

MHRA GUIDANCE ON THE APPLICATION FOR EXCLUSIVITY FOR CHANGE IN LEGAL STATUS OF A MEDICINE

1. Introduction

The Human Medicines Regulations, regulation 64A allows for one year's data protection following the change of classification of a medicinal product.

The wording of Regulation 64A is:

(1) In this regulation, "classification", in relation to a medicinal product, means the term of the product's UK marketing authorisation which determines the way in which the product is to be made available, as described in regulation 62(1).

(2) This regulation applies where—

(a) the licensing authority grants or varies

(i) a UK marketing authorisation;

(ii) an Article 126a authorisation;

(iii) a traditional herbal registration; or

(iv) a certificate of registration of a homeopathic medicinal product,

(b) the grant or variation of the UK marketing authorisation involves a change of the classification of the medicinal product to which the authorisation relates; and

(c) the application for the UK marketing authorisation or variation was supported by the results of significant pre-clinical tests or clinical trials relating to the proposed classification.

(3) Where this regulation applies, the licensing authority may not, for the period of one year beginning with the date on which the UK marketing authorisation was granted or varied, refer to the results of the tests or trials referred to in paragraph

(2)(c) when examining an application by another applicant or UK marketing authorisation holder for a change of classification of the same kind as that to which the tests or trials relate.

This document gives guidance on how Regulation 64A is applied in the United Kingdom by the MHRA during an application to reclassify a medicinal product from POM to P, or from P to GSL.

2. Principles of the Article

The Regulation provides that should an applicant for a reclassification submit the results of pre-clinical tests or clinical trials and those data are the basis for the change of classification, the competent authority (in the United Kingdom, the licensing authority acting by the MHRA) shall not refer to those data when examining an application by another applicant for the **same substance** for one year after the initial change. In order for this data protection period to be applied, the data in question must be pertinent, specific and integral to the argument for a successful switch. The data must be fundamental to the assessment made by the MHRA.

3. Scope

The provision for data protection contained in Regulation 64A will apply in relation to the results of tests or trials which form the basis of valid applications for reclassification; this includes both variation applications and applications for new marketing authorisations which involve a reclassification.

The provision in Regulation 64A applies only to changes from prescription only (POM) to non-prescription (either P or GSL) and to changes from P to GSL; where a company incurs the costs of conducting tests or trials to support a change, they should be able to obtain a benefit of that expenditure in the form of a period of data protection. . If pre-clinical tests or clinical trials are the basis for a reclassification from P to GSL, the MHRA will not refer to the results of those tests or trials when considering a subsequent P to GSL application for the same P switches. The guidance in the following sections applies to both POM-P and P-GSL reclassifications.

The one year period of data protection would start from the date of grant of the authorisation or variation which effects the reclassification. A year after the date of grant of the authorisation or variation the competent authority (in the United Kingdom, the licensing authority acting by the MHRA) can then refer to those data when examining an application by another applicant for the same substance. Applications which rely on those data will not be valid during the period of data exclusivity.

5. Interpretation of Use of Data

Where the data is accepted by MHRA as fundamental to a successful switch application, the Agency, though cognisant of that data, cannot use or refer to it in judging a subsequent application, for one year after the change is authorised in the first application. It follows that any subsequent applications made within the period of data protection would have to be self-sufficient and supported fully by its own data without reference to the data of the first applicant, in order to be considered valid.

6. Type of Data

The Regulation refers to “*significant pre-clinical tests or clinical trials*”. Additional preclinical i.e. animal toxicology or in vitro studies for products late in their life-cycle, may not have much practical relevance on a switch application, but the applicant is invited to give this due consideration.

The area in which applicants will have most opportunity of providing relevant data in support of exclusivity is clinical trials. 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.

The competent authority decision as to whether the application will gain additional exclusivity will be made on a case by case basis.

A product moving from POM to P to GSL over a period of time may be considered for one year's additional exclusivity on each occasion of reclassification but the "*significant pre-clinical tests or clinical trials*" test will be applied on each occasion. However, it is unlikely that additional presentations (both strengths and dosage forms) will be supported by 'significant' data in relation to a reclassification approval and, in this respect, exclusivity is envisaged for the initial switch only.

7. Access to advice

The MHRA will be happy to help and guide companies who consider they have data which might qualify for the period of data protection. Companies are welcome to seek advice from the MHRA as early as necessary.

8. Conclusion

Applicants are encouraged to include data in their switch applications which are considered essential to the assessment of the reclassification and which, if acceptable to MHRA, will be exclusive to the applicant. The data cannot be used in consideration of subsequent applications for the same substance for a period of one year. In effect, unless a subsequent applicant produces similar or other suitable material, this will grant the original applicant a minimum one year's exclusivity of marketing for the use of the product in the wider setting. Other companies may continue to market their products for the existing use as POM or P, as the case may be.

When an application, supported by exclusivity evidence, is granted, that fact will be published on the MHRA website.

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