

10th September 2004

Applications for registration of Qualified Persons (QPs)

Introduction

According to Art. 45–46 of the Medicines Act 2003, Art. 9–12 of Legal Notice 143/2004 of the same Act and Art. 48-52 of Directive 2001/83/EC, as amended by Directive 2004/27 EC, the holder of a manufacturer's licence must have permanently and continuously at his disposal a qualified person who is responsible:

a) either in the case of medicinal products manufactured, that each batch of medicinal products has been manufactured and checked in compliance with the laws in force and in accordance with the requirements of the marketing authorisation

or in the case of medicinal products imported from third countries that each batch imported in the EU member state has undergone, in an EU member state, a full qualitative and quantitative analysis of at least all the active constituents and all the other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorisation (except for third countries that have a Mutual Recognition Agreement (MRA) with the EU/EEA ie currently Switzerland, Canada, New Zealand, Australia when a manufacturer's batch certificate may be accepted in place of testing within the EU).

b) for certifying that each batch satisfies the above provisions.

Detailed guidance on the responsibilities of the qualified person and in particular as regards to the relationship of various qualified persons located at different sites, which may be involved in the manufacturing process, is given in annex 16 of the EC GMP guide.

Grandfather QP provisions

A person who on 1st May 2004 and for a year thereafter, was carrying out the duties as a qualified person for a period of at least six months, shall be eligible to continue in those activities even though he does not fulfil the conditions set out under the permanent provisions, as long as such activities have been carried out to the satisfaction of the Authority.

The minimum requirements for a grandfather QP include:

- Formal qualifications awarded on completion of a university course or a course recognized as equivalent, in a scientific discipline allowing him to perform the duties of a QP
- At least 6 months experience in the production and quality control of medicines at middle or senior level
- An ability to demonstrate knowledge of different aspects of GMP and of the duties of a QP including release of imported products (Medicines Act 2003, Directives 2001/83/EC and 2003/94/EC, EU GMP Annex 16) during interview
- Understanding of pharmaceutical aspects of different products and dosage forms

Permanent QP provisions

Persons may also apply for QP status under the permanent provisions in line with the qualification requirements of the Medicines Act 2003 and Directive 2001/83 EC as amended by Directive 2004/27 EC. Such persons must have acquired practical experience over at least 2 years over a range of areas of manufacturing activity, in particular relevant to the proposed activities.

Importation

In the case of medicinal products imported from a third country, the testing facility carrying out the full qualitative and quantitative analysis can be located at different sites within the EU and subject to different competent authorities' supervision.

Authorisation of QPs

It is mandatory for a QP to be named on :

- a) Manufacturer's licences
- b) Partial manufacturing/assembly only (eg repackaging) licences
- c) Importer's licence

QP status is granted once a person is nominated and accepted by the Medicines Authority obo the Licensing Authority (LA) on one of the above-mentioned licences. The QP status granted refers to that particular licence. Application to be named on another licence must be made to the Medicines Authority obo the LA and there may need to be reassessment at the discretion of the Authority granting or varying that licence.

Applications for next session of QP interviews

The Medicines Authority would like to inform interested parties that applications under the permanent and grandfather provisions for registration of QPs are now being accepted. Applications should be received by the 25th September 2004.

Following assessment of the applications received, applicants who appear to satisfy the requirements will be asked to attend an interview.

Applications will only be considered against a payment of LM50 which is non-refundable. Payments should be made by cheque payable to the Medicines Authority.

Applications should be addressed to:

The Administrator
Inspection and Enforcement Directorate
Medicines Authority
BMW Building
198, Rue D'Argens
Gzira

The relevant application form can be found on the Medicines Authority website <http://www.health.gov.mt/mru>

An information session regarding issues relating to the QP activities will be held at the Medicines Authority on Wednesday 6th October. During this session you will have the opportunity to review the latest developments and clarify any pending issues. Your participation will be highly appreciated.

Tonio Cassar
Director Inspectorate and Enforcement
Medicines Authority