



**Republika e Kosovës**  
**Republika Kosova-Republic of Kosovo**  
*Qeveria - Vlada - Government*

**MINISTRIA E SHËNDETËSISË/MINISTARSTVO ZDRAVSTVA/MINISTRY OF HEALTH**

**Udhëzimin Administrativ (në Shëndetësi) Nr. 20/2013 Për Plotësimin dhe Ndryshimin e Udhëzimit Administrativ Nr.17/2013 Mbi Autorizim të Marketingut për Plasimin e Produkteve Medicinale në Republikën e Kosovës**

**Administrative Instruction (Health) No. 20/2013 for ammending Administrative Instruction No.17/2013 For Marketing Authorization to be placed in the market of the Republic of Kosovo**




**Administrativno Upustvo( Zdravstvo) br. 20-2013 o izmeni Administrativnog Upustva br.17/2013 O ovlašćenju medicinskih proizvoda za plasiranje na tržište Republike Kosova**



<p><b>Ministri i Ministrisë së Shëndetësisë,</b></p> <p>Në mbështetje të nenit 18 paragrafi 10, të Ligjit Nr.03/L-188 për Produkte dhe Pajisje Medicinale (Gazeta Zyrtare Nr. 84/03 Nëntor 2010), nenit 8 nënparagrafi 1.4 të Rregullores Nr. 02/2011 për fushat e përgjegjësisë administrative të Zyrës së Kryeministrit dhe Ministrive si dhe nenit 38 paragrafit 6 të Rregullores së Punës së Qeverisë Nr.09/2011 (Gazeta Zyrtare Nr. 15, 12.09.2011), nxjerr:</p> <p><b>Udhëzimin Administrativ (në Shëndetësi) Nr.20-2013 Për Plotësimin dhe Ndryshimin e Udhëzimit Administrativ Nr.17/2013 Mbi Autorizim të Marketingut për Plasimin të Produkteve Medicinale në Republikën e Kosovës</b></p> <p style="text-align: center;"><b>Neni 1</b></p> <p>Nenit 5 të Udhëzimit Administrativ bazik, paragrafit 2 i shtohet një nën paragraf i ri, si në tekstin në vijim:</p> <p>1.Për produktet medicinale të cilat nuk posedojnë autorizim marketingu në Kosovë për terapi individuale për përdorim të mëshirshëm.</p>	<p><b>Minister of Ministry of Health,</b></p> <p>Based on article 93, paragraph 4, of the Constitution of the Republic of Kosovo;l based on article 20, paragraph 20.1 of Law 2004/50 on Private Health Activities; taking into consideration article 38, paragraph 2 and 6 of the Work Regulation of the Government of the Republic of Kosovo No.09/2011 and article 8 and Annex 9 of Regulation No.02/11 on the Fields of Administrative Responsibility of the Office of the Prime Minister and the Ministries, issues the following:</p> <p><b>Administrative Instruction (Health) No.20-2013 for ammending Administrative Instruction No.17/2013 For Marketing Authorization to be placed in the market of the Republic of Kosovo</b></p> <p style="text-align: center;"><b>Article 1</b></p> <p>Article 5 of the Basic Administrative Instruction, to paragraph 2 is added a new sub-paragraph as following:</p> <p>1.For medicinal products that do not have marketing authorization in Kosovo for individual therapy in compassionate use.</p>	<p><b>Ministar Ministarstva Zdravlja,</b></p> <p>Na osnovu člana 93, stav 4, Ustava Republike Kosova, na osnovu člana 20, stav 20.1 Zakona br.2004/50 o privatnoj zdravstvenoj delatnosti ; uzimajući u obzir član 38 stav 2 i 6 Pravilnika o radu Vlade Republike Kosova br. 09/2011 i člana 8 Priloga 9 Pravilnika br. 02/11 o oblastima administrativne odgovornosti Kancelarije Premijera i ministarstava, donosi:</p> <p><b>Administrativno Upustvo( Zdravstvo) Br. 20/2013 o izmeni Administrativnog Upustva br.17/2013 O ovlašćenju medicinskih proizvoda za plasiranje na trziste Republike Kosova</b></p> <p style="text-align: center;"><b>Član 1</b></p> <p>Član 5 bazičnog AU , stav 2. dodaje se nova tačka , kao u sledećem tekstu :</p> <p>1. Za lekovi koji nemaju dozvolu na Kosovu za individualnu terapiju za milostivosti upotrebu .</p>
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<p style="text-align: center;"><b>Neni 2</b></p> <p>1.Neni 10 i Udhëzimit Administrativ bazik, paragrafi 2, nën-paragrafi 2.6, ndryshohet dhe plotësohet si në tekstin në vijim:</p> <p>1.Mock-up në alfabetin latin ose në gjuhët zyrtare të Republikës së Kosovës kur nuk është në alfabetin latin.</p> <p>2.Nën-nënparagrafi i Udhëzimit Administrativ bazik 2.6.1, 2.6.2, 2.6.3, 2.6.4, 2.6.5.2.6.6, 2.6.7, 2.6.8, 2.6.9. fshihet nga teksti i Udhëzimit.</p>	<p style="text-align: center;"><b>Article 2</b></p> <p>Article 10 of the basic Administrative Instruction , paragraph 2, sub-paragraph 2.6, is amended and added as in the following text:</p> <p>1.Mock ups in latin alphabet or in official languages of the Republic of Kosovo, when it is not in latin alphabet.</p> <p>2.Sub-paragraph of the Basic Administrative Instruction 2.6.1, 2.6.2, 2.6.3, 2.6.4, 2.6.5.2.6.6, 2.6.7, 2.6.8,2.6.9. is deleted from the Instruction text.</p>	<p style="text-align: center;"><b>Član 2</b></p> <p>1. Član 10 Administrativnog Upustva 1 , stav 2 , tačka 2.6 , se izmeni i dopuni se u sledećem tekstu :</p> <p>1.Mock-up latinske azbuke ili na službenim jezicima Republike Kosova kada nije po latinskoj azbuci.</p> <p>2. Član – tačke Administrativnog Upustva 2.6.1 , 2.6.2 , 2.6.3 , 2.6.4 , 2.6.5.2.6.6 , 2.6.7 , 2.6.8 , 2.6.9. briše se od teksta ovog Administrativnog Upustva.</p>
<p style="text-align: center;"><b>Neni 3</b></p> <p>Neni 11 i Udhëzimit Administrativ bazik, paragrafi 2, nën-paragrafi 2.5 ndryshohet si në vijim:</p> <p>Mock- up si në nenin 10 paragrafin 2, nën-paragrafin 2.6 të këtij Udhëzimi Administrativ.</p>	<p style="text-align: center;"><b>Article 3</b></p> <p>Article 11 of the Basic Administrative Instruction, paragraph 2, sub-paragraph 2.5, is amended as follows:</p> <p>Mock up as in article 10, paragraph 2, sub-paragraph 2.6 of this Administrative Instruction.</p>	<p style="text-align: center;"><b>Član 3</b></p> <p>Član 11 osnovnog Administrativnog Upustva, stav 2 , tačka 2.5 menja se i glasi:</p> <p>Mock-up kao u članu 10. stav 2 , tačka 2.6 ovog Administrativnog Upustva .</p>
<p style="text-align: center;"><b>Neni 4</b></p> <p>Neni 13 i Udhëzimit Administrativ bazik, paragrafi 2, nën-paragrafi 2,5 ndryshohet si në vijim:</p> <p>Mock- up si në nenin 10 paragrafin 2, nën-paragrafin 2.6, të këtij Udhëzimi Administrativ</p>	<p style="text-align: center;"><b>Article 4</b></p> <p>Article 13 of the Basic Administrative Instruction, paragraph 2, sub-paragraph 2.5, is amended as following:</p> <p>Mock up as in article 10, paragraph 2, sub-paragraph 2.6 of this Administrative Instruction.</p>	<p style="text-align: center;"><b>Član 4</b></p> <p>Član 13 osnovnog Administrativnog Upustva, stav 2 , tačka 2.5 menja se i glasi :</p> <p>Mock-up kao u članu 10. stav 2 , tačka 2.6 ovog Administrativnog Upustva .</p>
<p style="text-align: center;"><b>Neni 5</b></p> <p>Neni 20 i Udhëzimit Adminstrativ bazik pas Nenit 21 fshihet dhe bëhet Neni 22 i cili ndryshohet dhe plotësohet si në vijim:</p>	<p style="text-align: center;"><b>Article 5</b></p> <p>Article 20 of the Basic Administrative instruction is deleted and becomes Article 22 which is amended and added as following:</p>	<p style="text-align: center;"><b>Član 5</b></p> <p>Član 20 Osnovnog Administrativnog uputstva 21 briše se i sledeći član je član 22 , koji se menja i dopunjuje glasi :</p>

