KMAG2.1
Common Technical Module 1 – Administrative Information

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3. Part II: Chemical, pharmaceutical, biological documentation

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1.2 Application Form
The application form is set out as Annex 1 to Administrative Instruction No. 2005/05 ‘On the Marketing Authorisation of Medicinal Products Placed in Kosovo’.

1.3 Summary of Product Characteristics, Labelling and Package Leaflet
A complete set of proposed Summary of Product Characteristics (SPC), packaging and labelling and package leaflet should be submitted in Albanian and Serbian languages (in English language also for the SPC and package leaflet) and use recognised scientific terminology. The proposed SPC, packaging and labelling and package leaflet should be submitted as the following Annexes to the application form:

- Packaging and labelling (i.e. mock-up) – Annex 5.8;
- SPC – Annex 5.9;
- Package leaflet – Annex 5.10.

1.3.1 Summary of Product Characteristics
The SPC is an obligatory part of the MA documentation and is an important subject of the MA application assessment procedure. It represents the approved summary of all essential particulars of the medicinal product. Therefore it is used as a basic source of information and it is not possible to modify it without consent of the competent authority. The SPC provides information primarily for physicians and pharmacists. The sequence of topics is structured to emphasise the clinical orientation and the section Clinical Particulars comes immediately following the introductory characteristics of the medicinal product.

The approval procedure for the SPC depends on the type of application:

- in the case of an application for MA of a medicinal product containing a new active substance in Kosovo, the accuracy of the information in the SPC is compared with the facts included in the MA dossier;
- in the case of an application for MA following the centralised procedure in the EU, it is assumed that the SPC as approved by the Committee for Proprietary Medicinal Products (CPMP) is correct from a factual point of view and the competent authority assesses only the quality of the translation from a linguistic perspective.
- In all other cases the information included in the SPC is assessed and compared with the information from the selected reference literature detailed below. If the information included in the SPC exceeds the scope of this literature, the applicant is asked to provide additional justification to support the proposed wording. The basic reference literature sources are the SPCs approved since January 1, 1995 in EU Member States, USP - DI for the Health Care Professional, PDR Generics and British National Formulary.
The SPC should contain information under all headings. If these are not applicable to the product, the fact that they do not apply should be briefly stated.

The SPC should not contain any advertisement or promotion-like information and must not contain any information about the application of the product to animals.

The text should not include quotes or references, or recommendations of procedures acknowledged in other countries. Likewise, it is not appropriate to include too many cross-references to other parts of the text. The text should not include tables which are not readily transferable into a computer database.

The applicant may use separate SPCs for various presentations of the medicinal product (different package sizes, strengths and pharmaceutical forms). A common SPC for several different presentations of a product may be submitted if all the parts of the SPC do in fact apply to all the presentations included and if the resultant information is not confusing.


The SPC should include the following items of information:

1. **Name of medicinal product**
   - trade name, INN and its ATC classification

2. **Qualitative and quantitative composition**
   - active ingredients (INN, generic name, as per Ph. Eur.),
   - excipients are listed only if they have a significant impact on the properties of the product (e.g. in an ethanol solution).

3. **Pharmaceutical form**
   - a description of the medicinal product with reference to the standardised CPMP terminology

4. **Clinical particulars**
   4.1 Therapeutic indications
   - avoid a global description; the indication(s) should relate as precisely as possible to the results of clinical trials. Indicate: treatment and/or prevention and/or diagnosis.

   4.2 Posology and method of administration
   - the dosage (if required by the nature of the product) should be defined in relation to the patient (body weight, age, gender) and to the indication,
• when the indication allows administration to children, this shall be stated and the relevant dosage and specific age groups shall be specified. If it is to be administered to children under three years of age, the suitability of the pharmaceutical form for this age shall be considered,
• the dosage shall be specified for all declared indications, the dosage assigned to specific indications shall be clear and understandable,
• dose interval and duration,
• dosage adjustment in renal or liver insufficiency or dialysis,
• maximum tolerated daily dose and the maximum dose for an entire course of therapy,
• administration prior or after meals, etc. shall be defined,
• monitoring advice.

