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POSTER APPLICATION FORM

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Poster title	A Risky Business. Improving Quality Assurance, Procurement, and Governance of Unlicensed Medicines

Please submit details of abstract overleaf

Please note: all poster applications must be submitted by 18th August 2023

Please return your application to:

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ABSTRACT

A Risky Business? Improving Quality Assurance, Procurement, and Governance of Unlicensed Medicines

Focal Points

- Objective: Improve management of risk associated with unlicensed medicines (ULMs)
- Results: 100% of ULMs now undergo QA risk assessment prior to reaching patients. This is in addition to tightened Procurement controls and improved governance arrangements
- Conclusion: A project instigated by a multi-disciplinary Pharmacy team has reduced the organisational risk associated with ULM use

Introduction

Although ULMs only form a small proportion of the medicines used within Aneurin Bevan University Health Board (ABUHB), due to regulatory restrictions and lack of assurance over quality they constitute a significant area of risk if not managed properly.[1] Historically ABUHB Pharmacy used the EDS stock management and dispensing system, which made it very difficult to track ULM procurement and usage. As a consequence, some ULMs used in clinical areas had no formal quality assessment. The introduction of the WellSky/CareFlow computer system in late 2020 (where drug files are set up centrally and ULMs are automatically flagged) provided an opportunity to significantly improve current processes.

Methods

A multidisciplinary team was formed to develop an improved system which would provide robust oversight of ULMs. Three workstreams were identified:

1. Clinical appraisal of ULM requests
2. Procurement of ULMs
3. Quality Assurance (QA) approval process for purchased ULMs

Task and finish groups were established for each of the above, with the aim of developing a comprehensive Standard Operating Procedure (SOP) for use across ABUHB's secondary care Pharmacy departments.

Results

A new QA Risk Assessment process was developed which was used to assign a Red/Amber/Green (RAG) rating to ULMs. This RAG rating was then used to stratify the level of Procurement and QA involvement required for future orders of the same product, with the aim of focusing resource on the highest-risk products. Alongside this, a revised clinical approval process was developed for ULM requests from clinicians to improve governance of ULM usage in clinical areas. All processes were incorporated into an overarching SOP, supported by a number of staff training and engagement sessions.

In the two years prior to the new system being implemented (Apr 2019-Mar 2021), there were 109 unique products which were assessed by QA. In the first two years of the new system (Apr 2021-Mar 2023), 181 unique products underwent QA assessment. This represents 100% of all items flagged on WellSky/CareFlow as ULMs in this time period. As of June 2023, 175 'Live' products are available under the new system, of which 52% (91) are "Green", 37% (64) are "Amber" and 11% (20) are "Red". Feedback from staff in all areas of Pharmacy is that they have an increased understanding of the risks associated with ULM use, and feel more confident in handling requests for ULMs.

Conclusions

Under the previous system, there was a substantial risk that quality issues with ULMs would pass undetected; since the introduction of the new ABUHB processes, 100% of WellSky/CareFlow-flagged ULMs undergo QA assessment. The RAG rating system has enabled the QA team to focus their limited resource on the highest risk products, improving both efficiency and risk management. Proactive engagement with other areas of Pharmacy has increased staff knowledge and awareness of the legal and clinical implications of using ULMs, and the new processes have received positive feedback across all secondary care sites.

References

[1] Medicines and Healthcare products Regulatory Agency. MHRA Guidance Note 14 – The supply of unlicensed medicinal products ("specials"). Crown Copyright. Published 2014, updated 2023.