Hormone replacement therapy (HRT) supply issues

- The Department of Health and Social Care (DHSC) are aware of the ongoing manufacturing issues that have affected the supply of some hormone replacement therapy (HRT) products throughout 2019.
- Please see Table 1, which provides the latest update on the availability of all HRT products marketed in the UK and the known resupply date for products that's are currently experiencing supply issues.
- This table also provides an update of all HRT preparations that remain available. Clinicians may be required to switch patients to alternative HRT products that contain the same active ingredients for a temporary period.
- Prescribing information regarding HRT equivalence to support local decision making is available through various sources such as the British National Formulary, Summary of Product Characteristics (SPC), The Monthly Index of Medical Specialities (MIMS), and other sources including local Medicines Information Centres.
- Clinicians are advised to work closely with community pharmacies to understand local availability of HRT products and use the table below to help make decision about appropriative HRT products for patients who are affected by the supply issues.
- DHSC will continue to provide updates on HRT availability in the monthly supply report, which is uploaded to the Specialist Pharmacist Services website. All registered user can access this update via this following link: https://www.sps.nhs.uk/articles/department-of-health-and-pharmaceutical-market-strategy-group-pmsg-supply-updates/
- Please share this information with relevant networks locally including GP practices and community pharmacies.

Table 1. HRT Availability

		Oestrogen Only				
Ingredient (s)	Manufacturer	Brand	Strength	Current Availability	Anticipated resupply	
		Oral preparations			date	
Estradiol hemihydrate	Mylan	Elleste Solo*	1mg	In stock	Continued availability to be confirmed. Please see below the	
			2mg	In stock	table for more information on the Elleste range *	
	Mylan	Zumenon*	1mg	OOS	Mid-September 2019	
			2mg	OOS	End of August 2019	
Estradiol valerate	Bayer	Progynova	1mg	In stock		
			2mg	In stock		
Estradiol	Resource Medical UK	Bedol	2mg	Long term OOS		
Transdermal patches						
Estradiol	Janssen-Cilag	Evorel **	25 mcg	In stock until mid to end of February 2020		
			50mcg	In stock until end of October 2019	Mid 2020 please see below the table for	
			75mcg	In stock until beginning of October 2019	more information on the Evorel range**.	
			100mcg	In stock until		

				beginning of October 2019	
			25 mcg	In stock	
		l [37.5mcg	In stock	
	Novartis	Estradot	50mcg	In stock	
		l [75mcg	In stock	
		l [100mcg	In stock	
			25 mcg	In stock	
	Merus	/ <u>-</u> [50mcg	In stock	
= 0.11 0	Labs/Norgine	Estraderm -	75mcg	In stock	
Estradiol hemihydrate		l I	100mcg	In stock	
			50mcg	In stock	
	Theramex	FemSeven	75mcg	In stock	
		Mono	100mcg	In stock	
		1	50mcg	In stock	
	Bayer	Progynova TS	100mcg	In stock	
		Elleste Solo	40mcg	In stock	Continued availability
	Mylan	MX *	80mcg	In stock	to be confirmed
			300mcg	In stock	
Conjugated oestrogen	Pfizer	Premarin	625mcg	In stock	
conjugated 555 20	5.	/ · · · · · · · · · · · · · · · · · · ·	1.25mcg	In stock	
	Topical (T	ransdermal gels/	creams/other delive		
	Besins	ansacrina. g,	Jeanis/ Cartor III	si y systems,	
Estradiol	Healthcare (UK) Ltd	Oestrogel	0.06%	In stock	
		Sandrena	0.5mg	In stock	
	Orion	Sandrena	1mg	In stock	
Estradiol hemihydrate	Pfizer	Estring vaginal delivery system	7.5mcg/ 24hours	In stock	
	Novo Nordisk	Vagifem vaginal tablets	10mcg	In stock	
	Flynn Pharma	Blissel	50mcg/g	In stock	
estriol	Marlborough Pharma	Estriol cream (generic)	0.01%	In stock	
	Aspen	Ovestin cream	1mg	In stock	
		Proges	stogen only		
Medroxyprogesterone	Resource Medical UK	Climanor	5mg	long term OOS	
Levonorgestrel	Bayer	Mirena Intrauterine device	20mcg/24hrs	In stock	
_	Besins	Utrogestan	100mg	In stock	
Progesterone	Healthcare (UK) Ltd	Utrogestan	200mg	In stock	

