Origin Fertility Care
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Inspector: Frances Gault
Inspection ID: IN023868

Announced Medicines Management Inspection of Origin Fertility Care

8 January 2016

The Regulation and Quality Improvement Authority
9th Floor Riverside Tower, 5 Lanyon Place, Belfast, BT1 3BT
Tel: 028 9051 7500 Fax: 028 9051 7501 Web: www.rqia.org.uk

Summary of Inspection

An announced medicines management inspection took place on 8 January 2016 from 10.25 to 11.40.

The management of medicines was found to be safe, effective and compassionate. The outcome of the inspection found no areas of concern. A Quality Improvement Plan (QIP) was not included in this report.

This inspection was underpinned by the Department of Health, Social Services and Public Safety (DHSSPS) Minimum Standards for Independent Healthcare Establishments, July 2014.

1.1 Actions/Enforcement Taken Following the Last Medicines Management Inspection

Other than those actions detailed in the QIP there were no further actions required to be taken following the last inspection on 17 December 2013.

1.2 Actions/Enforcement Resulting from this Inspection

Enforcement action did not result from the findings of this inspection.

1.3 Inspection Outcome

	Requirements	Recommendations
Total number of requirements and recommendations made at this inspection	0	0

This inspection resulted in no requirements or recommendations being made. Findings of the inspection can be found in the main body of the report.

2. Service Details

Registered Organisation/Registered Person: Origin Fertility Care Ltd Mr Glen Best (acting)	**Registered Manager:** Mrs Jennifer McLaughlin
Person in Charge of the Home at the Time of Inspection: Mrs Jennifer Eliza McLaughlin	**Date Manager Registered:** 22 May 2014
Categories of Care: PT(IVF), PD	**Number of Registered Places:** Day services only

3. Inspection Focus

The inspection sought to assess progress with the issues raised during and since the last medicines management inspection and to determine if the following standards have been met:

Standard 25: Management of Medicines
Standard 26: Medicines Storage
Standard 27: Controlled Drugs
Standard 28: Medicines Records

4. Methods/Process

Specific methods/processes used included the following:

Prior to the inspection, it was ascertained that no incidents involving medicines had been reported to RQIA since the last medicines management inspection.

The following records were examined:

Medicines requested and received
Personal medication records
Medicines disposed of or transferred
Controlled drug record book
Medicine audits
Policies and procedures
Medicines refrigerator temperatures

5. The Inspection

5.1 Review of Requirements and Recommendations from the Previous Inspection

The previous inspection of Origin Fertility Care was an estates inspection dated 19 November 2015. The completed QIP resulting from this inspection is due to be returned to RQIA by 15 January 2016.

5.2 Review of Requirements and Recommendations from the Last Medicines Management Inspection

Last Inspection Statutory Requirements		Validation of Compliance
Last Inspection Recommendations		**Validation of Compliance**
Recommendation 1 **Stated: First time**	The registered person should ensure that Standard Operating Procedures (SOPs) for controlled drugs are revised to reflect the procedure for the disposal of discarded controlled drugs.	**Partially Met**
	Action taken as confirmed during the inspection: The SOPs had been revised to include the disposal of controlled drugs. However, these did not reflect the arrangements for the disposal of discarded controlled drugs (eg partially used vials). Clarification was provided regarding the denaturing of these prior to disposal. Given the assurances from the registered manager, who is also the Accountable Officer and has overall accountability for the management of controlled drugs, this recommendation will not be repeated.	
Recommendation 2 **Stated: First time**	The registered person should ensure that a robust system is in place to track and record the action taken on the receipt of drug alerts.	**Met**
	Action taken as confirmed during the inspection: Drug alerts are actioned by the registered manager. A file is maintained detailing the action taken for each drug alert. They are included as a set agenda point for management meetings	