4.3 Contraindications
• situations where patients should NEVER or GENERALLY NOT be treated. In rare cases where the medicinal product should NEVER be given this must be specifically outlined,
• only undisputable contra-indications should be specified in this section. Conditional contra-indications should not be stated specifically here. If increased caution is required in certain circumstances, this shall be stated under 4.4.

4.4 Special warnings and special precautions for use
• includes both warnings and substantiated recommendations, as to what subgroups of patients this medicinal product should especially be applied,
• warns prescribers or suppliers of the possibility of class- or drug-related adverse reactions (ADR) occurring under normal conditions of use or in particular situations such as renal, hepatic or cardiac failure, elderly, young etc. (with the exception of pregnancy and lactation, ability to drive and use machines and interactions which are respectively dealt with in 4.5, 4.6, 4.7),
• parameters (e.g. biochemical, haematological) that should be monitored in the course of the treatment shall be stated here,
• this paragraph should also state possible development of tolerance and addiction, including measures to be taken in such cases, and information of the effects of sudden discontinuation of the drug. The SPC shall clearly define the level of addiction potential,
• the warning of fatal or serious adverse reactions may be accompanied by a recommendation of how to reduce the likelihood of their incidence or how these reactions can be alleviated,
• Serious adverse reactions that can be deduced from the nature of the medicinal product, but have not as yet been documented, may be indicated,
• emphasis can be given to a serious risk, by underlining the seriousness (i.e. possibility of death) and presenting the labelling at the top of the paragraph, in bold type, within a box,
• If there is any other data that could be, due to the properties of the product, of particular importance to health care professionals, then this also should be included under this heading.

4.5 Interaction with other medicinal products and other forms of interaction
Show interactions:
• which are observed and/or for which there is potential on the basis of experience with drugs of the same pharmacotherapeutic group which are or may be clinically meaningful,
• with medicinal products used for the same indication,
• with medicinal products used for other indications,
• which involve cross resistance to other medicinal products,
• connected with daily activities, e.g. meals.
• The following information should be given for each interaction:
• mechanism of action (if known),
• consequences on plasma levels of drugs and/or on laboratory and clinical parameters,
• recommendations:
• contra-indication (cross-referral with 4.3),
• not recommended association,
• precautions for use (i.e. dose adjustment),
• or to be taken into account.

4.6 Pregnancy and lactation
• conclusions from animal reproduction/fertility studies and human experience,
• the risk in humans at different times of pregnancy, as assessed from above,
• information on the possibility of using the medicinal product in fertile and pregnant women.
• when the active substance or its metabolites are excreted in the milk, a recommendation as to whether to stop or continue breast feeding, and the likelihood and degree of adverse reactions in the infant should be given,
• all components of the product, i.e. not only the active ingredient, shall be assessed, from the viewpoint of the impact on fetus.

4.7 Effects on ability to drive and use machines
• On the basis of the pharmacodynamic profile, reported ADR and/or impairment of driving performance or performance related to driving the medicinal product is
  a) presumed to be safe or unlikely to produce an effect,
  b) likely to produce minor or moderate adverse effects,
  c) likely to produce severe adverse effects or presumed to be potentially dangerous.
  For situations b) and c), special precautions for use/warnings should be mentioned.

4.8 Undesirable effects
• quantify adverse reactions (frequency in general terms and seriousness),
• significant adverse reactions observed or the most predictable on the basis of
  o toxicology, especially finding from repeated dose toxicity studies,
  o previous clinical experience with medicinal products of the same class.
• possible development of addiction,
• information should be provided about the medicinal product and its individual components.