<p>1.Tarifat që duhet të paguhen për shërbimet në AKPM janë të përcaktuara në ankesin 8.</p> <p style="text-align: center;"><b>Neni 6</b></p> <p>Neni 21 fshihet dhe bëhet neni 23, dhe i shtohet ankesi 8 në Udhëzimin Administrativ bazik.</p> <p>Neni 21 paragrafi 7 i Udhëzimit Administrativ bazik citojmë: Në këtë rast vlen për produktet e prodhura në Turqi plotësohet si në vijim:</p> <p>Në këtë rast vlen për produktet e prodhura në Turqi të cilat kanë të drejtë të Autorizimit për Marketing në Turqi.</p> <p style="text-align: center;"><b>Neni 7 Hyrja në fuqi</b></p> <p>Ky udhëzim administrativ hyn në fuqi ditën e nënshkrimit nga ana e Ministrit.</p> <p>Prishtinë, 19/11/2013</p> <p style="text-align: center;"><b>Ministri i Shëndetësisë Dr Ferid Agani</b></p> 	<p>Service fees which has to be paid to KMA are defined in Annex 8.</p> <p style="text-align: center;"><b>Article 6</b></p> <p>Article 21 is deleted and becomes Article 23, and is added to it Annex 8 in Basic Administrative Instruction.</p> <p>Article 21, paragraph 7 of the Basic Administrative Instruction we cite: In this case it is valid for medicinal products manufactured in Turkey is added as following:</p> <p>In this case it's valid for products manufactured in Turkey which posses the right of Marketing Authorization in Tureky.</p> <p style="text-align: center;"><b>Article 7 Entry into the force</b></p> <p>This Administrative Instruction enters into the force after the signature by the Minister.</p> <p>Prishtina, 19/11/2013</p> <p style="text-align: center;"><b>Minister of Health Dr Ferid Agani</b></p> 	<p>1.Tarife za usluge koje treba da budu plaćene za usluge u KAMP su navedene u aneks 8 .</p> <p style="text-align: center;"><b>Član 6</b></p> <p>Član 21 se briše i postaje član 23 , dodaje mu se aneks 8 u ovom Uputstvo.</p> <p>Član 21 , stav 7 osnovnog administrativnog uputstva citiramo: U ovom se slučaju odnosi na proizvode proizvedene u Turskoj dopunjen na sledeći način:</p> <p>U ovom slučaju se odnosi na proizvode proizvedene u Turskoj koji imaju ovlašćenja Marketinga za stavljanje u promet u Turskoj .</p> <p style="text-align: center;"><b>Član 7 Stupanje na snagu</b></p> <p>Ovo Administrativno uputstvo stupa na snagu na dan potpisivanja od strane ministra .</p> <p>Prishtina, 19/11/2013</p> <p style="text-align: center;"><b>Minister of Health Dr Ferid Agani</b></p> 
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## KMA MA Form No. 1

<b>Kosovo Medicines Agency</b> <b>Agjencioni i Kosovës për Produkte Medicinale</b> Rrethi i Spitalit (QKU) 10000, Prishtinë, Kosovë Tel: +381 (38) 512 066; Fax: +381 (38) 512 243 www.akpm-rks.org	Date Received:	Protocol No:
	Application processing start date :	
	MA No:	
<b>Application for a medicinal product marketing authorization</b>	MA issue date:	MA exp. date:
	(KMA to fill out)	

**Declaration and signature**

Product (invented) name:

Strength(s):

Pharmaceutical form:

Active substance(s):

Applicant:

Person authorized for communication on behalf of the applicant\*:

It is hereby confirmed that all existing data which are relevant to the quality, safety and efficacy of the medicinal products have been supplied in the dossier as appropriate and samples of the finished product, active substance(s) and excipient(s) sufficient for analysis\*\*.

It is hereby confirmed that the marketing authorization fees have been paid to the Kosovo Medicines Agency\*\*\*.

On behalf of the applicant

Signature \_\_\_\_\_

Name \_\_\_\_\_

Function \_\_\_\_\_

Place \_\_\_\_\_ Date (yyyy-mm-dd) \_\_\_\_\_

\* Attach letter of authorization for communication/signing on behalf of the applicant and agency agreement as Annex 5.1<sup>1</sup> ○ and proof of legal establishment of authorized person in Kosovo as Annex 5.2<sup>1</sup> ○

\*\* Attach two samples (in final immediate packaging without final labelling) in sufficient quantity to permit a full assay and the verification of the control methods used by the manufacturer (and reference substances if referred to in the testing procedure if requested) as Annex 5.3 ○

\*\*\* Attach proof of payment as Annex 5.4<sup>2</sup> ○

**1. Type of Product and Type of Application****1.1 Type of medicinal product<sup>3</sup>**

- |  |   |                           |
|--|---|---------------------------|
| (i) Chemical active substance(s) <input type="checkbox"/>    | (v) Dietary supplements <input type="checkbox"/>              |                           |
| (ii) Biological active substance(s) <input type="checkbox"/> | (vi) Vitamins and mineral substances <input type="checkbox"/> | (ix) Orphan / Exceptional |
| (iii) Radiopharmaceutical <input type="checkbox"/>           | (vii) Homeopathic <input type="checkbox"/>                    | (x) Other (Specify)       |
| (iv) Herbal <input type="checkbox"/>                         | (viii) Advanced therapy <input type="checkbox"/>              |                           |

(Mark relevant box(es) with X)

**1.2 Type of application**(i) Complete and independent (Stand alone) ☐<sup>4</sup>

- New active substance ☐
- Known active substance ☐

(ii) New fixed combination ☐<sup>5</sup>

(iii) Simplified procedure pursuant to:

(a) Well Established Medicinal Use (bibliographical) ☐<sup>6</sup>(b) Essential Similarity (Informed consent) ☐<sup>7</sup>

