ABSTRACT

The reclassification of tamsulosin hydrochloride 0.4mg (Flomax Relief®) in the UK from prescription only medicine (POM) status to ‘P’ medicine (for sale under the supervision of a pharmacist) was announced in November 2009. This is the first time that a treatment for Benign Prostatic Hyperplasia (BPH), a chronic, progressive symptomatic condition, has been available for self care. This switch has important potential benefits for men’s health, both relating to BPH and other conditions that affect an aging population.

This approval also breaks new ground since it represents a model of ‘collaborative care’ between pharmacist and doctor never before seen in practice. Specifically the doctor must see the patient to make a diagnosis and authorise continuation of self care with the drug. This new means for providing directed self medication might stimulate the fresh examination of some other chronic conditions for their self care potential. For the first time, the data which this reclassification relied upon, ostensibly from a study of the pharmacy supply model, have attracted 1 year of protection under European legislation.

This paper examines the innovative aspects of this development to stimulate debate on the possible implications, both positive and negative, for other potential switches. It may be that the very novelty of this self care model makes it a poor template for future switches in new indications.

Key Words: Tamsulosin, Benign Prostatic Hyperplasia, BPH, Collaborative Care, Pharmacy, Data Protection, self medication, ‘P’ medicine, ‘POM to P’ switch

THE TAMSULOSIN SWITCH

INTRODUCTION

The approval of a new medicine as suitable for self care is always a notable event, and the reclassification of tamsulosin hydrochloride 0.4mg (Flomax Relief) in the UK as a ‘P’ medicine (for sale under the supervision of a pharmacist) for the treatment of symptomatic Benign Prostatic Hyperplasia (BPH), is no exception. Each new ‘switch’ is always examined closely to divine the future direction of self-medication, but as always the signs should be read with caution.

The importance of an individual switch can extend beyond the expansion of treatment options for individual consumers. The switch of tamsulosin represents the movement of a new class
of drugs and a new indication into self care. But this particular switch also has broader connotations, since it is not only a new type of self medication model in Europe, but also the first reclassification for which data protection has been granted. This paper examines the implications for future switches and points to the potential for both positive and negative consequences.

PUBLIC HEALTH BENEFITS OF THE TAMSULOSIN SWITCH

The alpha-blocker tamsulosin has a well-established place in the symptomatic treatment of BPH. The approval of this drug for self-medication has potentially important benefits for male health:

• Men are good at ignoring health problems and bad at seeking help. Ignorance about what BPH is and what can be done about it, means many men and their families suffer unnecessarily for years before presenting their symptoms to a healthcare professional, if they do so at all\(^1\).

An important ancillary benefit of any new switch is the increased awareness it creates about the disease in question and the treatment options available. Many men consider lower urinary tract symptoms such as poor urinary stream, frequency, nocturia and urgency as ‘part of aging’ even when their quality of life is severely impaired\(^2\).

Extensive advertising is now underway (e.g. in urinals at motorway service stations) to encourage men to seek advice about this hidden problem.

• Anything that encourages men to present with a specific complaint also increases the opportunities for intervention in other areas of their health. Men aged 45 and over will be increasingly at risk of cardiovascular disease, for example\(^3\). Opportunistic screening to assess risk and the subsequent offering of appropriate interventions, whether in pharmacy or the physician’s surgery, can only happen when men consult.

DATA PROTECTION

In Europe, data protection for re-classified medicines is available under pharmaceutical legislation. Article 74a of Directive 2001/83/EC as amended by Directive 2004/27/EC sets out:

“Where a change of classification of a medicinal product has been authorised on the basis of significant pre-clinical tests or clinical trials, the competent authority shall not refer to the results of those tests or trials when examining an application by another applicant for or holder of marketing authorisation for a change of classification of the same substance for one year after the initial change was authorised.”