4.9 Overdose
• experience in animals and humans,
• management of overdose in humans,
• if a specific treatment is known and specific antidotes are indicated in cases of intoxication, the class of products may be stated, or the generic names of the active substances. Reference to trademarks of recommended products should not be included. It is not necessary to state precise dosing instructions for antidotes. The possibility of dialysis should be stipulated, where applicable for treatment of overdosage,
• if there is no known specific treatment, then it is sufficient to state this fact.
5. Pharmacological properties

*Information is given if relevant for therapeutic purposes. Statements should be brief and precise.*

5.1 Pharmacodynamic properties

- pharmacotherapeutic group,
- mechanism of action (if known),
- pharmacodynamic effects relevant for prescription (effects for which there is a demonstration or at least some evidence of a relationship with the therapeutic effect or which may induce ADR),
- the pharmacotherapeutic group is preferably defined in words in terminology based on the ATC classification, but a clear description in known terms is also acceptable.

5.2 Pharmacokinetic properties

*Relevant information should be given on:*

a) general characteristics of the active substance

- absorption, with the bioavailability of the dosage form and, for the oral route, whether it is due to liver first pass effect; incomplete absorption; the influence of food,
- distribution, with reference to plasma protein binding, volume of distribution, tissue and/or plasma concentrations, pronounced multi-compartment behaviour,
- biotransformation, to active metabolites, inactive metabolites and in the case of prodrugs, to the active substance,
- elimination with reference to:
  - the elimination half lives, the total clearance,
  - excretion (with partial clearances),
  - the unchanged substance and metabolites (and their activities),
  - linear or non-linear kinetics,

b) characteristics in patients

- any known relationship between plasma/blood concentrations and the therapeutic activity or adverse drug reactions,
- variations with respect to confounding factors, age, polymorphic metabolism and concomitant pathological situations (renal failure, hepatic insufficiency).

5.3 Preclinical safety data

- Information should be given on any findings in the preclinical testing which could be of relevance for the prescriber, in recognizing the safety and safety profile of the medicinal product used for the registered indication(s), and which is not already included in other relevant sections of the SPC,
- the information should be presented in a way that enables the prescribing physician to apply the benefit/risk of use of the medicinal product for the individual patient.

*Note: During the development of a new medicinal product, a variety of pre-clinical studies will be performed. These are assessed during evaluation of the application. If the results of the studies do not add to the information needed by the prescriber, then the results (either positive or negative) need not be repeated in the SPC.*

6. Pharmaceutical particulars

6.1 List of excipients

- a full statement of the excipients expressed qualitatively,
• international non-proprietary names recommended by WHO (INN) should always be used, the relevant codes may also be included.

6.2 Incompatibilities
Information on physical and chemical incompatibilities of the medicinal product with others with which it is likely to be mixed or co-administered. This will be particularly important for medicinal products to be diluted before parenteral administration. Significant problems of sorption of product to syringes, large volume parenteral containers etc. should be stated.

6.3 Shelf life
• shelf life of the medicinal product as packaged for sale,
• shelf life after dilution or reconstitution according to directions,
• shelf life after first opening the container.

6.4 Special precautions for storage
Storage conditions should be stated unless the stored medicinal product is stable at temperatures up to 25 °C when the medicinal product does not need to bear any special storage instructions. The maximum (or minimum) storage temperatures in Celsius and special precautions in relation to humidity and light should be stated.

6.5 Nature and contents of container / immediate packaging
• A description with reference to standardized CPMP terminology,
• type of packaging, including its size.

6.6 Instructions for use and handling
Instructions for use should not repeat the dosage information. This section should refer in particular to the "mechanical" instructions, e.g. preparation of a ready-to-use administration form (e.g. the way of dissolution, dilution, agitation), turbidity control, use of special applicators, dosage tools, pumps, the speed of application, etc.

Instructions for use/handling are needed where:
• the medicinal product as such is not intended for immediate use and has for instance to be suspended or diluted before administration; claims on compatibilities can be given here provided these have been proven in the dossier,
• due to the nature of the medicinal product or the packaging/closure, the way of using/handling the medicinal product is not obvious without instructions,
• a special dosing device to administer the medicinal product has to be used,
• additional requirements for radiopharmaceuticals.

