg.
- The 20mg strength of eletriptan may be used as the starting dose in patients with mild or moderate renal impairment.
- Although 40mg eletriptan tablets are available, there are no data on halving or crushing them to deliver a 20mg dose.
- However, there are several other 5HT₁-receptor agonists (triptans) available that patients can switch to. Please refer to BNF or local formulary.
- Choice of triptan will also depend on which ones have already been tried. In patients with renal impairment, please refer to SPC to check if a dose reduction is required.

Ethinylestradiol 10microgram/50microgram tablets

- UCB, sole supplier is out of stock due to manufacturing issues and currently unable to advise a resupply date.
- Unlicensed imports are available; lead times vary.

Fluoxetine 20mg dispersible tablets (Olena)

- Advanz Pharma, sole supplier is currently out of stock; further supplies are expected February 2020.
- An oral solution, fluoxetine 20mg/5ml, is available from alternative manufacturers.

Galantamine 8mg/12mg tablets

- Teva will be out of stock of their immediate release galantamine preparations (8mg and 12mg) until end March 2020.
- Galantamine modified release capsules (8mg, 16mg, 24mg) and galantamine 4mg/ml oral solution are available.
- UKMi guidance for switching preparations below:
 - It is recommended that the same total daily dose of galantamine is administered to patients. Patients switching to the once-daily regimen should take their last dose of galantamine tablets or oral solution in the evening and start prolonged- release capsules once daily the following morning.

Haloperidol (Serenace) 500 microgram capsules

- Teva, sole supplier of the capsule formulation is out of stock and currently unable to provide a resupply date.
- Haloperidol 500 microgram tablets are currently available.
- A medicine supply notification has been shared with the NHS on 18 December (attached) which provides further information.
- A serious shortage protocol (SSP) is currently in place. See the below link for further information: <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/serious-shortage-protocols-ssps>

Hormone Replacement Therapy products (HRT)

There are still some ongoing supply issues, please see **Table 2** in the Appendix for a full update on the availability of all HRT products.

Elleste oral HRT Range

- Mylan, sole supplier, has been experiencing ongoing manufacturing issues at their contract manufacturing site since the beginning of 2019.

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- Mylan have now advised whilst new manufacturing arrangements are being confirmed, the Elleste range will be unavailable until mid-2020.
- Current forecasted out of stock dates for specific Elleste products are listed in **Table 1 and 2**.
- See **Table 1** below for equivalent alternatives to the Elleste range.

Table 1. Equivalent HRT alternatives for the Elleste HRT range

Brand	Ingredient(s)	Current Availability	Equivalent	Ingredient(s)	Current Availability
Elleste Solo 1mg	estradiol hemihydrate	Out of stock	Progynova 1mg	estradiol hemihydrate	In stock
			Zumenon 1mg		In stock
Elleste Solo 2mg	estradiol hemihydrate	In stock until late January	Progynova 2mg	estradiol hemihydrate	In stock
			Zumenon 2mg		In stock
Elleste Duet Conti	estradiol 2mg/ norethisterone 1mg	Out of stock	Kliofem	estradiol 2mg/ norethisterone 1mg	In stock
Elleste Duet 1mg	estradiol 1mg/ norethisterone 1mg	Out of stock	NovoFem	estradiol 1mg/ norethisterone 1mg	In stock

Evorel transdermal patch range

- On 24 October 2019, Janssen-Cilag divested the Evorel range (Evorel, Evorel Conti and Evorel Sequi) to Theramex UK Ltd.
- Theramex have advised a resupply date of February 2020.
- All preparations are now out of stock.
- UKMi have published guidance to advise on suitable alternatives. This provides a range of alternative options and highlights the need for prescribers to seek specialist advice for more complex patients and consider prioritising the use of transdermal HRT therapy for women at increased risk of venous thrombosis:
<https://www.sps.nhs.uk/articles/shortage-of-evorel-hormone-replacement-therapy-hrt-patch-range/>
- The British Menopausal Society (BMS) with the support of the Royal College of Obstetrics and Gynaecologists have published a document advising on HRT preparations and equivalent alternatives, to aid prescribing during this period: <https://thebms.org.uk/2019/11/british-menopause-society-further-update-on-hrt-supply-shortages-26-november-2019/>
- Unlicensed imports are available; lead times vary.

FemSeven transdermal patch range

(FemSeven Mono (estradiol only); FemSeven Sequi and Conti (estradiol/ levonorgestrel)).