Recommendation 3 **Stated: First time**	The registered person should ensure that the audit tool is further developed to monitor the stock balances of all Schedule 4 and 5 controlled drugs held in the clinic.	
	Action taken as confirmed during the inspection: All stock balances of these drugs are monitored each month. Further discussion revealed that there is no reconciliation with the stock that has been administered or supplied to patients. It was agreed that this would be reviewed.	**Met**
Recommendation 4 **Stated: First time**	The registered person should ensure that a robust system is in place to check that the controlled drug record book has been accurately maintained.	
	Action taken as confirmed during the inspection: The registered manager advised that this is undertaken monthly and includes cross referencing all medicine and doctors records to ensure they correspond. She advised that it had highlighted that staff recorded doses in different ways and this is currently being addressed.	**Met**

5.3 The Management of Medicines

Is Care Safe? (Quality of Life)

Staff had access to up to date information relating to relevant legislation, medicines reference sources and guidance with respect to the safe and secure handling of medicines.

There were incident reporting systems in place for identifying, recording, reporting, analysing and learning from adverse incidents and near misses involving medicines and medicinal products. No incidents in relation to medicines management have occurred in the clinic.

The registered manager advised of the processes in place for the management of any drug alerts, medical device alerts and safety warnings about medicines.

Medicines were safely and securely stored. Medicines were stored in accordance with the manufacturers' instructions. There were systems in place to monitor medicine equipment so it remains in good working order e.g. medicine refrigerators.

Equipment for medical emergencies was checked each month to ensure that they remain in date.
Robust arrangements were in place for the safe keeping of all medicine keys when the clinic is not operational.

Medicine records were legible and accurately maintained to ensure that there was a clear audit trail. The registered manager was reminded of the need to ensure that the quantity of medicines detailed in records was consistently documented by all staff. This matter had also been identified through the internal audit process.

The registered manager had recently become the Accountable Officer for Origin Fertility Care and is accountable for all aspects of the management of controlled drugs. She advised that the internal practices in relation to controlled drugs will be regularly reviewed as a result of her meetings with other Accountable Officers.

As the clinic was in operation at the time of the inspection, the arrangements for the safe storage of controlled drugs was not examined.

The receipt, storage, administration and disposal of all controlled drugs subject to record keeping requirements were maintained in a controlled drug record book.

Is Care Effective? (Quality of Management)

Written policies and procedures for the management of medicines were up to date and covered all aspects of medicines management. These were kept under review. The registered manager advised that these had been reviewed to include the management of injectable medicines.

The stock of medicines kept in the clinic is decided by senior medical staff.

Standard Operating Procedures (SOPs) were in place that cover, with one exception, all aspects of the management of controlled drugs in line with DHSSPS guidelines for the management of controlled drugs in primary care (see section 5.2).

The management of medicines was undertaken by qualified, trained and competent staff and there was evidence that systems were in place to review staff competency annually in the management of medicines. Evidence was available of the induction process undergone by nurses new to the clinic. Training in relation to medicines had been provided to nurses.

There were arrangements in place to audit all aspects of the management of medicines. The manager advised that recently there had been short comings in staff signing the records and systems were now in place to minimise this happening.

Is Care Compassionate? (Quality of Care)

Patients are provided with detailed information regarding any medication prescribed within the clinic and which is self-administered at home.

The clinic also provides a 24 hour phone service/help line for patients.

Areas for Improvement

No areas for improvement were identified during this inspection.

Number of Requirements:	**0**	**Number of Recommendations**:	**0**

No requirements or recommendations resulted from this inspection.

I agree with the content of the report.			
Registered Manager	J McLaughlin	**Date Completed**	17/2/16
Registered Person		**Date Approved**	
RQIA Inspector Assessing Response		**Date Approved**	

Please provide any additional comments or observations you may wish to make below:

Please ensure this document is completed in full and returned to pharmacists@rqia.org.uk from the authorised email address

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and weaknesses that exist in the home. The findings set out are only those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not absolve the registered person/manager from their responsibility for maintaining compliance with minimum standards and regulations.

RQIA Inspector Assessing Response	Frances Gault	**Date Approved**	17/2/16