This section can include the classification of a medicinal product for supply purposes (dispensed by medical prescription only or OTC), and also whether it is included in the list of narcotic or psychotropic substances. The applicant shall decide whether or not the method of supply is to be stated. If indications or dosage differ between the product sold OTC or dispensed by medical prescription only, this shall be pointed out in the relevant paragraphs.

6.7 Special precautions for disposal of unused medicinal products

Environmental risk
7. **Classification**  
*Prescription status - not subject to medical prescription or subject to medical prescription (indicate if medicinal product is on renewable or non-renewable prescription, subject to special medical prescription or on restricted medical prescription reserved for use in certain specialized areas)*

8. Marketing authorisation holder (name and address)  
*The marketing authorisation holder is the applicant*

9. Marketing authorisation number  
*To be issued by the competent authority*

10. Date of first authorisation/renewal of the authorisation  
*To be issued by the competent authority*

11. Data of last/partial revision of the text

For **radiopharmaceutical products**, the following information shall additionally be submitted:

- full details of internal radiation dosimetry;
- detailed instructions for extemporaneous preparation and quality control of such preparation;
- maximum storage time during which any intermediate preparation such as an eluate or the ready-to-use pharmaceutical will conform with its specifications.

1.3.2 **Labelling**

(i). The particulars that shall appear on the outer packaging of medicinal products or, where there is no outer packaging on the immediate packaging, shall consist of:

- the **name of the medicinal product** followed by the common name (international non-proprietary name) of the active substance(s). Where a medicinal product is available in several pharmaceutical forms and/or several strengths, the pharmaceutical form and or the strength (baby, child or adult as appropriate) must be included in the name of the medicinal product;
- a **statement of active substance(s)** expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names;
- the **pharmaceutical form and contents** by weight, by volume or by number of doses of the medicinal product;
- the **list of excipients** known to have a recognised action or effect. If the product is injectable, or a topical or eye preparation, all excipients must be stated;
• the method and route of administration;
• a special warning that the medicinal product must be stored out of reach and sight of children;
• other special warning(s), if necessary;
• the expiry date in a form comprehensible to the user (month/year);
• special storage conditions, if any;
• special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate;
• the name and address of the marketing authorisation holder and the manufacturer (if not the MAH), and where applicable the name of the responsible person appointed by the holder to represent him/her;
• the marketing authorisation number for placing the medicinal product on the market and the authorisation stamp of the competent authority;
• the manufacturer's batch number;
• general classification for supply;
• in the case of non-prescription medicinal products, the instructions on use of the medicinal product;
• EAN Code (if exists).

(ii). Instruction on use shall consist of dosage per 24 hours, method of administration, indication(s) and cautions.

(iii). The outer packaging and the package leaflet may include symbols and pictograms designed to clarify the required information and other information in compliance with the summary of product characteristics which is useful for the patient, to the exclusion of any element of a promotional nature with the exception of a logo or other symbol of the marketing authorisation holder.

(iv). The following particulars at least shall appear on immediate packaging which takes the form of blister packs and are placed in an outer packaging that complies with the requirements set out above:

• name of the medicinal product (trade name, common name, strength and form);
• name of the marketing authorisation holder;
• expiry date;
• batch number.

(v). The following particulars at least shall appear on small immediate packaging units on which the particulars set out in (i) and (iii) cannot be displayed:

• name of the medicinal product (trade name, common name, strength and form);
• route and method of administration;
• name of the marketing authorisation holder;
• expiry date;
• batch number;
• contents by weight, by volume or by unit.
(vi). The information required to be set out on the outer and immediate packaging and on the package leaflet (patient information leaflet) shall be easily legible, clearly comprehensible and indelible.