The Medicines and Healthcare products Regulatory Agency (MHRA) have issued specific guidance as to what kind of tests or trial might qualify for protection\(^4\):

A key word is ‘significant’, which is interpreted to exclude tests or trials which have no genuine
impact or effect on, or relevance to, the assessment or to whether the product should be
reclassified. The tests or trials must contain data which are worth considering and which
makes an unequivocal contribution to the recommendations to reclassify the product, without
which the application would be rejected. It may be data that:

(a) demonstrates the safe use of the product in the P or GSL setting

(b) identifies clearly the target population

(c) involves patients or consumers and results in guidance to pharmacists on safe and effective
use in the context of a pharmacy based trial or experience of pharmacist supply.

This re-classification is the first to attract some protection against a generic copy under the
European Directive. Specifically, the clinical data which was relied upon to secure the re-
classification, in this case believed to be a study of the proposed mechanism for pharmacy
supply, cannot be referenced in support of an application by a competitor company for a
period of one year from the time of marketing authorisation. It is welcome to see this rather
limited European incentive to pursue innovative switches finally granted.

THE TAMSULOSIN PHARMACY MODEL

BPH is a chronic, slowly progressive, symptomatic condition and these features mean it is
almost certainly unique among the current indications for self-medication. Despite the ubiquity
of mild BPH in aging males, advanced BPH can present as a medical emergency if acute urinary
retention supervenes. No doubt partly in recognition of this potential, self care in the case of
Flomax Relief means a limited 10 week window for self medication (or 2 weeks if symptomatic
response is poor) before a formal doctor diagnosis is required. Thereafter, a man may be
referred back to the pharmacy for continued self-medication with the intention that he should
return for an annual physician review.

To qualify for treatment in the first place, a man must undergo an evaluation in pharmacy
involving a questionnaire which incorporates the International Prostate Symptom Score (IPSS) to
gauge severity of symptoms; together with questions to identify ‘red flag’ symptoms (e.g.
haematuria) that might indicate other pathology requiring an immediate medical referral.

Taken together, these features make this a relatively complicated protocol. The additional step
created by the requirement for referral between pharmacy and doctor – and potentially back
again – is a feature exclusive to this model of ‘collaborative care’.

IMPLICATIONS FOR FUTURE SWITCHES:

COLLABORATIVE CARE

In my view it would be wrong to-interpret the detail of this POM to P switch as creating
precedents that other switches should expect to follow. In particular there is no reason to
suppose that this type of ‘collaborative care’ is appropriate for any but the more problematic candidate conditions for self-medication. It would negate the purpose of self care to require doctor involvement unless this is truly necessary.

In BPH there is a reasonable argument that a doctor diagnosis is required for the optimal future management of a man with indicative symptoms. Even so, it remains to be seen whether men who are non-consulters by nature will comply readily when instructed to attend their doctor for a consultation which they know should, at the very least, involve a digital rectal examination. It is equally uncertain whether doctors will encourage these men to return to the pharmacy to continue self-care rather than simply prescribing tamsulosin, thereby completing their ‘medicalization’. Educating doctors as to their role in this unfamiliar collaborative process of self care will be every bit as important as educating pharmacists, and may present a greater challenge.

In most instances self care should continue to mean exactly what it implies: the involvement of healthcare professionals only when the individual chooses. A consumer may be offered advice to consult a doctor and given good reasons to do so, but ultimately this cannot be something which is mandated. It would be a mistake to see ‘collaborative care’ as simply a mechanism to encourage physician consultation. In most instances ‘collaborative care’ should still mean self care, with physician involvement only when this adds something which is not available otherwise.

Similarly, it would be wrong to conclude that self care in the management of chronic conditions should necessarily involve a physician at some point. Examples that do not, such as primary prevention of cardiovascular disease (with simvastatin) already exist, and others such as treatment of overactive bladder symptoms in women have been discussed in the past.

