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Prescribing, Using the Proprietary 'Trade' Name, is Safer than Using the Generic Active Ingredient, as the Defined Identifier of the Required Medication

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ABSTRACT

Introduction: Development of medications, by research based pharmaceutical companies, costs of the order of > 2.5 billion US dollars, especially when amortised over the costs involved with other failed attempts to develop innovative compounds of which > 90% fail at the animal testing stages and others fail while undergoing human trials. The cost of developing a generic alternative is far cheaper, hence leading to support for generic substitution by funding bodies.

Prescribing by Proprietary Trade Name: The active ingredient, of any medicinal compound, is but a fraction of what it contains, allowing for excipients and variations in salts, resulting in potential lack of bioequivalence between different generic alternatives. It has been shown that the difference between generic alternatives can equate to doubling or halving the effective dosage. Irrespective of whether one prescribes the parent compound upon which the generic is based or a generic alternative, the only protection to be afforded the patient is to prescribe using the proprietary trade name of either the parent compound or the chosen and identified generic alternative to the parent compound and also denying the dispensing pharmacist the option of brand substitution

Conclusion: Generic substitution is a real potential, if one prescribes the medication by identifying it, using its generic active ingredient. The name of many generics includes the active ingredient, making it confusing for patients. The way to ensure patients receive the chosen brand, be it the parent compound or a generic alternative, is to adopt the approach of prescribing using the proprietary trade name as the identifier, rather than prescribing the generic name attached to the active ingredient within the medicine and to deny brand substitution.

INTRODUCTION

From conceptual thought, through to marketable, formulary inclusive branded medication is estimated to cost an innovative, research based, pharmaceutical company of the order of 2.7 billion US dollars (USD) [1]. Mean time from development to being marketed is estimated to be almost 7.5 years [1], ranging from ~ 6 to > 15 years [1], in which time the Research and Development (R&D) costs are borne by the R&D arm of the relevant company. There has been a concerted effort to demonstrate that the estimated R&D costs, per isolated medication, are nowhere near as high as this amount of > 2.5 billion USD [1], but this does not allow for the failure

of many 'conceptual thoughts' ever reaching fruition on the market. It is argued that > 90% of medications, tested at the initial animal stages of drug development, fail to proceed to human trials [2]. Those criticising the estimated costs of R&D, in drug development, often ignore this cost, when considering the overall expenditure [1], but this approach is fallacious as, even at the animal experimentation stage, only <10% of potential medicinal compounds progress to human trials [2] and a significant number of this <10% still fail once entering human trials. All stages of drug development incur costs which must be amortised over the spectrum of medications being developed by any R&D based pharmaceutical company to reach a justifiable overall cost.

The cost of developing a generic competitor, to an innovative, original R&D medicine, is estimated to be far lower than even sale prices in developed nations would suggest [3], especially if developed in India, the home of many generic compounds [3]. It follows that generic competitors are favoured by most agencies which have responsibility for health costs in their relevant jurisdiction [4]. The argument is that the generic compound is identical to the original, innovative medicine, based on bioequivalence studies [5]. This implies that the generic compound will give identical efficacy and tolerability to the parent, innovative compound upon which it is based but this need not be the case, especially with illnesses such as epilepsy which has a narrow therapeutic index [6].

The paper to follow argues in favour of prescribing, using the proprietary trade name, rather than the generic name of the active ingredient, to protect the patient from potential fluctuations in bioavailability that may follow from generic substitution, especially when substituting from one generic for another which could result in almost doubling or halving the effective dosage [7].

PRESCRIBING BY PROPRIETARY TRADE NAME

The active, generic medicinal component of a medication is only a fraction of what is included in any prescribed tablet/pill which is consumed by the patient [8,9]. The active ingredient is carried by an excipient, thought to be inert although this may not be the case [10] and there may be alternative salt components which may have the capacity to alter bioavailability. One generic compound is not test against other generic medications [6], nor is there batch testing and the only measure of equivalence is the comparison to the innovative medicine upon which it is based, requiring the generic to fall within 80-125% parameters of the parent bioavailability [6]. Prescribing, using the generic name of the active ingredients, allows the dispensing pharmacist to dispense the currently cheapest variant of generic agent held in that pharmacy's formulary. Often the pharmacist will encourage the patient to accept the generic alternative, as there is a financial incentive for the pharmacist, irrespective of, whether or not, the prescriber has indicated that brand substitution is denied [11].

Accepting that moving from one generic 'equivalent' medicine to another generic compound may half or double the effective dosage [7], this should not restrict the prescriber from using generic compounds but it does necessitate stipulating which brand of generic compound is to be dispensed. When treating Parkinson's Disease (PD), the author starts treatment with tiny dose of the combined drug, L-Dopa/Carbidopa [12], at a dosage of ½ x100: 25mg combination tablet twice daily. Sinemet® changed its formulation from a scored tablet to a rounded, unscored pill, whereas Kinson®, a generic alternative to Sinemet®, also with similar active ingredients in the same combination of 100: 25, remained a scored tablet, making it easier for patients to break the tablet in half, breaking it along the scored divider. As a result, the generic alternative of Kinson® 100: 25, became the favoured medication over the parent innovator, Sinemet®. To ensure that patients received this formulation and a scored tablet, each patient received a prescription for Kinson 100: 25, ½ bd, with the box stating, "Brand substitution not allowed", being marked, thereby denying the potential to dispense an alternative generic agent to the one prescribed, acknowledging that MIMS, the Australian widely available listing of available medications, list 4 different brands of L-Dopa/Carbidopa 100:25 including the 2 already mentioned.

In Australia, the parent, innovative agent of amitriptyline, Tryptanol®, became unavailable thereby necessitating the use of a generic alternative, such as Endep®, to maintain treatment with the active ingredient. MIMS lists 6 alternative generic 'equivalents' of amitriptyline. Were one to prescribe 'amitriptyline', using the generic name, rather than a proprietary trade name of the chosen generic alternative, would allow the pharmacist to offer whatever formulation was

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cheaper to him/her at the time of dispensing, without transgressing any regulatory imperative. One needs to appreciate that 4 of these 6 alternatives of amitriptyline include 'amitriptyline' within their proprietary trade name, making it confusing for patients who may well believe that these generic alternatives were identical, even though this may not be the true situation. To protect patients, against substitution, of one generic for another, it becomes imperative to prescribe, using the proprietary trade name, and to deny the option of brand substitution.

It follows that, irrespective of whether one wishes to prescribe the innovative parent compound or a specific alternative generic agent, the only protection, offered to the patient, to obviate brand substitution and to prescribe the chosen medication, using its proprietary trade name.

CONCLUSION

Generic substitution, as a change for innovative R&D developed medications or as an alternative generic formulation, is a real potential, if one prescribes the medication by identifying it, using its generic active ingredient. Many generics may have very similar names, often including the active ingredient, making it confusing for patients, should one prescribe using the generic name, not recognising that each generic need not be identical to another, and may result in doubling or halving the effective dosage [7]. It follows that the only way to ensure that patients receive the chosen brand, be it the parent compound or a generic alternative, is to adopt the approach of prescribing using the proprietary trade name as the identifier, rather than prescribing the generic name attached to the active ingredient within the medicine.

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