Existing authorized product (in EU Member State, or EU-accessing state):

- Product name, strength, pharmaceutical form:
- Marketing authorization holder:
- Marketing authorization number(s):
- Attach latest SPC and package leaflet as Annex 5.5 ☐
- Attach informed consent letter of marketing authorization holder of authorized medicinal product as Annex 5.6 ☐

(c) Essential Similarity (Generic) ☐<sup>8</sup>

I. Original medicinal product (authorized for not less than 10 years in either an EU Member State or EU-accessing state):

- Product name, strength, pharmaceutical form:
- Marketing authorization holder:
- First authorization date (yyyy-mm-dd):
- State where first authorized:
- Attach latest SPC and package leaflet as Annex 5.5 ☐

II. Reference medicinal product (if different from the original medicinal product, the reference medicinal product should have a valid full non abridged dossier available and should be currently marketed in either an EU Member State, or EU-accessing state):

- Product name, strength, pharmaceutical form:
- Marketing authorization holder:
- Marketing authorization number(s):
- State where first authorized:
- Attach latest SPC and package leaflet as Annex 5.5 ☐

III. Medicinal Product used for bioequivalence study (where applicable):

- Product name, strength, pharmaceutical form:
- Marketing authorization holder:
- State of source:





**2.4 Pharmaceutical form and strength<sup>20</sup>****2.5 Route(s) of administration<sup>21</sup>****2.6 Packaging and package size(s)<sup>22</sup> (attach list of Mock-ups or Samples/specimens as Annex 5.7 ○)**

(i) Immediate packaging:	(ii) Outer packaging:	(iii) Package size(s):
(iv) Shelf life (as specified in the SPC proposal):	(v) Shelf life (after first opening container):	(vi) Shelf life (after reconstitution or dilution):
(vii) Storage conditions: (as specified in the SPC proposal)		(viii) Storage conditions after first opening: (as specified in the SPC proposal)

**2.7 Summary of Product Characteristics (SPC) proposal<sup>23</sup> (attach as Annex 5.8 ○)**English ☐ Other languages (optional) ☐ (Specify):**2.8 Package Leaflet proposal<sup>24</sup> (attach as Annex 5.9 ○)**Albanian ☐ Serbian ☐ English ☐ Other ☐ (Specify):**2.9 Description of the medicinal product<sup>25</sup>****2.10 Proposed dispensing classification (legal status) (Tick appropriate box(es) with X)**

Subject to medicinal prescription <input type="checkbox"/>		Not subject to medicinal prescription <input type="checkbox"/>	
If subject to medicinal prescription:			
(i) prescription which may be automatically renewed <input type="checkbox"/>	(iv) product on restricted prescription <input type="checkbox"/>		
(ii) prescription which may not be automatically renewed <input type="checkbox"/>	(v) product for use only in in-patient health facilities <input type="checkbox"/>		
(iii) product on special prescription <input type="checkbox"/>			
Promotion of products not subject to medicinal prescription:			
Promotion to health care professionals only <input type="checkbox"/>		Promotion to the general public and health care professionals <input type="checkbox"/>	

**2.11 "Birth date" of the product for pharmacovigilance purposes<sup>26</sup>**

EU ☐ International ☐

Active substance contained in a medicinal product registered in the world more than 5 years Yes ☐ No ☐

**2.12 Qualitative and quantitative composition****(i) Qualitative and quantitative composition in terms of the active substance(s) and the excipient(s):**

Dosage type (e.g. capsule):			
Name	Quantity	Unit	Reference/Monograph standard
Active substance (s)			
Excipient (s) ampoules			

Details of any overages should not be included in the formulation columns but stated below.

- active substance(s): \_\_\_\_\_
- excipient(s): \_\_\_\_\_

(ii) Are materials of animal and / or human origin contained or used in the manufacturing process of the medicinal product?

No ☐Yes ☐ (if yes, please fill out the separate form attached to this application form and attach as Annex 5.10 ☐; attach Ph. Eur. Certificate of Suitability for TSE if available as Annex 5.11 ☐; if not available include appropriate data in the dossier)

(iii) Does the medicinal product contain or consist of Genetically Modified Organisms (GMOs)?

No ☐Yes ☐ (if yes, complete relevant section of Annex to CTD Module 1/EU Part I)**2.13 Marketing authorization holder / contact persons / company**

(i) Applicant :

Company name:

Address

Country:

Tel:

Fax :

Contact person at this address:

(ii) Authorized person in Kosovo<sup>27</sup> :

Name:

Company name

Address

Tel:

Fax:

E-mail:

• Attach power of attorney, copy of contract with MAH and, proof of establishment of authorized person as Annex 5.2 ☐

(iii) Qualified person for Pharmacovigilance<sup>28</sup> :

Name:

Company name:

Address:

Tel

Fax:

E-mail:

• Attach CV and copy of contract of qualified person for pharmacovigilance with MAH, as Annex 5.12 ☐

**2.14 Manufacturer(s)**

(i) Authorized manufacturer(s) (or importer) responsible for batch release (as shown in the package leaflet and where applicable in the labeling):

Company name

Address:

Country:

Tel:

Fax :

E-mail:

Contact person at this address:

Manufacturing Authorization number:

- Attach original /copy of valid manufacturing authorization (Annex 5.13 )☐
- Attach latest GMP certificate (Annex 5.16)

**For Blood Products and Vaccines:**

Details of the state laboratory or laboratory designated for that purpose (OMCL) where the official batch release takes place:

Name:

Address:

Country:

Tel:

Fax:

E-mail:

(ii) **Manufacturer(s) of the medicinal product and site(s) of manufacture** (including a description of the manufacturing steps performed) <sup>29</sup>:

Company name:

Address

Country:

Tel

**Fax :**

E-mail:

Contact person at this address:

Brief description of manufacturing steps performed:

Manufacturing Authorization number:

- Attach original /copy of valid manufacturing authorization (Annex 5.15 )☐
- Attach latest GMP certificate (Annex 5.16)



**(iii) Manufacturer of the active substance(s):<sup>50</sup>**

I. Substance:

Company name:

Address:Tel:Fax:**(a) Has a Ph. Eur. Certificate of Suitability been issued for the active substance(s):** ☐ No ☐ Yes

If yes,

- substance:
- manufacturer name:
- reference number:
- date of last update (yyyy-mm-dd):
- provide copy of Certificate of Suitability as Annex 5.18 ☐

**(b) Is a European Drug Master File to be used for the active substance(s) reference / original?** ☐ No ☐ Yes

If yes,

- substance:
- manufacturer name:
- reference number:
- date of last update (yyyy-mm-dd):
- attach letter of access for the Kosovo Medicines Agency
- attach copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications as Annex 5.19 ☐

Provide statement from competent authority that conducted last GMP inspection that site is GMP compliant (for each site) as Annex 5.16 ☐

OR

For each active substance, attach a copy of Qualified Person declaration that the active substance is manufactured in compliance with the detailed guidelines on good manufacturing practice for starting materials (Annex 5.16)

- attach copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications as Annex 5.19 ☐

**(iv) Contract companies used for bioavailability / bioequivalence or used for the validation of blood product manufacturing processes**

Manufacturer name:

Address:

Tel:

Fax:

E-mail:

Duty performed according to contract:

Location of performance of analytical tests and clinical data collection:

Country:  
Date of authorization (yyyy-mm-dd).  
Invented name:  
Authorization number:  
Attach copy of marketing authorization in Annex 5.200

Date of authorization (yyyy-mm-dd):  
 Invented name:  
 Authorization number:  
 \* Attach copy of marketing authorization in Annex 5.200

Country: \_\_\_\_\_  
Date of submission (yyyy-mm-dd): \_\_\_\_\_

Country: \_\_\_\_\_  
Date of refusal (yyyy-mm-dd): \_\_\_\_\_  
Reason for refusal: \_\_\_\_\_

Country:  
Date of withdrawal (yyyy-mm-dd):  
Reason for withdrawal:

Country:  
Date of withdrawal (yyyy-mm-dd):  
Invented name:  
Authorization number:  
Reason for withdrawal:

Country:  
Date of suspension/revocation (yyyy-mm-dd):  
Invented name:  
Reason for suspension/revocation:

[illegible]

(iii) Intellectual property protection to be applied for in Kosovo :

- Product composition ☐ No ☐ Yes (if applicable, attach declaration of originality as Annex 5.21 O)  
 • Trade name ☐ No ☐ Yes (if applicable, attach declaration of originality as Annex 5.21 O)

**5. Annexed documents**

		Yes	N/A
5.1	Letter of authorization for communication on behalf of the applicant(MAH) and agency agreement (original or legally attested copy)	<input type="checkbox"/>	<input type="checkbox"/>
5.2	Proof of legal establishment of authorized person in Kosovo	<input type="checkbox"/>	<input type="checkbox"/>
5.3	Samples of the finished medicinal product. Active substance(s), excipient(s) and reference substances (if requested from Control Laboratory of KMA)	<input type="checkbox"/>	<input type="checkbox"/>
5.4	Evidence of fee payment	<input type="checkbox"/>	<input type="checkbox"/>
5.5	Packaging mock-ups or samples/specimens attached to the application	<input type="checkbox"/>	<input type="checkbox"/>
5.6	SPC proposal (in English language)	<input type="checkbox"/>	<input type="checkbox"/>
5.7	Package leaflet / PIL / Package insert proposal (in Albanian & Serbian languages)	<input type="checkbox"/>	<input type="checkbox"/>
5.8	Materials of animal/human origin form completed	<input type="checkbox"/>	<input type="checkbox"/>
5.9	Ph.Eur. Certificate of Suitability for TSE	<input type="checkbox"/>	<input type="checkbox"/>
5.10	Attach CV and copy of contract of qualified person for pharmacovigilance with MAH, as Annex 5.12 <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.11	Manufacturing authorization for manufacturer releasing batches (original or copy)	<input type="checkbox"/>	<input type="checkbox"/>
5.12	Manufacturing authorization for all manufacturing sites mentioned in the application (original or copy)	<input type="checkbox"/>	<input type="checkbox"/>
5.13	Statement from competent authority that conducted last GMP inspection that site is GMP compliant (for each site including manufacturer of the active substance(s), or Declaration from Qualified Person from batch release that the active substance is manufactured in compliance with the detailed guidelines on good manufacturing practice for starting materials.	<input type="checkbox"/>	<input type="checkbox"/>
5.14	CPP (original)	<input type="checkbox"/>	<input type="checkbox"/>
5.15	Ph. Eur. Certificate of Suitability or Drug Master File(s)	<input type="checkbox"/>	<input type="checkbox"/>
5.16	Copy of marketing authorization(s) in country of origin and third countries (a photocopy of the pages which give the marketing authorization number, the date of authorization and the page which has been signed by the authorizing competent authority)	<input type="checkbox"/>	<input type="checkbox"/>
5.17	Declaration of originality (copy of property protection) if applicable	<input type="checkbox"/>	<input type="checkbox"/>
5.18	CTD Module 1: Administrative information	<input type="checkbox"/>	<input type="checkbox"/>
5.19	CTD Module 2: CTD Summaries	<input type="checkbox"/>	<input type="checkbox"/>
5.20	CTD Module 3: Chemical, pharmaceutical and biological information	<input type="checkbox"/>	<input type="checkbox"/>
5.21	CTD Module 4: Non clinical reports	<input type="checkbox"/>	<input type="checkbox"/>
5.22	CTD Module 5: Clinical study reports	<input type="checkbox"/>	<input type="checkbox"/>
5.23	CD Rom of full dossier / pharmbridge-DAMOS format / PDF / HTML / XML (in addition to the paper documentation of identical content)	<input type="checkbox"/>	<input type="checkbox"/>
5.24	SPC, package leaflet (PIL) and mock-up in the required languages on a CD in Word format	<input type="checkbox"/>	<input type="checkbox"/>

Number of pages added by the applicant because of lack of space in any part of the application form:

All documentation:	submitted / not submitted
All pages and volumes present and marked:	yes / no
Documentation:	accepted / not accepted
Documentation not accepted for reasons :	
Signature of KMA officer:	
Date:	(KMA to fill out)



**Instructions for the applicant**

The application form may be completed by typewriter or computer. If there is insufficient space to complete any part of the application form, please use additional pages, which then will become an integral part of the application. In the appropriate part, specify that there is an additional appendix. References to already submitted documentation are not permitted. The application should be completed in compliance with valid KMA guidelines or other documents that are referred to. All guidelines can be found on the KMA web site ([www.kma.gov.mk](http://www.kma.gov.mk)) or are obtainable directly from the KMA premises.

1. Any legal or physical entity, authorized by the applicant to communicate with KMA is considered as the authorized person. This person submits to KMA the officially verified authorization by the applicant. Each applicant without a permanent residence or a registered office in Kosovo has a duty to authorize an authorized person with an address in Kosovo to submit the application and to communicate with KMA. The following documents should be provided:

- \* a letter of authorization to communicate on behalf of the applicant (MAH) and original of agency agreement or a legally attested copy of the agency agreement between the applicant/MAH and the authorized person (attach as Annex 5.1 to the application);
- \* proof of the legal establishment of the authorized person in Kosovo, e.g. certificate of registration of a legal entity with the relevant competent authority in Kosovo (attach to the application as Annex 5.2).

2. Marketing authorization fee payment. The schedule of fees is set out as KMA guideline KMAG20 to the MA Regulation. Payment method: this should be paid to KMA Account. *Pay to:*

Raiffeisen Zentralbank Österreich AG SWIFT/BIC-Code: RZBAATWW Bank Sort Code: 31000

*Account:* Central Bank of the Republic of Kosovo

Account no: 55044937

IBAN: AT26310000055044937

For further credit to: ...please insert here the final beneficiary's account details (name + number) in this case *Ajenzioni i Produktëve Medicinale* and account number **1000400070002508**

The fee shall be paid before submission of the application. Evidence of fee payment: a copy of the bank transfer statement should be provided as a part of the application documentation. The marketing authorization procedure can only proceed when the fee is paid.

3. A product can fall into more than one category simultaneously. Biological active substance(s) includes medicinal products derived from blood and plasma and immunological products. Advanced therapy medicinal products means any medicinal product based on processes focused on various gene transfer-produced bio-molecules, and biologically advanced therapeutic modified cells and tissues as active substances or part of active substances. Orphan applies to medicinal products defined by the EMEA as possessing orphan status and exceptional applies to medicinal products for which a MA may be granted under exceptional circumstances.

