

## **MHRA FEES – DEFINITIONS**

This is an extract from the MHRA fees legislation the Medicines (Products for Human Use) (Fees) Regulations 2013 S.I. 2013 No. 532 which defines each of the different types of application.

**“active ingredient”** means an ingredient of a medicinal product in respect of which efficacy is claimed (whether therapeutic, diagnostic or otherwise);

**“active ingredient from a new source”** means an active ingredient in respect of which the application names as manufacturer a manufacturer not previously named as the manufacturer of that active ingredient included in a medicinal product in respect of which a marketing authorisation (other than a product licence of right) or a traditional herbal registration has previously been granted;

**“certificate of registration”** means a certificate for the purposes of Part 6 of the Human Medicines Regulations

**“complex application”** means an application, other than a major application, or a marketing authorisation where the application falls within one or more of the following sub-paragraphs (a) to (s) –

- (a) the application relates to a medicinal product which is intended to be used in accordance with an indication for use in respect of a new category of patients or as treatment for a new category of disease;
- (b) the application relates to a medicinal product containing a new combination of active ingredients that have not previously been included in that combination in a medicinal product in respect of which a marketing authorisation (other than a product licence of right) has previously been granted;
- (c) the application relates to a medicinal product containing a new excipient;
- (d) the application relates to a medicinal product that is intended to be administered by a route of administration different from that used in the administration of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorisation (other than a product licence of right) has previously been granted;
- (e) the application relates to a medicinal product containing an active ingredient, the manufacture of which involves a route of synthesis (or, in the case of a medicinal product not synthetically produced, a method of manufacture) different from that used in the manufacture of the active ingredient of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorisation (other than a product licence of right) has previously been granted;

- (f) the application relates to a medicinal product which is a controlled release preparation and is not a simple application;
- (g) the application relates to a sterile medicinal product the manufacture of which involves a method of sterilisation different from that used in the manufacture of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorisation (other than a product licence of right) has previously been granted;
- (h) the application relates to a sterile medicinal product the container of which is directly in contact with the medicinal product and is made from different material in the container of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorisation (other than a product licence of right) has previously been granted;
- (i) unless a European Pharmacopoeia certificate of suitability covering the active ingredient has been submitted with the application, the application names as manufacturer of the active ingredient of the medicinal product in question and in respect of which a marketing authorisation (other than a product licence of right) has previously been granted;
- (j) the application relates to a medicinal product which is an influenza vaccine and in respect of which the manufacturer or the manufacturing process is different from that specified in any other marketing authorisation which the applicant holds in respect of that product;
- (k) the application is for the grant of a marketing authorisation for a medicinal product which is an influenza vaccine, except where it relates only to an influenza vaccine containing a different strain or strains from that specified in any other marketing authorisation which the applicant holds;
- (l) the application is for the grant of a marketing authorisation for a medicinal product which is to be delivered by way of a metered dose inhaler;
- (m) the application is for the grant of a marketing authorisation for a medicinal product which is in a powdered form and is to be delivered by way of inhalation;
- (n) the application relates to a medicinal product –
  - (i) which is administered to the site of action or absorption by a method which has not previously been authorised in relation to any authorised medicinal product which contains the same active ingredient as the product in question and,
  - (ii) in respect of that other product, a marketing authorisation (other than a product licence of right) has previously been granted;

- (o) the application is an application for a marketing authorisation to which Article 10(3) of the 2001 Directive applies;
- (p) an application where the sole or primary evidence for the safety and efficacy of the medicinal product consists of published scientific literature
- (q) the application is an extension application;
- (r) the application –
  - (i) is not an application in accordance with Article 10, 10a or 10c of the 2001 Directive, and
  - (ii) includes the results of the pre-clinical tests or clinical trials as specified in Article 8(3)(i) of the 2001 Directive; or
- (s) the application is an application for a marketing authorisation to which the first sub-paragraph of paragraph 3 of Part II of Annex I to the 2001 Directive applies;

**“complex registration application”** means an application for a traditional herbal registration relating to a medicinal product containing an active ingredient that has not previously been included as an active ingredient in a medicinal product in respect of which a marketing authorisation (other than a product licence of right) or a traditional herbal registration has previously been granted;

**“decentralised procedure application”** means a major application, a complex application, a standard application or a simple application for a marketing authorisation for a medicinal product in respect of which at the time of the application –

- (a) a marketing authorisation has not been granted in any EEA State;  
and
- (b) an application for a marketing authorisation has been made in more than one EEA State pursuant to the procedure in Title III, Chapter 4 of the 2001 Directive;

**“EU marketing authorisation”** means –

- (a) a United Kingdom marketing authorisation granted by the licensing authority under Part 5 (marketing authorisations) of the Human Medicines Regulations;
- (b) a marketing authorisation granted by the competent authority of an EEA State other than the United Kingdom in accordance with the 2001 Directive; or
- (c) a European Union marketing authorisation;

**“relevant medicinal product”** means a medicinal product for human use to which the provisions of the 2001 Directive apply.