- Teva divested the FemSeven product range to Theramex UK Ltd mid-2018.
- Theramex have confirmed that whilst new manufacturing arrangements are being established, the FemSeven range will be out of stock until end of 2020.
- Unlicensed imports for FemSeven Mono are available; lead times vary.

Indivina (estradiol/medroxyprogesterone) 1mg/2.5mg, 1mg/5mg and 2mg/5mg tablets

- Orion, sole manufacturer is out of stock of both strengths until early February 2020 due to manufacturing issues.
- Unlicensed imports are available; lead times vary.

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Sandrena (estradiol hemihydrate) 0.5mg gel

- Orion are out of stock of 0.5mg Sandrena gel. They anticipate resupply in late January 2020.
- Please refer to the 'HRT preparations and equivalent alternatives' document developed by the BMS to aid HRT prescribing via: <https://thebms.org.uk/2019/11/british-menopause-society-further-update-on-hrt-supply-shortages-26-november-2019/>

Lansoprazole (Zoton FasTabs) 15mg and 30mg dispersible tablets

- Pfizer have limited supplies until early February 2020.
- Generic lansoprazole 15mg and 30mg orodispersible tablets remain available.
- For patients prescribed Zoton FasTabs by brand who do not have sufficient supplies for the out of stock period, clinicians should consider prescribing the generic product.

Levofloxacin 250mg tablets

- Accord, sole suppliers are out of stock until February 2020
- UKMi have confirmed that levofloxacin 500mg tablets can be divided into equal doses to provide a 250mg dose.
- Supplies of levofloxacin 500mg tablets are currently available from Accord and Teva.

Methadone (Physeptone) 1mg/ml sugar free oral solution

- Martindale are out of stock of Physeptone 1mg/ml sugar free oral solution (100ml) until mid-March 2020.
- All other methadone preparations and pack sizes remain available.

Metoprolol 50mg and 100mg tablets

- There are ongoing supply issues affecting metoprolol 50mg and 100mg tablets.
- The issue has been caused by some manufacturers discontinuing the products and others having supply difficulties.
- Aurobindo-Milpharm are currently the sole supplier of both presentations in the UK.
- Supplies of both presentations are currently available but may be limited; supply is likely to be intermittent for several months.
- See the link below for a UKMi memo with input from clinical experts at NHSE/I, which advises on management options:
<https://www.sps.nhs.uk/articles/shoratge-of-metoprolol-50mg-and-100mg-tablets/>
- The manufacturer of carvedilol has indicated it would be unable to meet demand if patients were switched to this product. Manufacturers of bisoprolol, atenolol and propranolol have indicated they have capacity to support any additional demand on their products.

Mianserin 10mg/30mg tablets

- Mylan, sole supplier is out of stock of both strengths until June 2020.
- For patients who do not have sufficient supplies of mianserin tablets for the duration of the expected out of stock period, **clinicians should consider prescribing an unlicensed preparation** of mianserin tablets as soon as possible in order to avoid abrupt withdrawal.
- Unlicensed imports can be sourced from abroad; lead times may vary.
- In order for pharmacies to dispense an unlicensed drug, FP10 prescriptions must indicate that a special is required/prescribed by the GP. This could include the GP annotating the prescription with the following wording: "special order".
- For patients in whom unlicensed imports are not appropriate, DHSC have commissioned clinical advice which recommends:

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Patients who have been prescribed mianserin for < 6 months

1. GP to start mirtazapine at a low dose depending on clinical judgement and the Summary of Product Characteristics (SPC)
2. Consider psychological therapies

Patients who have been prescribed mianserin for > 6 months

1. GP to start mirtazapine at a low dose depending on clinical judgement and the SPC
2. Seek specialist secondary care advice on management options

Moclobemide 150mg and 300mg tablets

- Mylan is currently out of stock of moclobemide 150mg and 300mg tablets with resupply expected March 2020 and April 2020, respectively.
- Sandoz is in stock of moclobemide 150mg tablets, however, is out of stock of moclobemide 300mg until March 2020.
- Unlicensed moclobemide 300mg tablets are available from importers; lead times vary.
- A medicine supply notification with further information will be shared with the NHS shortly.