4. A complete and independent application (stand alone) requires a complete dossier with administrative, quality, pre-clinical and clinical data. A new active substance refers to a constituent of a product not yet authorized by a competent authority; a known active substance refers to a constituent of a product already authorized by a competent authority whether by the same or a different marketing authorization holder.

5. For a new product containing known active substances not used previously in combination (so called new fixed combination), complete administrative, quality, preclinical and clinical data on the combination only should be provided. For line extensions of new fixed combination applications, cross references can only be made to pre-clinical and clinical data.

6. For applications under the well established medicinal use simplified procedure, refer to guidelines set out in Annex 3 to the Kosovo marketing authorization Administrative Instruction.

7. An application under the essential similarity (informed consent) procedure requires consent being by the existing marketing authorization holder to use their data in support of this application. Complete administrative and quality data should be provided with consent to pre-clinical and clinical data. The authorized product and the informed consent application can have the same or different MAJL.

8. For an application under the essential similarity (generic) procedure, refer to guidelines set out in Annex 3 to the Kosovo marketing authorization Administrative Instruction.

9. An application under the essential similarity (generic different) procedure concerns essentially similar generic medicinal products that have a different therapeutic use, route of administration, dosage or pharmacological presentation to the original/reference medicinal product. The results of appropriate toxicological and pharmacological tests and/or of appropriate clinical trials must be provided concerning the indicated differences and refer also to KMA guideline KMAG9.V110/05 to the Kosovo marketing authorization Administrative Instruction concerning demonstration of bioavailability and bioequivalence.

10. A MA application for a vitamin/mineral substance must include complete administrative and quality data. If necessary, the Kosovo Medicines Agency may request that the applicant provide information concerning the combinations of vitamins and minerals and the efficacy and safety of the quantities of vitamins and minerals used in the combinations.

11. Marketing authorization following EU centralised procedure. If the applicant is following this procedure for marketing authorization of its product(s) in Kosovo, then it is necessary for the applicant to submit the documentation set out in AI Nr.17/2013, Article 11 on the marketing authorization procedure.

12. Marketing authorization following EU decentralised procedure. If the applicant is following this procedure for marketing authorization of its product(s) in Kosovo, then it is necessary for the applicant to submit the documentation set out in KMA guideline KMAG11.V1 10/05 on the simplified marketing authorization procedure pursuant to the EU decentralised procedure to the marketing authorization regulation.

13. Unilateral /Mutual recognition procedure for medicinal products. If the applicant is following this procedure for marketing authorization of its product(s) in Kosovo, then it is necessary for the applicant to submit documentation (in addition to the required documents of the dossier) set out in MH -AI Nr 03/2011 (Recognition by the Kosovo Medicines Agency-KMA of Marketing



Authorization for medicinal Products for human use issued by the German Federal Institute for drugs and Medical Devices (BfArM) -accessing states as Annex 5.6 to this application

14. Line extensions. Refer to the strength and form of the product to which a line extension is referenced. For line extensions of both stand alone and simplified applications, cross references can only be made to pre-clinical (safety) and clinical data.

15. Herbal (traditional) medicinal products. Refer to the KMA guideline KMAG16.V1 10/05 on 'Special provisions for herbal medicinal products'.

16. Homeopathic medicinal products. Refer to the KMA guideline KMAG15.V1 10/05 on 'Special provisions for homeopathic medicinal products'.

17. Simplified procedure for the Marketing Authorization of medicinal products approved nationally in Schengen States of the EU countries, USA, Canada, Switzerland, Turkey\*\*, Israel\*, Japan, UK and Australia according to the Article 10 of AI Nr.17/2013 on the marketing authorization procedure.

18. Only one name should be given in the following order of priority: INN\*, Ph.Eur., National Pharmacopoeia, common name, scientific name.

\* the active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant (for further details consult WHO Cumulative List No. 10 of International Nonproprietary Names (INN) for pharmaceutical substances).

19. Specify a broad therapeutic indication group (e.g. antihypertensives, diuretics) and indicate the ATC code for the main therapeutic indication. If the ATC code is not assigned, propose it and state that it is a proposal. The ATC code will be assigned during the marketing authorization procedure according to the latest WHO ATC classification code valid for the authorization period. This item is for information purposes only and does not affect the outcome of the authorization decision-making process.

20. An application for authorization of one dosage form and one strength of the medicinal product should be made on each application form except for homeopathics, where more dilution degrees can be included in an application. If the active substance is present as a salt, hydrate etc., it must be clearly and unambiguously stated whether the strength refers to the molecular substance or the active entity of the molecule. Use the list of standard Ph.Eur. terms.

21. In the case of parenteral products specify all proposed routes of administration, e.g. intravenous, intraarterial, intramuscular, subcutaneous and as specified in the SPC proposal.

22. This table should be completed in such a way, that it is clear which immediate and outer packaging belong to a single package size, and should be unambiguous how many product presentations are included in this application. Include administration devices where applicable. A list of mock-ups\* or samples/specimens\*\* sent with the application should be attached.

\* 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 insert.

23. Summary of Product Characteristics (SPC). The SPC should be submitted in English and follow the structure set out in KMA guideline KMAG2.1.V1 10/05 on CTD Module 1 – Administrative information or KMA guideline KMAG2.2.V1 10/05 on Part I – Summary of the dossier.

24. Package leaflet. The package leaflet proposal shall be provided in Albanian and Serbian languages and in conformance with KMA guideline KMAG2.1.V1 10/05 on CTD Module 1 – Administrative information or KMA guideline KMAG2.2.V1 10/05 on Part I – Summary of the dossier.

25. Provide a detailed description of the dosage form appearance (color, shape, dimensions, imprint, markings, consistency, flavour etc.).

26. To specify the "birth date" KMA applies rules given in the European Notice to Marketing Authorization Holders, Pharmacovigilance Guidelines (CPMP/PhVWP/108/99 corr.). Most frequently the birth date is considered to be the date of first granting a marketing authorization in the EU (or in the world) to the relevant marketing authorization holder or his contract partners for a medicinal product with that active substance. On this date the sequence of Periodic Safety Update Reports submissions is based also for all further marketing authorization holders, i.e. generic manufacturers. The KMA prefers specification of the "EU birth date", if it does not exist, the "international birth date" should be specified. The birth date is significant in those cases where the first marketing authorization has been granted less than 5 years ago. Therefore it is not necessary to indicate the date in cases of active substances contained in a medicinal product registered in the world for more than 5 years as of the date of application for a marketing authorization in Kosovo.

27. The responsible person is the person making the application on behalf of the applicant and is the same person as described in Note 1 above

28. The qualified person responsible for pharmacovigilance should hold a university degree in pharmacy or human medicine.

29. All manufacturing steps and the site of manufacture must be indicated.

30. Only the final manufacturer of the active substance(s) should be mentioned.

31. Marketing Authorization of the same medicinal product in other countries.

32. Specify the EAN bar code, if available. This item is for information purposes only and does not affect the marketing authorization decision-making process.