However, it is possible to envisage future ‘collaborative’ models for self care of other progressive conditions where the diagnosis requires physician assessment or a specialist test to guide future management. One example might be osteoporosis, where the vulnerability of a large population often becomes apparent only when the disease leads to serious fractures. Women having the well-recognised risk factors for developing osteoporosis could have bone mineral density (BMD) measured to confirm osteopenia and to qualify them for self-care. This could mean that a sizeable group of people would have the opportunity for primary prevention of osteoporosis through self care – an opportunity that is unlikely to be afforded to many within current health care systems. For example recent National Institute for Clinical Excellence (NICE) guidance restricts pharmacological primary prevention of fractures (rather than prevention of osteoporosis) in the UK to women who have independent risk factors for fracture and BMD confirmation of pre-existing osteoporosis.

The final emergence of the much discussed ‘collaborative care’ model in Europe should encourage creative self care approaches to some of the more intractable problems facing
health care systems. But ‘collaborative care’ of this type should be viewed as the exception and not as a way to introduce doctors as ‘risk absorbers’ into self care models.

THE PHARMACY MODEL AND DATA PROTECTION

The use of self-administered questionnaires in pharmacy is problematic because: a) they must be found when needed, b) there must be space for them to be completed and c) access to a pharmacist may be necessary to assist completion and/or interpret the outcome. In this instance the rationale for use of a questionnaire at the initial pharmacy visit may be sound, although it is questionable whether a repeated IPSS score on follow up will add much to a more pragmatic assessment of symptom improvement. However, if each new switch were to be accompanied by a questionnaire, the pharmacy environment would quickly become unmanageable. In recent research, 42.5% of UK pharmacists surveyed identified ‘the need to complete a questionnaire to determine patient suitability prior to sale’ as a major barrier to recommending a switched POM to P drug.

It is axiomatic that the more complex a pharmacy model becomes, the less likely it is to be adhered to. Future switches should continue the search for the simplest possible pharmacy interaction consistent with consumer safety. A well-trained pharmacist exercising professional judgement and recommending a product that includes a comprehensible information leaflet must be preferable to the false sense of security offered by an exhaustive questionnaire and a complex algorithm for supply. These ‘tools’ may be useful in training pharmacy staff (particularly in new therapeutic categories) or as optional reminders for reference, but mandatory use may be counterproductive. The putative public health benefits of a switch can be easily wiped out if the complexity of the model discourages consumers, or pharmacists, or both.

There is a further potential problem with a complex pharmacy model. It is conceivable that companies may see it as in their commercial interest to construct and test a pharmacy model – perhaps based on a questionnaire which then becomes proprietary – as a means of generating protectable data for a switch. Once established as a precedent, this supply model easily becomes the requirement for the next entrant (e.g. a new member of the same therapeutic class). Thus a mechanism intended to encourage innovation in switch might perversely inhibit subsequent innovation aimed at improving and/or simplifying the supply model. This may be a touch Machiavellian, but perhaps regulators should consider these possible unintended consequences.

CONCLUSION

Every new switch has unique features, but the switch of a medicine for a condition entirely new to mainstream self care is a major event. The switch of tamsulosin hydrochloride 0.4 mg (Flomax Relief) in the UK brings BPH into the range of conditions manageable to some extent by self-medication. In this instance, the model for supply envisages involvement of a physician to confirm the diagnosis after an initial period of self-medication, before the individual is
returned to pharmacy to continue self care. This ‘collaborative care’ approach may signal the potential for a range of chronic conditions characterised by low consultation rates and poor knowledge of treatment options to become candidates for self care in the future. However the supply model for tamsulosin is complex and cannot be viewed as a template for switches that do not have the same need for a physician diagnosis step.

This re-classification was the first to attract 1 year of protection under European legislation for data that were relied upon for the switch. In this instance the data protected are reportedly from a study of the supply model in pharmacy. This may be appropriate for a ‘collaborative care’ supply model of this complexity, but validation studies of unnecessarily complex models (perhaps involving questionnaires) in an attempt to secure data protection for future switches would be a retrograde step and ultimately counterproductive commercially.

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REFERENCES


