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INTA Legislation and Regulation, Pharmaceuticals Subcommittee

Comments on the UK Department of Health's Consultation Document, *Proposed Implementation of "Generic Substitution" in Primary Care Further to the Pharmaceutical Price Regulation Scheme (PPRS)*

30 March 2010

The Legislation and Regulation, Pharmaceuticals Subcommittee of the International Trademark Association (INTA) wishes to express the Association's concerns with Options 2 and 3 in *The proposals to implement "Generic Substitution" in primary care, further to the Pharmaceutical Price Regulation Scheme (PPRS) 2009 Consultation Document*.

INTA is a 132-year old not-for-profit membership organization representing over 5,600 trademark owners and professionals worldwide, from more than 190 countries. INTA's membership, which crosses all industry lines and includes both manufacturers and retailers, is united in its goals of supporting the essential role trademarks play in promoting effective commerce, protecting the interests of consumers, and encouraging free and fair competition. INTA only takes positions on matters of public policy when the underlying principles and functions of trademarks or the trademark system are involved.

The *Consultation Document* presented three Options:

- Option 1 – Maintain the *status quo*.
- Option 2 – Introduction of generic substitution but with specific exclusions so substitution does not apply to products on an exempt list. Under this Option, a statement would be included on prescriptions that confirms that if a prescriber wrote the name of a branded version of a medicine, the prescriber meant that either the branded version or a generic could be dispensed, unless the medicine was on the exempt list.
- Option 3 – Introduction of generic substitution for a selected group of products. Under this Option, a statement would be included on prescriptions that confirms that if a prescriber wrote the name of the branded version of a medicine, the prescriber meant either the branded version or a generic could be dispensed, if the product appeared on the list of products for which substitution is acceptable.

INTA does not believe that either Option 2 or 3 is acceptable, as they (a) diminish the source function of trademarks (brand names); (b) are likely to cause consumer confusion; and (c) are likely to lead to difficulties in monitoring adverse reactions.

Function of Trademarks as Source Indicators is Diminished

Options 2 and 3 greatly diminish the function of trademarks as source indicators to the detriment of brand owners, health care professionals and consumers. A trademark is a word, phrase, symbol or design, or a combination thereof, that identifies and distinguishes the source of the goods of one party from those of others. By providing a consistent method of identification, trademarks help consumers select the goods and services they want, and the quality they have come to expect, engendering goodwill in the mark and providing incentive for manufacturers to produce goods and services of a consistent quality. In the absence of strong trademark protection, consumers would face constant confusion as to what choices they face in the marketplace. The development of a trademark for a new pharmaceutical product is a complex process that involves legal, regulatory, linguistic, and marketing considerations and often requires significant resources.¹

Pharmaceutical trademarks play an especially important role. Trademarks enhance public health by assisting health professionals reduce medication errors, enabling consumers to choose the medications that are right for them, and providing manufacturers with the incentive to develop new drugs and monitor the safety of existing drugs.²

Options 2 and 3 do not allow trademarks to function as source identifiers. Rather, the use of trademarks on prescriptions under Options 2 and 3 will denote a particular *type* of medicine, and not a particular medicine from a particular source.

Consumer Confusion Is Likely to Occur

Options 2 and 3 do not address the issue of consumer confusion, which may result from generic substitution. Once consumers find a brand name drug that works for them, they are often reluctant to change to another drug, particularly a generic version. In some cases, the generic may not seem to work as well, perhaps due to the particular consumer's reaction to different inactive ingredients in the new drug. For others, it can also simply be the peace of mind that comes from taking the brand name medicine with which they are familiar. Neither Options 2 nor 3 address the potential for confusion for consumers who have seen the brand name drug prescribed and/or have previously taken the brand name drug and may not understand the notations on their prescription mandating substitution.

In addition, one of the reasons put forward in support of adopting Options 2 and 3 is that prescribing by generic name tends to remind clinicians of the therapeutic action of the drug so

¹ INTA Educational Brief: *The Importance of Pharmaceutical Trademarks in Protecting Public Health*, April 2007: <http://www.inta.org/images/stories/downloads/educationalbrief.pdf>

² *Id.*

they are less likely to prescribe a drug of similar action unintentionally resulting in duplication or prescribing of a second incompatible medicine. However, while International Non-proprietary Names (INNs) are *unique*, that does not mean they are always *distinctive*. In fact, because drugs in the same class share the same stem, there is a degree of similarity for INNs for pharmaceuticals that are in the same class. Such similarity may be useful to dispensers in identifying the pharmacological properties of a particular drug, but it also creates its own type of potential confusion.

Difficulties in Monitoring Adverse Reactions

Options 2 and 3 also fail to address possible difficulties arising with the monitoring of adverse reactions. For consumers, knowing that they have taken a brand name drug is also helpful in the rare event of adverse reactions. Identifying a particular manufacturer's drug would be very difficult if the consumer did not appreciate whether she or he had been prescribed or dispensed the brand name or generic drug product.

In conclusion, pharmaceutical trademarks allow health care professionals to minimize prescription errors, allow dispensers and consumers to readily identify the specific medications they are dispensing and/or taking, and allow drug manufacturers to monitor their products. Pharmaceutical trademarks and their correct and proper use by both prescribers and dispensers foster the health and safety of patients and in turn, the entire healthcare system.

For the reasons above, INTA does not believe that either Options 2 or 3 is acceptable, and we feel that further review is warranted if any change from the current regime is to be made. We would welcome the opportunity to discuss any of these issues with you further if you so wish, and in conclusion we thank you for considering our views.