

Regional Medicines Optimisation Committees

Standardising strengths of high risk, unlicensed oral liquids formulations for anti-TB medicines.

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| Meeting date: | October 26 th 2017 |
| RMOC Region: | North |
| Background: | |
| <p>Four drugs form the mainstay of anti-TB treatment in children. Rifampicin is available as a licensed oral liquid. Ethambutol, pyrazinamide and isoniazid oral liquids are available only as unlicensed products. Data shows significant variation in strengths and formulations of all three drugs (eight different concentrations of ethambutol, for example) within primary and acute care and between the two. In primary care it's likely that most dispensed products are individually prepared under the supervision of a pharmacist which means there is no quality control testing. Patients are therefore being exposed to multiple different formulations, and potentially to an unnecessarily increased risk of prescribing, dispensing and dosing errors and adverse events.</p> <p>The lack of product standardisation also means that the supply chain is not efficient or robust and supply problems are very common. This is especially important in this context because adherence to treatment is critical to disease eradication.</p> | |
| Recommendation: | |
| <p>In light of the above, at the meeting on 26th October 2017 the Regional Medicines Optimisation Committee (North) endorsed the following approach put forward by the NHS Pharmaceutical Quality Assurance Committee Sub-Group on Unlicensed Medicines:</p> <ul style="list-style-type: none"> • A 3-year, multidisciplinary work programme has generated a consensus in support of a standardised specification for each of the 3 main products Ethambutol 400mg in 5ml, Pyrazinamide 500mg in 5ml, Isoniazid 50mg in 5ml • This consensus has been translated into manufacturing specifications which have been agreed by the NHS Pharmaceutical Production Committee. • These standardised products will be submitted for addition to the British Pharmacopoeia and BNF-C • NHS prescribers are encouraged to restrict prescribing of these three drugs to the three products listed above | |
| February 2018 | |