Combined HRTs (Progestogen and oestrogen)							
Continuous combined therapy							
			reparations				
Estradiol hemihydrate / norethisterone acetate	Mylan	Elleste Duet Conti*	2mg / 1mg	In stock at wholesalers	Continued availability to be confirmed		
	Novo Nordisk	Kliofem	2mg/ 1mg	In stock			
		Kliovance	1mg/ 500mcg	In stock			
Estradiol hemihydrate /	Mylan	Femoston	500mcg/ 2.5mg	In stock			
dydrogesterone		Conti	1mg/5mg	In stock			
Estradiol	Orion	Indivina	1mg /2.5mg	In stock			
valerate/medroxyprogeste			2mg/5mg	OOS	End of August 2019.		
rone			1mg/5mg	In stock			
low dose conjugated oestrogen/medroxyproges terone	Pfizer	Premique	300mcg/1.5mg	In stock			
		Transd	lermal patch				
Estradiol hemihydrate/ norethisterone acetate	Janssen-Cilag	Evorel Conti	3.2mg/11.2mg	In stock - mid to end of October 2019	Mid 2020 See below **		
Estradiol hemihydrate/ levonorgestrel	Theramex	FemSeven C onti	1.5mg/ 0.525mg	Long term OOS	Q2 2020		
Sequential combined therapy							
		•	reparations				
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 /		Elleste Duet	1mg/ 1mg	In stock	Continued availability		
norethisterone acetate		*	2mg/ 1mg	In stock	to be confirmed		
Estradiol hemihydrate/		Femoston	1mg/ 10mg	limited stock			
dydrogesterone			2mg/10mg	In stock			
Estradiol hemihydrate / norethisterone acetate		Novofem	1mg/ 1mg	In stock			
Estradiol valerate/ medroxyprogesterone acetate	Novo Nordisk	Tridestra	2mg/20mg	In stock			
Estradiol hemihydrate [X,X,X]/ norethisterone acetate	Orion	Trisequens	[2mg, 2mg, 1mg]/ 1mg	In stock			
Transdermal patch							
a) Estradiol hemihydrate and b) estradiol hemihydrate/ norethisterone acetate	Janssen-Cilag	Evorel Sequi**	a)3.2mg b) 3.2 mg /11.2 mg	In stock until mid- September 2019	Mid 2020 See below **		
a) 1.5mg of estradiol hemihydrate b) Estradiol hemihydrate /levonorgestrel	Theramex	FemSeven Se qui	a) 1.5mg b) 1.5mg /1.5mg	Long term OOS	Q2 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						
Conjugated oestrogen 300mcg/ bazedoxifene 20mg	Pfizer	Duavive	conjugated oestrogen 300mcg/ bazedoxifene 20mg	In stock		

*Elleste HRT Range:

- Mylan have recently advised that supplies of all the Elleste Range (Elleste Duet Conti, Elleste
 Duet 2mg tablets, Elleste solo 1mg and 2mg tablets, Elleste Duet 1mg and 2mg and Elleste
 MX 40 and 80micrograms patches) have been replenished and are now available.
- However, Mylan have advised they are still experiencing on going manufacturing problems, therefore, currently they do not have visibility on future supplies.
- DHSC are working with Mylan and awaiting further information to understand the long-term implications of this.

**Evorel HRT transdermal patch range:

- Janssen-Cilag, the manufacturer of the Evorel HRT transdermal patch range (Evorel; Evorel Conti; Evorel Sequi) have notified the DHSC that due to manufacturing constrictions, the whole range will be out of stock from October 2019 for most presentations and others are expected to last until early 2020. Current forecasted stock out dates for specific Evorel products are listed in Table 1.
- Currently, Janssen-Cilag are unable to give an exact resupply date beyond mid-2020.
- UK Medicine Information 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/