Nifedipine (Adalat) tablets

- There are ongoing supply issues with the Adalat Retard and LA range from Bayer. Alternative nifedipine presentations continue to remain available from generic suppliers.
- Supplies of nifedipine 5mg and 10mg immediate release soft gel capsules are now available from Relonchem.
- Please see the attached letter from Bayer and the shortages memo from UKMI:
<https://www.sps.nhs.uk/articles/shortage-of-adalat-nifedipine/>

Oral Contraceptive Pill products (OCP)

Noriday (norethisterone) 350 micrograms tablet

- Pfizer have limited supplies until end February 2020.
- UKMi have advised that there are no exact equivalent preparations in the UK market and clinicians should refer to CKS guidance for advice on alternative POPs:
<https://cks.nice.org.uk/contraception-progestogen-only-methods#!scenario>

Norimin (ethinylestradiol/norethisterone) 0.035mg/1mg tablets

- Pfizer are out of stock and are unable to provide a resupply date.
- UKMi have advised that there are no exact equivalent preparations to Norimin available in the UK market.
- Other ethinylestradiol and norethisterone OCP products should be available.
- Clinicians are advised to refer to CKS guidance for advice COCs:
<https://cks.nice.org.uk/contraception-combined-hormonal-methods>

Synphase (ethinylestradiol and norethisterone) tablets

- Pfizer are out of stock until end January 2020.
- Alternative brands of phasic oral contraceptive tablets with a different dosing schedule and containing a different progestogen remain available.
- Unlicensed imports are available; lead times vary.

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- A medicine supply notification has been shared with the NHS on 15 November (attached) which provides further information.

Paroxetine (Seroxat) 10mg/5ml oral solution

- GSK are out of stock until end February 2020.
- Paroxetine tablets remain available and UKMi have advised that tablets can be crushed and mixed with water for administration (off-label use). The crushed tablets are bitter and have a slight local anaesthetic effect.
- Unlicensed imports of paroxetine 10mg/5ml oral solution are available; lead times vary.
- Communications have been shared with the NHS on 24 October (attached), which provide further information.

Pethidine 50mg tablets

- Martindale are out of stock until mid-February 2020.
- Teva can support the full market until Martindale's resupply.

Phenelzine sulfate (Nardil) 15mg tablets

- Kyowa Kirin, sole supplier is out of stock until at least March 2020 due to manufacturing delays.
- Unlicensed imports are available from the following specialist importer companies: Clinigen, Target, Alium, Mawdsleys, Durbin, WEP Clinical and Waymade. Lead times may vary.
- Unlicensed imports can be obtained through normal wholesaler routes. If unable to obtain through wholesalers, pharmacists are advised to contact the relevant specialist importers directly.
- UKMi have also published guidance on management including the need for specialist referral to mental health teams if unlicensed supplies of phenelzine sulfate 15mg tablets are deemed unsuitable:

<https://www.sps.nhs.uk/articles/shortage-of-phenelzine-15mg-tablets-nardil/>

Phenytoin (Epanutin) 50mg Chewable Infatabs

- Pfizer are out of stock until mid-2020 due to a manufacturing delay.
- Pfizer has obtained approval from the MHRA to import stock of Dilantin (phenytoin) Infatabs from Canada.
- Canadian packs of Dilantin are considered unlicensed in the UK.
- A copy of the DHCP letter can be found attached.

Prazosin (Hypovase) 1mg tablets

- Pfizer, sole supplier is out of stock until March 2020.
- See above for information on Hypovase 500mcg tablets.
- UKMi have advised: Prazosin (Hypovase) is licensed for the treatment of hypertension and benign prostatic hyperplasia (BPH). If stock is depleted, there are other alpha blockers that patients can be switched to:
 - Doxazosin and terazosin are approved for both these indications
 - Tamsulosin and alfuzosin are licensed to treat BPH.
- There are no direct dose conversion data, so treatment should be titrated according to the patient's clinical response.
- Although prazosin is also licensed for treating heart failure and Raynaud's disease (RD), alpha blockers do not feature in heart failure guidelines and prazosin is not considered effective for RD.

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Quinapril (Accupro) 40mg tablets

- Pfizer, sole supplier is out of stock until the end of January 2020.
- Accupro 5mg, 10mg and 20mg tablets remain available.

Quinapril 10mg/hydrochlorothiazide 12.5mg (Accuretic) tablets

- Pfizer are currently out of stock until early March 2020.
- There are several alternative combination preparations of ACE-Inhibitors with diuretics and UKMi have advised that patients can be safely switched, with clinical supervision.
- Unlicensed quinapril 10mg/hydrochlorothiazide 12.5mg tablets are available from importers; lead times vary.