(vii). The instructions for use on the outer packaging (in the absence of that, on the immediate packaging) must be in at least Albanian and worded so as to be easily legible and comprehensible by a patient. The information may be in other languages in addition.

(viii). One or more mock-ups of the outer and immediate packaging of the medicinal product as well as a draft label, which shall be affixed on the immediate packaging, shall be submitted to the competent authority. A mock-up is a flat artwork, design in full colour, presented so that, following cutting and folding, it provides a replica of both the outer and immediate packaging so that the three dimensional presentation of the label text is clear.

1.3.3 Package Leaflet

Reference should be made to the package leaflet section in the EC Notice to Applicants Volume 2B 2001 Edition.

(i). The package leaflet shall be drawn up in accordance with the Summary of Product Characteristics and shall include, in the following order:

a) for the identification of the medicinal product:

- name of the medicinal product followed by its strength and pharmaceutical form (baby, child or adult as appropriate). The common name (international non-proprietary name) shall be included where the product contains only one active substance and if its name is an invented name;
- pharmaco-therapeutic group or type of activity in terms easily comprehensible for the patient;
- a full statement of the active substance(s) and excipients expressed qualitatively and a statement of the active substance(s) expressed quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names;
- pharmaceutical form and the contents by weight, by volume or by number of doses of the medicinal product;
- name and address of the local representative of the marketing authorisation holder.

b) therapeutic indications.

c) list of information which is necessary before taking the medicinal product and which must take into account the particular condition of certain categories of users (e.g. children, pregnant or breastfeeding women, the elderly, persons with specific pathological conditions), potential effects on the ability to drive vehicles or to operate machinery, list of excipients knowledge of which is important for the safe and effective use of the medicinal product:

- contra-indications;
- appropriate precautions for use;
• forms of interaction with other medicinal products and other forms of interaction (e.g. alcohol, tobacco, foodstuffs) which may affect the action of the medicinal product;
• special warnings.

d) the necessary and usual instructions for proper use, in particular:
• dosage;
• method and, if necessary, the route of administration;
• frequency of administration, specifying if necessary, the appropriate time at which the medicinal product may or must be administered;
and, as appropriate, depending on the nature of the medicinal product:
• duration of treatment, where it should be limited;
• action to be taken in the case of an overdose (e.g. symptoms, emergency procedures);
• course of action to take when one or more doses have not been taken;
• indication, if necessary, of the risk of withdrawal effects.

e) description of the adverse reactions which can occur under normal use of the medicinal product and, if necessary, the action to be taken in such a case. The patient should be expressly invited to communicate any undesirable effect which is not mentioned in the leaflet to his doctor or to his pharmacist.

f) a reference to the expiry date indicated in the labelling with:
• a warning against using the medicinal product after this date;
• where appropriate, special storage precautions;
• if necessary, a warning against certain visible signs of deterioration.

g) the date on which the package leaflet was last revised.

(ii). If contraindications and side effects are not known, such facts must be literally written in the package leaflet, that is, it cannot be stated that contraindications and side effects do not exist.

(iii). The package leaflet may include other information in conformance with the SPC that are useful for health education with exclusion of any element of a promotional nature.

(iv). The package leaflet must be in both Albanian and Serbian languages (English is optional, but if not included in the package leaflet mock-up then a copy in English should be provided), in clear and understandable terms for the patient and be clearly legible.

