Contract Manufacturing of Sildenafil Suspension for Paediatric Patients

Singapore Healthcare Management 2018

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Introduction

Sildenafil is used in the treatment of paediatric pulmonary hypertension at KK Women's and Children's Hospital. Administration to paediatric patients is a challenge as there are no registered liquid formulations available in Singapore . Pharmacy has been compounding a suspension extemporaneously to meet this requirement since 2007. An average of 12,000mL is prepared each month with 75 hours of manpower spent.



Aim

We identified a need to explore the production of Sildenafil suspension on a larger scale with the aim to:

- **Reduce cost to hospital** Ο
- **Reduce manpower time spent on compounding** Ο

Significant Cost Savings

• New formulation \$0.43/mL cheaper than previous extemporaneous preparation • 61.4% price drop

Manpower Time Savings

•74.5 man hours saved per month • 99.3% decrease

Methods

Vendor engagement

Formula

development

local manufacturer with Good • Engage Manufacturing Practice certification • Establish contract manufacturing agreement



Collaborate with manufacturer to develop suitable formula for Sildenafil suspension

Conduct sourcing, evaluation, and purchase of raw materials

• Work out costing for production twice a month Costing Conduct further testing on assay content and stability of formulation Final product ready for production in Dec Product 2017 finalization

Discussion

The new Sildenafil Suspension was rolled out hospital-wide in January 2018 and was well-received. However the shelf-life was shorter compared to the previous preparation. Further stability testing was explored with manufacturer. In June 2018, the shelf life was further extended to 70 days.

Pharmacy also embarked on a home-delivery service to improve patient convenience and reduce waiting times at **Outpatient Pharmacy.** Patients no longer have to return to Pharmacy every 2 months before their suspension expires.

Conclusion

The contract manufacturing in collaboration with a local manufacturer is effective in reducing cost and manpower time spent by Pharmacy.

Pharmacy is currently reviewing all extemporaneous preparations to explore if this initiative can be extended to other labour-intensive and high-cost products.