33. If the medicinal product is currently protected by intellectual property rights conventions in terms of either its trade name or composition and the applicant wishes to apply these rights in the territory of Kosovo this has to be clearly stated. The existing rights should be clearly stated in Annex 5.17 to this application at the discretion of the applicant. The Annex should state the nature of the patent(s), under which jurisdiction(s) and when the patent(s) were issued, expiry dates of patent(s) and registration and expiry of registered trade names.

Name of medicinal product
Active substance(s)
Applicant
Date of completion of table

Name of material				
Source of material (tissue, plasma etc.)				
Country of origin of the source animal for the material cited				
Is the material a derivative of SRM*?				
Category of the tissue of which the material is a derivative**				
Use of material	As active substance			
	As reagent/culture medium component			
	Starting material used in manufacture of active substance			
	As excipient			
	Starting material used in manufacture of excipient			
	Other, give details			

Name of material				
Source of material (tissue, plasma etc.)				
Country/ies where donation took place				
Is the material contained in a product authorized for marketing? If yes, specify states including MA numbers				
Use of material	As active substance			
	As excipient			
	Other, give details			

\* Specified risk material = SRM = materials defined in Commission Decision 97/534/EC

- | Specified risk material | Criteria  | Material defined in Commission Decision 2002/276/EC |
|-------------------------|---|---|
| (a)                     | the skull, including the brain and eyes, tonsils and spinal cord of <ul style="list-style-type: none"> <li>– bovine animals aged over 12 months</li> <li>– ovine and caprine animals which are aged over 12 months or have a permanent incisor tooth erupted through the gum</li> </ul> |   |
| (b)                     | the spleens of ovine and caprine animals  |   |

I **High infectivity:** brain, spinal cord, (eye)  
 II **Medium infectivity:** ileum, lymph nodes, proximal colon, spleen, tonsil, (dura mater, pineal gland, placenta), cerebrospinal fluid, pituitary, adrenal  
 III **Low infectivity:** distal colon, nasal mucosa, peripheral nerves, bone marrow, liver, lung, pancreas, thymus  
 IV **No detectable infectivity:** blood clot, faeces, heart, kidney, mammary gland, milk, ovary, saliva, salivary gland, seminal vesicle, serum, skeletal muscle, testis, thyroid, uterus, foetal tissue, (bile, bone, cartilaginous tissue, connective tissue, hair, skin, urine)

13/13



## KMA MA Form No. 2

<b>Kosovo Medicines Agency</b> <b>Agjencioni i Kosovës për Produkte Medicinale</b> Rrethi i Spitalit (QKU) 10000, Prishtinë, Kosovë Tel: +381 (38) 512 066; Fax: +381 (38) 512 243 www.akpm-rks.org	Date received:	Protocol No:
	Application processing start date:	
	MA Variation No:	
<b>Application for a variation to a medicinal product marketing authorisation</b>	Issue date:	Exp. date:

(KMA to fill out)

**1. Type of medicinal product and type of variation application**

<b>1.1 Type of medicinal product</b>	
(i) Chemical active substance(s) <input type="checkbox"/>	(v) Homeopathic medicinal product <input type="checkbox"/>
(ii) Biological active substance(s) <input type="checkbox"/>	(vi) Herbal medicinal product <input type="checkbox"/>
(iv) Radio pharmaceutical <input type="checkbox"/>	(vii) Advanced therapy medicinal product <input type="checkbox"/>
	(viii) Other (Specify) _____ <input type="checkbox"/>

<b>1.2 Type of variation applied for <sup>1,2,3</sup></b>				
Notification of a Type I Variation <input type="checkbox"/>	Notification of a Type I variation requiring an approval decision <sup>4</sup> <input type="checkbox"/>	Type II <input type="checkbox"/>	Urgent safety restriction (Type II) <input type="checkbox"/>	Annual variation for human influenza or other vaccines (Type II) <input type="checkbox"/>

**2. Application particulars**

<b>2.1 Trade(invented) name of the medicinal product (as is specified in the original MA decision)</b>

<b>2.2 Name of the active substance(s) <sup>5</sup></b>
Name: _____

<b>2.3 Pharmaceutical form and strength</b>
Form: _____ Strength <sup>6</sup> : _____

<b>2.4 Kosovo MA number</b>

<b>2.5 Package sizes</b>
Variation requested for all authorised package sizes Yes <input type="checkbox"/> No <input type="checkbox"/>
Specify package sizes for which the variation is requested: _____

<b>2.6 Name and address of applicant <sup>7</sup>:</b>
Name: _____
Address: _____
Country: _____
Tel: _____
Fax: _____
E-mail: _____
Contact person at this address: _____

## 3. Manufacturer(s)

(j) **Authorised manufacturer(s) (or importer) responsible for batch release (as shown in the package leaflet and where applicable in the labelling):**

Company name.

Address:

Country.

**Tel:**

Fax:

E-mail

Manufacturing Authorisation number:

**For Blood Products and Vaccines:**

Details of the state laboratory or laboratory designated for that purpose (OMCL) where the official batch release takes place:

Name:

Address:

Country:

**Tel:**

Fax:

E-mail:

**(ii) Manufacturer(s) of the medicinal product and site(s) of manufacture (including a description of the manufacturing steps performed):****1. Company name:**

Address:

Tel:

Fax:

E-mail:

Brief description of manufacturing steps performed:

Manufacturing Authorisation number:

**2. Company name:**

Address:

Tel:

Fax:

E-mail:

Brief description of manufacturing steps performed:

Manufacturing Authorisation number:

**3. Company name:**

Address:

Tel:

Fax:

E-mail:

Brief description of manufacturing steps performed:

Manufacturing Authorisation number:

**(iii) Manufacturer of the active substance(s):**

Substance:

Manufacturer name:

Address:

Tel:

Fax:

E-mail:



4. Type I variations	
1 a. Change in name of the manufacturer of the medicinal product <input type="checkbox"/>	16. Change in the batch size of the finished product <input type="checkbox"/>
1. b. Change of the manufacturing site of the medicinal product <input type="checkbox"/>	17. Change in the specification of the finished product <input type="checkbox"/>
1. c. Withdrawal of the manufacturing authorisation for a site of manufacture <input type="checkbox"/>	18. Change in the synthesis/recovery of the non-pharmacopoeial excipient(s) which had been described in the original dossier <input type="checkbox"/>
2. Change in the name of the medicinal product (either invented name or common name) <input type="checkbox"/>	19. Change in the specification of excipients(s) in the medicinal product (excl. adjuvants for vaccines) <input type="checkbox"/>
3. Change in the name and/or address of the marketing authorisation holder <input type="checkbox"/>	20. Extension of shelf-life as foreseen at time of authorisation <input type="checkbox"/>
4. Replacement of an excipient with a comparable excipient (excl. adjuvants for vaccines and biologically derived excipients) <input type="checkbox"/>	20.a. Extension of shelf life or retest period of the active substance <input type="checkbox"/>
5. Change, addition, deletion or replacement of a colorant(s) <input type="checkbox"/>	21. Change in shelf-life after first opening of container <input type="checkbox"/>
6. Change, addition, deletion or replacement of a flavour(s) <input type="checkbox"/>	22. Change in shelf-life after reconstitution <input type="checkbox"/>
7. Change in coating weight of tablets or change in weight of capsule shells <input type="checkbox"/>	23. Change in storage conditions <input type="checkbox"/>
8. Change in the qualitative composition of immediate packaging material <input type="checkbox"/>	24. Change in test procedures of the active substance <input type="checkbox"/>
9. Deletion of an indication <input type="checkbox"/>	24.a. Change in test procedures for a starting material or intermediate used in the manufacture of the active substance(s) <input type="checkbox"/>
10. Deletion of a route of administration <input type="checkbox"/>	25. Change in test procedures of the finished medicinal product <input type="checkbox"/>
10.a. Addition or change of measuring device for oral liquid dosage forms and other dosage forms <input type="checkbox"/>	26. Changes to comply with supplements to pharmacopoeia <input type="checkbox"/>
11. Change in the manufacturer(s) of the active substance(s) <input type="checkbox"/>	27. Change in test procedures of non-pharmacopoeial excipients <input type="checkbox"/>
11. a. Change in the name of a manufacturer of the active substance(s) <input type="checkbox"/>	28. Change in test procedures of immediate packaging <input type="checkbox"/>
11. b. Change in the supplier of an intermediate compound used in the manufacture of the active substance <input type="checkbox"/>	29. Change in test procedures of administration device <input type="checkbox"/>
12. Minor change of manufacturing process of the active substance <input type="checkbox"/>	30. Change in the package size <input type="checkbox"/>
12.a. Change in specification of starting material or intermediate used in the manufacture of the active substance <input type="checkbox"/>	31. Change in the container shape <input type="checkbox"/>
13. Change in the batch size of the active substance <input type="checkbox"/>	32. Change of imprints, bossing or other markings (except scoring) on tablets or printing on capsules, including addition or change of ink used for product marking <input type="checkbox"/>
14. Change in the specification of the active substance <input type="checkbox"/>	33. Change of dimensions of tablets, capsules, suppositories or pessaries <input type="checkbox"/>
15. Minor change of manufacturing process of the finished product <input type="checkbox"/>	34. Change to the labelling not connected with a change in the summary of product characteristics <input type="checkbox"/>
15.a. Change in in-process controls applied during the manufacture of the product <input type="checkbox"/>	35. Change to package information leaflet not connected with a change in the summary of product characteristics <input type="checkbox"/>
15.b. Change in the manufacturing process for components <input type="checkbox"/>	36.a. Change in the manufacturing process of a non proteinaceous component due to the subsequent introduction of a biotechnology step – compliant with the pharmacopoeial monograph <input type="checkbox"/>
15.c. Change in the manufacturing process for components requiring a new impurities test procedure <input type="checkbox"/>	36.b. Change in the manufacturing process of a non proteinaceous component due to the subsequent introduction of a biotechnology step – requesting a new impurities test procedure <input type="checkbox"/>

5. Type II variations			
<b>Changes to Part I: Summary of the dossier (or CTD Module 1: Administrative information)</b>			
A.1. Change in the legal status (dispensing/classification) - switch from «medical prescription only» to OTC	<input type="checkbox"/>	A.3. Change in the package size	<input type="checkbox"/>
A.2. Change in the legal status (dispensing/classification) - switch from OTC to «medical prescription only»	<input type="checkbox"/>	A.4. Other change in part I, specify	<input type="checkbox"/>
<b>Changes to Part II: chemical, biological and pharmaceutical documentation (or CTD Module 3: Quality)</b>			
B.1. Change in the quantitative and qualitative composition of the medicinal product with respect to excipients only Is a new excipient of biological origin used? <sup>8</sup> Yes <input type="checkbox"/> No <input type="checkbox"/>			
B.2. Change of the immediate packaging	<input type="checkbox"/>	B.7. Change in the specification of the excipient	<input type="checkbox"/>
B.3. Change in the manufacturing process of the finished medicinal product	<input type="checkbox"/>	B.8. Change in the specification of the medicinal product	<input type="checkbox"/>
B.4. Change in the manufacturing process of the active substance	<input type="checkbox"/>	B.9. Change in the shelf life of the medicinal product	<input type="checkbox"/>
B.5. Change in the specification of the active substance	<input type="checkbox"/>	B.10. Change in the storage conditions	<input type="checkbox"/>
B.6. Change in the manufacturing process of the excipient which has been described in the original MA documentation	<input type="checkbox"/>	B.11. Other change in part II / module 3, specify	<input type="checkbox"/>
<b>Changes to Part III: pharmacological-toxicological documentation (or CTD Module 4: Non clinical reports) that cause changes to the SPC</b>			
C.1. Change in part III / Module 4, specify			
<b>Changes to Part IV: clinical documentation (or CTD Module 5: Clinical study reports) that cause changes to the SPC</b>			
D1. Change «Therapeutic indications» (in same therapeutic area already approved)	<input type="checkbox"/>	D.6. Changes «Interactions»	<input type="checkbox"/>
D.2. Change «Group of patients»	<input type="checkbox"/>	D.7. Change «Pregnancy and lactation»	<input type="checkbox"/>
D.3. Change «Dosage»	<input type="checkbox"/>	D.8. Change «Effects on ability to drive and use machines»	<input type="checkbox"/>
D.4. Change «Contra-indications»	<input type="checkbox"/>	D.9. Change «Undesirable effects»	<input type="checkbox"/>
D.5. Change «Special warnings and special precautions for use»	<input type="checkbox"/>	D.10. Change «Overdose»	<input type="checkbox"/>
D.11. Other change in part IV / Module 5, specify <input type="checkbox"/>			
<b>6. Expert report<sup>9</sup></b>			
Updated <input type="checkbox"/> Addendum <input type="checkbox"/>			
Updated Expert report or the Addendum is submitted as either:			
Update / Addendum to Section 1C of EU Part I <input type="checkbox"/> Update / Addendum to CTD Module 2 <input type="checkbox"/>			
<b>7. Main change (in case of consequential changes)</b>			
The main change covered by this variation application is change number/letter _____ (1 to 36 / A to D)			



8. Specification of wording which is proposed to be changed	
Present	Proposed

**9. Background explanation and justification for the proposed change to the MA <sup>10</sup>:**

**10. Related applications (specify nature of application, name of the product, MA number and date of submission):**

**11. Variation to a product authorised in Kosovo following the EU Centralised procedure** Yes ☐ No ☐

This variation was applied for in EU <sup>11</sup> Yes ☐ Date of the application: No ☐  
 Classification of this variation in EU Type I ☐ No: Type II ☐ Letter: EMEA Procedure No. <sup>12</sup>  
 This variation was approved or was deemed to have been accepted Yes ☐ Date: No ☐

**12. Variation to a product authorised in Kosovo following the EU Decentralised procedure** Yes ☐ No ☐

This variation was applied for in EU <sup>13</sup> Yes ☐ Date of the application: No ☐  
 Classification of this variation in EU Type I ☐ No: Type II ☐ Letter:  
 This variation was approved or was deemed to have been accepted Yes ☐ Date: No ☐

**13. Variation to a product authorised in Kosovo following the Kosovo Unilateral Recognition procedure** Yes ☐ No ☐

This variation was applied for in the reference EU Member State or EU Accessing State <sup>14</sup> Yes ☐ Date of the application: No ☐  
 Classification of this variation in EU MS or EU AS Type I ☐ No: Type II ☐ Letter:  
 This variation was approved or was deemed to have been accepted Yes ☐ Date: No ☐