(v). Special provisions for Radiopharmaceuticals
For radiopharmaceuticals, labelling and package leaflet shall also be in conformance with the following provisions:
a). the outer carton and container of medicinal products containing radionuclides shall be labelled in accordance with the regulations for the safe transport of radioactive materials laid down by the International Atomic Energy Agency;

b). the label on the shielding shall include the particulars set out in Para 1.3.2 (i) above. In addition, the labelling on the shielding shall explain in full the codings used on the vial and shall indicate, where necessary, for a given time and date, the amount of radioactivity per dose or per vial and the number of capsules or, for liquids, the number of milliliters in the container;

c). the vial shall be labelled with the following information:
   - name or code of the medicinal product, including the name or chemical symbol of the radionuclide;
   - batch identification and expiry date;
   - international symbol for radioactivity;
   - name of the manufacturer;
   - amount of radioactivity as specified in b) above.

d). a detailed package leaflet should be provided for radiopharmaceuticals, radionuclide generators, radionuclide kits and radionuclide precursors in accordance with the provisions set out in 1.3.3. In addition, the package leaflet shall include any precautions to be taken by the user and the patient during the preparation and administration of the medicinal product and special precautions for the disposal of the packaging and its unused contents.

1.3.4 Mock-ups and specimens
A mock-up or specimen of the sales presentation must be included with the application as Annex 5.8 to the application form.

A ‘mock up’ is a copy of the flat artwork design in full colour, providing a replica of both the outer and immediate packaging, providing a two dimensional presentation of the packaging / labelling of the medicinal product. It is generally referred to as a ‘paper copy’ or ‘computer generated version’.

A ‘specimen’ should be interpreted as referring to a sample of the actual printed inner and outer packaging and package leaflet.

1.3.5 SPCs already approved in other European countries
The currently valid SPCs approved for use in all European countries where the medicinal product is authorised should be submitted with the application as Annex 5.23 to the application form.
1.4 Information about the Experts

Experts must provide detailed reports of their observations on the documents and particulars which constitute the marketing authorisation dossier and in particular on Modules 3, 4, and 5 (Part II, III and IV in ‘old EU’ format).

The experts are required to address the critical points related to the quality of the medicinal product and of the investigations carried out on animals and human beings and bring out all the data relevant for evaluation.

These requirements shall be met by providing a quality overall summary (Part II expert report in ‘old EU’ format), a nonclinical overview / summary (Part III expert report in ‘old EU’ format) providing data from studies carried out in animals and a clinical overview / summary Part IV expert report in ‘old EU’ format) that shall be located in Module 2 of the marketing authorisation application dossier as described in Volume 2 B of The rules governing medicinal products in the European Community.

A declaration signed by the experts together with brief information on their educational background, training and occupational experience shall be presented in Section 1.4 of Module 1. The professional relationship of the expert to the applicant shall be declared.

The required qualifications for experts are as follows:

- Quality Overall Summary (Part II expert report) – qualifications in pharmaceutical science (i.e. at least BSc.Pharm. or its equivalent) and practical experience in development and research and/or manufacture of medicinal products and/or quality control of medicinal products;
- Non Clinical Overview / Summary (Part III expert report) - qualifications in toxicology and/or pharmacology (i.e. at least BSc.Pharm. or Bsc.Med or its equivalent), and specialising in the toxicology and pharmacology area with practical experience in that area;
- Clinical Overview / Summary (Part IV expert report) - qualifications in clinical usage of the product (i.e. at least Bsc.Med or its equivalent) and working experience in pharmacovigilance.

The experts should state in particular:

- in the case of the quality expert, whether the medicinal product is consistent with the declared composition, giving any substantiation of the control methods employed by the manufacturer;
- in the case of the non clinical expert, the toxicity of the medicinal product and the pharmacological properties observed;
- in the case of the clinical expert, whether he has been able to ascertain effects on persons treated with the medicinal product which correspond to the particulars given by the applicant and whether the patient tolerates the medicinal product well, the posology the clinician advises and any contra-indications and adverse reactions;
- in the case of an application for authorisation of a medicinal product claiming well established medicinal use, the grounds for using the bibliography submitted.
1.4.1 Information about the Expert - Quality

According to his / her respective qualifications the undersigned expert declares hereby to have performed the duties set out in …………… in accordance with …………

Quality:

Name of the expert: ________________________                   Signature: ________________________
Address:                   ________________________
                                  ________________________
                                  ________________________
                                  ________________________

Date:
Brief information on the educational background, training and occupational experience is attached.