Ranitidine oral preparations

- Ranitidine tablets, effervescent tablets and oral solution are expected to be out of stock until further notice due to global regulatory investigations.
- An updated supply disruption alert with additional guidance on clinical alternatives in paediatrics was issued on 20 December 2019 and is available at [SDA/2019/005-U2](#)

Trifluoperazine tablets

- There have been ongoing manufacturing issues affecting trifluoperazine 1mg and 5mg tablets causing long term issues with supplies not expected before mid-2020.
- Concordia and Rosemont have trifluoperazine liquid and supplies are available.
- Unlicensed imports of trifluoperazine tablets are available from importers; lead times vary.

Tuberculosis medications

- See the table below for a summary of the supply position with tuberculosis medications.
- A medicine supply notification has been shared with the NHS on 19 December (attached) which provides further information.

Product	Supplier	Current stock position	Anticipated re-supply date	Suggested management plan
Rifampicin 150mg capsules	Sanofi	In stock		n/a
	Mylan	In stock		
Rifampicin 300mg capsules	Sanofi	Out of stock	w/c 20 Jan	Order direct from DrugsRUs or from major wholesalers for Sandoz and Mylan stock.
	Sandoz	In stock		
	Mylan	In stock		
	DrugsRUs	In stock		
Rifampicin 100mg/5ml syrup	Sanofi	In stock		n/a
Ethambutol 100mg tablets	Morningside	Out of stock	w/c 20 Jan	Place orders for T&R product, and Morningside product when available at local depot.
	Thornton & Ross	In stock		

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	Kent	Out of stock		
Ethambutol 400mg tablets	Kent	Out of stock	Feb 2020	Place orders for Morningside product via AAH or Phoenix if you cannot obtain contracted product.
	Thornton & Ross	Out of stock	w/c 24 Jan	
	Intrapharm	Out of stock	Late Feb 2020	
	Morningside	In stock		
Pyrazinamide 500mg tablets	Thornton & Ross	In stock		n/a
	Morningside	In stock		
Isoniazid 50mg tablets	RPH Pharmaceutic als	Out of stock	Feb 2020	Isoniazid 100mg tablets are available from Morningside: https://www.sps.nhs.uk/articles/shortage-of-isoniazid-tablets-50mg/ SPS memo on halving 100mg tablets. Unlicensed specially manufactured liquid is available from Ennogen and Rosemont.
Isoniazid 100mg tablets	Morningside	In stock		n/a
Rifinah 150 tablets (rifampicin 150mg/isoniazid 100mg)	Sanofi	In stock		n/a
Rifinah 300 tablets (rifampicin 300mg/isoniazid 150mg)	Sanofi	In stock		Place orders for Sanofi product.
	DrugsRUs	Out of stock	Early Feb	
Rifater tablets (rifampicin 120mg/pyrazina mide 300mg/isoniazid 50mg)	Sanofi	In stock		n/a
	DrugsRUs (Parallel Import)	Out of stock	TBC	
Voractiv (Rimstar) tablets	Thornton & Ross	Out of stock	March 2020	Prescribe/dispense as individual ingredients or place orders for imports. Importer companies have indicated that unlicensed imports can be sourced, lead times vary. Do not use Rifater or Rifinah products as these presentations cannot meet an increase in demand.

Others

Anusol Ointment

- Church & Dwight UK Limited have resolved the problems with supply.
- Anusol ointment will be back in stock during January 2020.

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Capsaicin (Zacin) 0.025%/(Axsain) 0.075% cream

- Teva, sole supplier is out of stock until late January 2020.
- Unlicensed imports are available from importers; lead times vary.
- For patients in whom unlicensed imports are not appropriate, UKMI have produced a clinical memo on alternative treatments:
<https://www.sps.nhs.uk/articles/shortage-of-capsaicin-cream-zacin-and-axsain/>

Fentanyl (Instanyl) 50mcg nasal spray

- Takeda are out of stock of Instanyl 50mcg nasal spray and are unable to provide a resupply date.
- Instanyl 100mcg and 200mcg nasal sprays remain available.
- Immediate release fentanyl products are not interchangeable and when considering switching patients from one product to another, patients should not be converted on a microgram per microgram basis from one to another; it is necessary to titrate the new formulation with advice from a specialist.
- UKMi memo on management options below:
<https://www.sps.nhs.uk/articles/shortage-of-actiq-lozenges-and-instanyl-nasal-spray-immediate-release-fentanyl-citrate/>

Fludrocortide 0.0125% cream and ointment

- Typharm Limited cannot release further stock of fludrocortide cream and ointment due to updates to their licences and changes to regulatory standards.
- Resupply is expected by March 2020.
- Fludrocortide 4micrograms/cm² tape remains available.