**“European reference product application”** means an application for a marketing authorisation to which the third sub-paragraph of Article 10(1) of the 2001 Directive applies;

**“Extension application”** means an application

- (a) for an extension of a marketing authorisation within the meaning of Article 2 (4) of EC regulation No 1234/2008; and
- (b) which includes the result of pre-clinical tests or clinical trials as specified in Article 8(3)(i) of the 2001 Directive.

**“major application”** means an application for a marketing authorisation made to the licensing authority on the grounds that a medicinal product contains a new active ingredient;

**“the MHRA portal”** means the internet-based hosted platform which enables persons to carry out business with the Medicines and Healthcare products Regulatory Agency of the Department of Health electronically, known as “the MHRA Portal”

**“mutual recognition procedure incoming application”** means a major application, a complex application, or a standard application for a marketing authorisation for a medicinal product in respect of which –

- (a) a marketing authorisation has already been granted in another EEA State; and
- (b) recognition of that marketing authorisation is sought from the licensing authority by way of grant of a marketing authorisation in the United Kingdom, pursuant to the procedure in Title III, Chapter 4 of the 2001 Directive.

**“new active ingredient”** means an active ingredient has not previously been included as an active ingredient in a medicinal product in respect of which a marketing authorisation (other than a product licence of right) has previously been granted;

**“new excipient”** means –

- (a) except in Part 2, paragraph 35 and Part 4, any ingredient of a medicinal product, other than an active ingredient, that has not previously been included in a medicinal product –

- (i) which is intended to be administered by the same route of administration as the product in question; and
  - (ii) in respect of which a marketing authorisation (other than a product licence of right) a certificate of registration or a traditional herbal registration has previously been granted,

except that in the case of a medicinal product intended to be administered orally, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the

European Community) as an approved ingredient or additive in food or in a food product;

(b) in Part 2, paragraph 35 and Part 4, any ingredient of a medicinal product, other than an active ingredient, that has not previously been included in a medicinal product which is intended to be administered by the same route of administration as the product in question and in respect of which a marketing authorisation (other than a product licence of right), a certificate of registration or a traditional herbal registration has previously been granted, except that –

(i) in the case of a medicinal product intended to be administered orally, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Union) as an approved ingredient or additive in food or in a food product; and

(ii) in the case of a medicinal product intended for external use only, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Union) as an approved ingredient or additive in a cosmetic product;

**“Phase I trial”** means a clinical trial to study the pharmacology of a medicinal product when administered to humans, where the sponsor and investigator have no knowledge of any evidence that the product has effects likely to be beneficial to the subjects of the trial;

**“Phase II or Phase III trial”** means a clinical trial, other than a Phase I trial, where the medicinal product being tested –

(a) does not have an EU marketing authorisation; or

(b) has an EU marketing authorisation, but –

(i) there has been a change –  
(aa) to the process of manufacture of the product or its active ingredient, or  
(bb) of manufacturer of that product, or

(ii) the product is to be used in the trial other than in accordance with the terms of the summary of product characteristics under that authorisation;

**“Phase IV trial”** means a clinical trial other than a Phase I trial or a Phase II or Phase III trial;

**“reduced registration application category I”** means an application, other than a complex registration application, for a traditional herbal registration relating to a medicinal product which is presented in the form of a herbal tea;

**“reduced registration application category II”** means an application, other than a complex registration application, for a traditional herbal registration where the application falls within one of the descriptions specified in sub-paragraphs (a) to (d) as follows –

- (a) the application relates to a medicinal product which is presented in the form of a herbal tincture;
- (b) the application relates to a medicinal product which is presented in the form of an essential oil;
- (c) the application relates to a medicinal product which is presented in the form of a fatty oil; or
- (d) the application relates to a medicinal product which contains only herbal substances in a capsule;

**“simple application”** means –

- (a) an application for a marketing authorisation to which Article 10c of the 2001 Directive applies; or
- (b) an application, made no later than three months after the expiry of a marketing authorisation, which is for a marketing authorisation containing identical provisions to those contained in the expired authorisation and which is made by the person who held the expired authorisation;

**“standard application”** means any application for the grant of a marketing authorisation which is not a major application, a complex application, a simple application, a change of ownership application or an application for a parallel import licence;

**“standard registration application”** means any application for the grant of a traditional herbal registration which is not a complex registration application, a reduced registration category I, a reduced registration application category II or a change of ownership application;

**“TSE risk excipient from a new source”** and **“TSE risk excipient from a new source”** mean an active ingredient or excipient, respectively, which has been manufactured from raw material of ruminant origin or which has had raw material of ruminant origin used in its manufacture and in respect of which –

- (a) the application names as manufacturer a manufacturer not previously named as the manufacturer of that ingredient or excipient included in a medicinal product in respect of which a marketing authorisation (other

than a product licence of right), a certificate of registration or a traditional herbal registration has previously been granted; and

- (b) no European Pharmacopoeia certificate of suitability covering the excipient has been submitted with the application;

**“vitamin or mineral from a new source”** means a vitamin or mineral in respect of which the application names as manufacturer a manufacturer not previously named as the manufacturer of that vitamin or mineral included in a medicinal product in respect of which a marketing authorisation (other than a product licence of right) or a traditional herbal registration has previously been granted”.