1.4.2 Information about the Expert – Non Clinical

According to his / her respective qualifications the undersigned expert declares hereby to have performed the duties set out in …………… in accordance with …………

Non Clinical (pharmacology, pharmacokinetics, toxicology):

Name of the expert: ________________________                   Signature: ________________________
Address:                   ________________________
                                  ________________________
                                  ________________________
                                  ________________________

Date:
Brief information on the educational background, training and occupational experience is attached.

1.4.3 Information about the Expert - Clinical

According to his / her respective qualifications the undersigned expert declares hereby to have performed the duties set out in …………… in accordance with …………

Clinical:

Name of the expert: ________________________                   Signature: ________________________
Address:                   ________________________
                                  ________________________
                                  ________________________
                                  ________________________

Date:
Brief information on the educational background, training and occupational experience is attached.

1.5 Specific requirements for different types of applications

1.5.1 Information for well established medicinal use (bibliographical) applications
In this section a concise document (up to 5 pages) should be provided that summarises the grounds and evidence used for demonstrating that the constituent(s) of the medicinal product have a well established use with an acceptable level of safety and efficacy.

Guidelines are provided in ‘Annex 3 - Guidelines for applications under the well established medicinal use (bibliographical) simplified procedure’.

1.5.2 Information for applications under other simplified procedures and certain types of medicinal product

This section applies to the following types of applications:

<table>
<thead>
<tr>
<th>Application type</th>
<th>Regulation reference / Guideline</th>
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<tbody>
<tr>
<td>(a) Simplified procedure pursuant to:</td>
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<tr>
<td>Essential Similarity (Informed consent)</td>
<td>• specific reference to requirements set out in Section 6 Para 2.1 of the MA regulation</td>
</tr>
<tr>
<td></td>
<td>• KMAG9 - Essentially similar medicinal products and guidelines for substantiation of bioavailability and bioequivalence</td>
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<tr>
<td>Essential Similarity (Generic)</td>
<td>• specific reference to requirements set out in Section 6 Para 2.2 of the MA regulation</td>
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<td></td>
<td>• KMAG9</td>
</tr>
<tr>
<td>Essential Similarity (Generic different)</td>
<td>• specific reference to requirements set out in Section 6 Para 2.3 of the MA regulation</td>
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<td></td>
<td>• KMAG9</td>
</tr>
<tr>
<td>Vitamins / mineral substances</td>
<td>• specific reference to requirements set out in Section 6 Para 5 of the MA regulation</td>
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<tr>
<td>New fixed combination</td>
<td>• specific reference to requirements set out in Section 6 Para 3 of the MA regulation</td>
</tr>
<tr>
<td>EU-CADREAC Centralised procedure</td>
<td>• specific reference to requirements set out in Section 6 Para 7 of the MA regulation</td>
</tr>
<tr>
<td>EU – CADREAC Decentralised procedure</td>
<td>• specific reference to requirements set out in Section 6 Para 8 of the MA regulation</td>
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<tr>
<td>(b) medicinal product type:</td>
<td></td>
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<tr>
<td>Biological medicinal product</td>
<td>• KMAG13 - Special provisions for Biological Medicinal Products</td>
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<td>KMAG Numbers and Additional Provisions</td>
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<td>Advanced therapy medicinal product</td>
<td>KMAG17 - Special provisions for Advanced Therapy Medicinal Products</td>
</tr>
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</table>

For applications using the simplified procedures stated above or applications based on medicinal product type’s state above, a brief statement should be made that the application dossier incorporates the additional information required in accordance with the relevant regulation reference and/or guideline.

**Annex to Module 1 – Environmental Risk Assessment**

Applications for marketing authorisations shall include a risk assessment overview evaluating possible risks to the environment due to the use and/or disposal of the medicinal product and make proposals for appropriate labelling provisions. This report shall be signed and information on educational background, training and occupational experience of the author should be included.