Mesalazine (Salofalk) 500mg/1g suppositories

- Dr Falk Pharma are out of stock of Salofalk 1g suppositories and are currently unable to provide a resupply date.
- Salofalk 500mg suppositories are also out of stock with further deliveries expected mid-April 2020.
- Pentasa 1g suppositories remain available.
- UKMi memo on management options below:
<https://www.sps.nhs.uk/articles/shortage-of-salofalk-mesalazine-suppositories-500mg-and-1g/>
- A medicine supply notification has been shared with the NHS on 1 November (attached) which provides further information.

Eye drops/treatments

Cyclopentolate hydrochloride 0.5%/1% Minims (Bausch and Lomb)

- Out of stock until March 2020.
- Further information is available on The Royal College of Ophthalmologists website and a Medicines Supply Notification was shared with the NHS (attached) on 20 December 2019, which provides further information.
- Preservative containing supplies of cyclopentolate hydrochloride 0.5% and 1% eye drops (Mydrilate) continue to remain available.

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Phenylephrine 2.5%/10% Minims eye drops solution (Bausch and Lomb)

- Out of stock with resupply date to be confirmed.
- Limited unlicensed imports can be sourced; lead times vary.
- The Royal College of Ophthalmologists (RCOphth) has provided clinical guidance to support local prioritisation of remaining supplies and advice on alternative options where appropriate.
- See link below for the Supply Disruption Alert issued 14 November 2019:
<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102923>

Trifluorothymidine (trifluridine F3T) 1% eye drops (unlicensed special)

- Stockport Pharmaceuticals are out of stock until end of January 2020.
- Unlicensed imports are available; lead times may vary.

Vaccines

For updates on other vaccine supply positions, please refer to PHE's Vaccine Update Bulletin found at the following address:

<https://www.gov.uk/government/collections/vaccine-update#2019>

Hepatitis B Vaccines

Renal dose

- MSD's renal vaccine HBVAXPRO 40micrograms are still out of stock of until further notice. Please see statement: <http://www.msduk.com/products/vaccines.xhtml>
- GSK's Hepatitis B renal vaccine, Fendrix, is currently available.

Adult dose

- MSD are out of stock HBVAXPRO 10mcg vaccine until further notice
- GSK are confident they can support the increased demand during this time.

Measles, Mumps and Rubella (MMR) vaccine

- Limited supplies of Priorix (GSK) and MMRVAXPRO (MSD) are available for the private market (locally procured stock) until end of January and March 2020 respectively due to global increase in demand.
- This supply issue does not impact the nationally procured MMR vaccine used for the Public Health England's (PHE) national programme.
- Most of the MMR vaccinations provided in the UK are nationally procured by PHE and delivered as part of a national immunisation programme.

Pneumococcal Polysaccharide Vaccine 23-valent vaccine (PPV23) vials and Pneumovax 23 pre-filled syringes

- MSD, sole supplier of PPV23 vaccine, have limited supplies of both the PPV23 vials and Pneumovax pre-filled syringes until February 2020.
- Public Health England (PHE) have issued guidance on how available supplies should be managed at this time. This guidance advises the need for the prioritisation of patients considered to be in the high priority clinical risk group. Find full guidance on PHE's Vaccine Update Issue 300 (page 12):
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/844742/PHE_11388_vaccine_update_300_bug_special_october2019ppv.pdf

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Rabies vaccine (Rabipur)

- Limited supply of GSK's Rabipur is currently available. Supply issues resulting from manufacturing constraints have now resolved, however, GSK do not expect the situation to fully normalise until February 2020.
- Sanofi Pasteur have confirmed they are able to support the full market during this time with their unlicensed Rabies vaccine, Verorab
- NATHNAC have issued further information available at the following link:
<https://travelhealthpro.org.uk/news/389/rabies-vaccine-availability>

Combined hepatitis A & B (Twinrix)

- Limited supplies of Twinrix Adult singles and packs of 10 are currently available until February 2020.
- Twinrix paediatric and Ambrix remain available.
- Monovalent hepatitis A and hepatitis B vaccines also remain available.

