



**Forum Consultation Response -
MHRA Consultation - Proposal to make Aquiette 2.5mg Tablets (oxybutynin
hydrochloride) available from pharmacies**

MAY 2022

In May 2022, Pharmacy Forum NI responded to the MHRA consultation on the Proposal to make Aquiette 2.5mg Tablets (oxybutynin hydrochloride) available from pharmacies.

Overview: Aquiette 2.5mg Tablets are a medicine for treatment of long-standing (present for over 1 month) symptoms of overactive bladder (OAB) which are not adequately controlled by bladder training alone, in women 18 to 65 years of age.

The applicant proposing to make Aquiette available from pharmacies is Maxwellia Ltd. The Commission on Human Medicines has advised that this product could be made available as a Pharmacy (P) medicine. The MHRA is proposing to make it available through pharmacies.

In suitable women and following at least 6 weeks of bladder training alone, a 6 week course of Aquiette may be tried. If symptoms of OAB are adequately controlled, a further 6 weeks treatment may be given. A maximum of 12 weeks treatment may be provided in the pharmacy.

Medicines containing oxybutynin, the active ingredient in Aquiette will still be available on prescription. Women will have a choice in where they obtain supply of this medicine from, either on prescription or from pharmacies.

Source: www.gov.uk/government/consultations/consultation-on-proposal-to-make-aquiette-25mg-tablets-oxybutynin-hydrochloride-available-from-pharmacies

The consultation closed on 13 May 2022. Below outlined is the response provided by Pharmacy Forum NI that was submitted via an online form.

Response submitted by Roisin Hughes, Policy & Communications Officer – Pharmacy Forum NI.

Q. Do you consider that Aquiette should be available as a Pharmacy (P) medicine? *

No.

Q. Do you have other comments on the reclassification?

Pharmacy Forum NI is against this proposed reclassification for reasons cited below which are:

- A) specific to the safe supply and side effects associated with this medicine;
- B) more generally concerned with the growing number of MHRA proposals relating to Prescription Only Medicine (POM) to P medicine switches, a move which is shifting the locus of healthcare.
- C) the need to maintain equitable access to healthcare for all

A) Safe supply & side effects related to Aquiette

While Pharmacy Forum NI is confident that if Aquiette were supplied as a pharmacy 'P' medicine, pharmacy teams will do a great deal to manage safety, identify red flags prior to supply and ensure it is safe and appropriate use, due to concerns over anticholinergic activity and increasing evidence implicating association with cognitive decline, changes in brain architecture and causation of dementia, Pharmacy Forum NI is against the move to make Oxybutynin available without prescription.

The hazards of Aquiette's anticholinergic side effects especially in older women or those at risk of rapid cognitive decline are well document. Indeed, it is telling that some trusts in GB have removed it from their treatment pathways. The cumulative anticholinergic exposure for older people taking medications for multiple health conditions can be underestimated. In the case of anticholinergic drugs, some adverse effects may be insidious and irreversible – one such concern related to long-term anticholinergic burden (ACB) is a possible contribution to cognitive decline and dementia. This is supported by a 2021 review published by the global independent network, Cochrane, recognised globally as the gold standard in health evidence. See: www.cochranelibrary.com/cdsr/doi/10.1002/14651858.ED000154/full).

Other evidence published in 2021 by a group of experts including Tony Avery, the new National Clinical Director of Prescribing at NHS England shows also that the use of oxybutynin satisfies the Bradford Hill criteria for establishing a causal link with the development of dementia, and this may also be the case for other anticholinergics that easily cross the blood–brain barrier. See: www.ncbi.nlm.nih.gov/pmc/articles/PMC8177062

The safe supply of Aquiette, and the reduction of risk of harm from its use, relies on the patient being aware of and reporting the presence of symptoms other than those associated with an overactive bladder. There is the possibility that the absence, or lack of awareness, of these symptoms could open up the risk of missing more sinister condition (e.g. ovarian cancer, which can masquerade as other conditions due to the vague symptoms). The delay in diagnosis for an underlying condition could pose risks.

Finally, such proposals present a complexity that needs to be thought through and analysed; Pharmacy Forum NI would urge the MHRA to reassess the existing evidence base and align the safety profile of the drug, the potential for masking underlying symptoms, the ability for patients to have multiple access points in parallel from community pharmacies against the requirement for Aquiette to be readily available as a P medicine.

B) Appropriate funding required

Pharmacy Forum NI is alarmed and concerned that the MHRA has been increasingly making similar such POM to P proposals. Indeed, this is the second in a consistent stream of consultations

published recently by the MHRA, which presents a range of potential issues, which the Forum outlined in our response related to making Estradiol available from pharmacies. See:

www.pfni.org.uk/wp-content/uploads/2022/03/PharmacyForumNI_ConsultationResponse_MHRAGina-23.02.22-FV.pdf

Pharmacy Forum NI is aware that the pandemic has had a significant impact on people's behaviour and attitudes towards self-care and access to treatment. However, while this change in legislation is designed to improve access to therapy, the profession is challenged with a 'back wall' of multiple medicines that require an enhanced and direct patient-pharmacist consultation. Having these higher risk or more complex medicines downgraded to P requires a significant increase in pharmacist time which would need to be reflected in the retail selling price of the product.

We support the move for patients to have access to medicines where cost does not present a significant barrier. We would caution that if the retail price is required by necessity to be high and potentially the expected volume low then the investment in time for training individuals to a competent standard does not add up for commercial businesses. We would advise that this needs to be taken into consideration.

Pharmacists are arguably one of the most accessible healthcare providers to the public, which has been highlighted during the Covid-19 pandemic. They are highly trained clinical experts helping patients and the public by assessing conditions and making decisions about which medicines or treatments are most suitable, dispensing prescriptions and providing health checks and consultations. All of that work needs to be financed and be commercially viable.

C) Ensuring equitable access to healthcare treatment and medicines for all

According to the World Health Organisation (WHO), Universal Health Coverage (UHC) is when all individuals and communities receive the essential health services they need without facing any financial hardship.

We would point out that the UK has in excess more P medicines than anywhere else in the world. This development is pushing the cost of care back onto the patient, which represents an incremental shift towards a two-tiered healthcare system.

Many of the recent POM to P switches proposed by the MHRA involve issues affecting women in the main. By previously charging a price for the product, which encompasses a consultation cost, pharmacy has come under significant pressure from women's health advocacy groups and social media campaigns to provide these medicines at a fair price. We do not regard it appropriate to pass on the cost of this to the consumer.