Discontinuations

Fluphenazine decanoate (Modecate) injection (Sanofi)

- Manufacture of Modecate (fluphenazine decanoate) injection has ceased
- Existing stock of Modecate Injection (25 mg/ml) expired in August 2019.
- Existing stock of Modecate Concentrate Injection (100 mg/ml) will expire in August 2020 – stock will not be released after 29th February 2020.
- Prescribers should complete arrangements to transfer patients on Modecate to therapeutic alternatives under medical supervision.
- Unlicensed imports are available; lead times vary.

Ketotifen (Zaditen) 1mg/5ml elixir (Alfasigma)

- Alfasigma are withdrawing Zaditen 1mg/5ml elixir from the UK market.
- Unlicensed ketotifen 1mg/5ml oral solution is available from importers; lead times vary.

Ribavirin (Rebetol) 200mg capsules (MSD)

- MSD are discontinuing Rebetol 200mg capsules at the end of January 2020.
- Supplies of generic ribavirin remain available from Aurobindo-Milpharm.

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Resolved (date resolved)

Alprostadil (Muse) 500mcg/1000mcg urethral sticks (1/20)
Cefuroxime (Zinnat) 125mg/5ml oral suspension (16/12/19)
Colestipol (Colestid) Orange 5g granules (23/12/19)
Diclofenac 75mg and misoprostol 200mcg (Arthrotec 75) modified release tablets (13/1/20)
Digoxin (Lanoxin) 250mcg/ml injection (9/1/20)
Estraderm 100 microgram transdermal patch (10/1/2020)
Flixotide 2mg/2ml nebulules (1/20)
Fluorouracil (Efudix) 5% cream (19/12/19)
Fluoxetine 30mg capsules (8/1/20)
Loteprednol etabonate (Lotemax) 0.5% eye drops (1/20)
Medroxyprogesterone (Provera) 100mg tablets (6/1/20)
Medroxyprogesterone (Provera) 200mg tablets (20/12/19)
Mydrane (lidocaine 10mg/1ml+tropicamide 0.2 mg/1ml+phenylephrine 3.1 mg/1ml) solution for injection (19/12/19)
Testosterone (Tostran) 2% gel (1/20)
Tobramycin 240mg/6ml injection (20/1/20)

Appendix

Table 2: HRT availability and anticipated resolution dates

		Oestrogen Only			
Ingredient (s)	Manufacturer	Brand	Strength	Current Availability	Anticipated resupply date
		Oral preparations			
Estradiol hemihydrate	Mylan	Elleste Solo	1mg	OOS	Mid to end of 2020
			2mg	In stock until late January	
	Mylan	Zumenon	1mg	In stock	
			2mg	In stock	
Estradiol valerate	Bayer	Progynova	1mg	In stock	
			2mg	In stock	
Estradiol	Resource Medical UK	Bedol	2mg	Long term OOS	
Conjugated oestrogen	Pfizer	Premarin	300mcg	In stock	
			625mcg	In stock	
			1.25mg	In stock	
Ethinylestradiol	UCB pharma Ltd.	Ethinylestradiol	10mcg	OOS	Resupply date unavailable. Unlicensed imports available; lead times vary
			50mcg	OOS	
			1mg	In stock	
Transdermal patches					
Estradiol	New owner: <u>Theramex</u>	Evorel	25 mcg	OOS	February 2020. Unlicensed imports available; lead times vary
			50mcg	OOS	
			75mcg	OOS	
			100mcg	OOS	
Estradiol hemihydrate	Novartis	Estradot	25 mcg	In stock	
			37.5mcg	In stock	
			50mcg	In stock	
			75mcg	In stock	
			100mcg	In stock	
	Merus Labs/Norgine	Estraderm	25 mcg	In stock	
			50mcg	In stock	
			75mcg	In stock	
			100mcg	In stock	
	Theramex	FemSeven Mono	50mcg	Long term OOS	End of 2020 Unlicensed imports available; lead times vary
			75mcg	Long term OOS	
			100mcg	Long term OOS	End of 2020
	Bayer	Progynova TS	50mcg	In stock	
			100mcg	In stock	
Mylan	Elleste Solo MX	40mcg	In stock		

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			80mcg	In stock	
Topical (Transdermal gels/creams/other delivery systems)					
Estradiol	Besins Healthcare (UK) Ltd	Oestrogel	0.06%	In stock	
Estradiol hemihydrate	Orion	Sandrena	0.5mg	OOS	Late January 2020
			1mg (28)	In stock	
			1mg (91)	In stock	
	Pfizer	E-string vaginal delivery system	7.5mcg/24hours	In stock	
	Novo Nordisk	Vagifem vaginal tablets	10mcg	In stock	
Estriol	Flynn Pharma	Blissel	50mcg/g	In stock	
	Marlborough Pharma	Estriol cream (generic)	0.01%	In stock	
	Aspen	Ovestin cream	1mg	In stock	
Progestogen only					
Medroxyprogesterone	Resource Medical UK	Climanor	5mg	long term OOS	
Levonorgestrel	Bayer	Mirena Intrauterine device	20mcg/24hrs	In stock	
Progesterone	Besins Healthcare (UK) Ltd	Utrogestan	100mg	In stock	
		Utrogestan	200mg	In stock	
Combined HRTs (Progestogen and oestrogen)					
Continuous combined therapy					
Oral preparations					
Estradiol hemihydrate / norethisterone acetate	Mylan	Elleste Duet Conti	2mg / 1mg	OOS	Mid to end of 2020
	Novo Nordisk	Kliofem	2mg/ 1mg	In stock	
Kliovance		1mg/ 500mcg	In stock		
Estradiol hemihydrate / dydrogesterone	Mylan	Femoston Conti	500mcg/ 2.5mg	In stock	
			1mg/ 5mg	In stock	
Estradiol valerate/medroxyprogesterone	Orion	Indivina	1mg /2.5mg	OOS	February 2020. Unlicensed imports available; lead times vary.
			2mg/ 5mg	OOS	
			1mg/5mg	OOS	February 2020. Unlicensed imports available; lead times vary.

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low dose conjugated oestrogen/medroxyprogesterone	Pfizer	Premique	300mcg/1.5 mg	In stock	
Transdermal patch					
Estradiol hemihydrate/norethisterone acetate	New Owner: <u>Theramex</u>	Evorel Conti	3.2mg/11.2 mg	OOS	February 2020 Unlicensed imports available; lead times vary
Estradiol hemihydrate/levonorgestrel	Theramex	FemSeven Conti	1.5mg/0.525mg	Long term OOS	End of 2020
Sequential combined therapy					
Oral preparations					
Estradiol [X,X] / norethisterone acetate	Resource Medical UK	Clinorette	[2mg, 2mg]/1mg	Long term OOS	
Estradiol/norgestrel	Mylan	Cyclo-progynova	2mg/500mcg	Long term OOS	
Estradiol hemihydrate / norethisterone acetate		Elleste Duet	1mg/ 1mg	OOS	Mid to end of 2020.
			2mg/ 1mg	In stock until late January	
Estradiol hemihydrate/dydrogesterone		Femoston	1mg/ 10mg	In stock	
	2mg/10mg		In stock		
Estradiol hemihydrate / norethisterone acetate	Novo Nordisk	Novofem	1mg/ 1mg	In stock	
Estradiol hemihydrate [X,X,X]/ norethisterone acetate		Trisequens	[2mg, 2mg, 1mg]/ 1mg	In stock	
Estradiol valerate/ medroxyprogesterone acetate	Orion	Tridestra	2mg/20mg	In stock	
Transdermal patch					
a) Estradiol hemihydrate and b) estradiol hemihydrate/norethisterone acetate	New Owner: <u>Theramex</u>	Evorel Sequi	a)3.2mg b) 3.2 mg /11.2 mg	OOS	February 2020. Unlicensed imports available; lead times vary
a) 1.5mg of estradiol hemihydrate b) Estradiol hemihydrate /levonorgestrel	Theramex	FemSeven Sequi	a) 1.5mg b) 1.5mg /1.5mg	Long term OOS	End of 2020
Gonadomimetic (s)					
Tibolone 2.5mg	Advanz Pharma	Livial tablets	Tibolone 2.5mg	In stock	
Selective oestrogen receptor modulator					
Ospemifene 60mg tablets	Shionogi	Senshio tablets	Ospemifene 60mg tablets	In stock	
Tissue-selective oestrogen complex					

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Conjugated oestrogen 300mcg/ bazedoxifene 20mg	Pfizer	Duavive	conjugated oestrogen 300mcg/ bazedoxifen e 20mg	In stock	
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