**14. Date from which only a changed product will be marketed**

**15. EAN bar code**

Assigned Yes ☐ Code:  No ☐





16. Annexed documents<sup>15</sup>

		Yes	N/A
16.1	Evidence of fee payment <sup>16</sup>	<input type="checkbox"/>	<input type="checkbox"/>
16.2	List of contents of documentation submitted, inc page numbers	<input type="checkbox"/>	<input type="checkbox"/>
16.3	Letter of authorisation of the person submitting the application and for communication	<input type="checkbox"/>	<input type="checkbox"/>
16.4	Manufacturing authorisation of the manufacturer of the medicinal product <sup>17</sup>	<input type="checkbox"/>	<input type="checkbox"/>
16.5	Comparative dissolution profile data of changed and original product	<input type="checkbox"/>	<input type="checkbox"/>
16.6	Copy of approved specifications	<input type="checkbox"/>	<input type="checkbox"/>
16.7	Certificate of suitability of monographs of the Ph.Eur.	<input type="checkbox"/>	<input type="checkbox"/>
16.8	SPC in Albanian, Serbian and English <sup>18</sup>	<input type="checkbox"/>	<input type="checkbox"/>
16.9	Proposal for Package leaflet (PIL) in Albanian, Serbian and English <sup>18</sup>	<input type="checkbox"/>	<input type="checkbox"/>
16.10	Proposed labelling in Albanian and English <sup>18</sup>	<input type="checkbox"/>	<input type="checkbox"/>
16.11	SPC approved in other countries <sup>19</sup>	<input type="checkbox"/>	<input type="checkbox"/>
16.12	Package leaflet (PIL) approved in other countries <sup>19</sup>	<input type="checkbox"/>	<input type="checkbox"/>
16.13	Updated expert report for EU Part II / Module 3 of documentation or Addendum	<input type="checkbox"/>	<input type="checkbox"/>
16.14	Updated expert report for EU Part III / Module 4 of documentation or Addendum	<input type="checkbox"/>	<input type="checkbox"/>
16.15	Updated expert report for EU Part IV / Module 5 of documentation or Addendum	<input type="checkbox"/>	<input type="checkbox"/>
16.16	EU Part II / Module 3 of MA dossier or appropriate section	<input type="checkbox"/>	<input type="checkbox"/>
16.17	EU Part III / Module 4 of MA dossier or appropriate section	<input type="checkbox"/>	<input type="checkbox"/>
16.18	EU Part IV / Module 5 of MA dossier or appropriate section	<input type="checkbox"/>	<input type="checkbox"/>
16.19	New bioequivalence study	<input type="checkbox"/>	<input type="checkbox"/>
16.20	Sample of the medicinal product <sup>20</sup>	<input type="checkbox"/>	<input type="checkbox"/>
16.21	Materials of animal / human origin form completed (form attached to this application form)	<input type="checkbox"/>	<input type="checkbox"/>
16.22	Variation to a product authorized in Kosovo following the EU CADREAC Centralised procedure	<input type="checkbox"/>	<input type="checkbox"/>
a	Variation assessment report from CPMP	<input type="checkbox"/>	<input type="checkbox"/>
b	European Commission Decision varying the terms of the MA	<input type="checkbox"/>	<input type="checkbox"/>
c	Notification on a type I variation to the terms of MA from EMEA	<input type="checkbox"/>	<input type="checkbox"/>
16.23	Variation to a product authorized in Kosovo following the EU CADREAC Decentralised procedure	<input type="checkbox"/>	<input type="checkbox"/>
a	Copy of the letter from RMS concluding MRP for variation	<input type="checkbox"/>	<input type="checkbox"/>
b	Harmonised SPC	<input type="checkbox"/>	<input type="checkbox"/>
c	Variation assessment report from RMS	<input type="checkbox"/>	<input type="checkbox"/>
16.24	Variation to a product authorized in Kosovo following the Kosovo Unilateral recognition procedure	<input type="checkbox"/>	<input type="checkbox"/>
a	Variation assessment report from competent authority of reference EU MS or EU AS	<input type="checkbox"/>	<input type="checkbox"/>
b	Letter of acceptance of the variation from competent authority of reference EU MS or EU AS	<input type="checkbox"/>	<input type="checkbox"/>
c	Revised SPC approved by competent authority of reference EU MS or EU AS	<input type="checkbox"/>	<input type="checkbox"/>
16.25	List of product presentations affected by a single variation	<input type="checkbox"/>	<input type="checkbox"/>
16.26	List of related variations not covered by this application	<input type="checkbox"/>	<input type="checkbox"/>
16.27	Other documents – Specify:	<input type="checkbox"/>	<input type="checkbox"/>

Number of pages added by the applicant because of lack of space in any part of the application form <sup>21</sup>

I certify that the changes specified above will not adversely affect the quality, efficacy and safety of the medicinal product. I declare that all changes have been identified and there are no other changes in the amended documentation. I declare that the data in the application and accompanying documentation are true.

Date \_\_\_\_\_

Signature of the applicant, resp. person authorised by him

First name, family name  
Address:

All documentation:	submitted / not submitted
All pages and volumes present and marked:	yes / no
Documentation:	accepted / not accepted
Documentation not accepted for reasons :	
Signature of KMA officer:	
Date:	

### Instructions for the applicant

1. An application for a single variation to the existing medicinal product marketing authorisation should be made on one application form. If consequential changes are caused by the applied variation, all changes should be indicated in the application form for the main variation. The main variation should be clearly specified in Section 6 of the application form. If changes are not consequential a separate application form should be completed for such changes.
2. For identical changes to several presentations of a product, for example different strengths, it is acceptable to complete one form and append a list of all the products affected as Annex 16.25. The list should identify the products and include the relevant MA numbers.
3. All related variation applications not covered by one application (i.e. a variation and its consequential variations) should be specified in Annex 16.26 to the application form whether they are for the same existing marketing authorisation or other related marketing authorisations. For a related variation application, the existing Kosovo MA number and nature of variation should be stated.
4. An approval decision based on the opinion of the Kosovo Committee for Medicines Evaluation is required for Type I variations that concern Type I Variation No. 11, 11b, 12, 13, 15, 16, and for variations 24, 24a and 25 where the test procedure is not a physico-chemical method in the case of biological and advanced therapy medicinal products.
5. Only one name should be given in the following order of priority: INN\*, Ph.Eur., National Pharmacopoeia, common name, scientific name.  
\* the active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant (for further details consult WHO Cumulative List No. 10 of International Nonproprietary Names (INN) for pharmaceutical substances)
6. If the active substance is present as a salt, hydrate etc, it must be clearly and unambiguously stated whether the strength refers to the molecular substance or the active entity of the molecule.
7. Any legal or physical entity, authorised by the applicant to communicate with KMA is considered as the responsible person; this person submits to KMA the officially verified authorisation by the applicant. Each applicant without a permanent residence or a registered office in Kosovo has a duty to authorise a responsible person with an address in Kosovo to submit the application and to communicate with KMA.
8. If a new excipient of biological origin is used, it is necessary to fill in the form 'List of materials of animal and/or human origin contained or used in the manufacturing process of the medicinal product' that is annexed to this application form.
9. An updated or Addendum to the expert report should be submitted as a part of the variation application either as an amendment to the Section IC of Part I – Summary of the dossier or as an amendment to CTD Module 2 – CTD Summaries
10. Applicants can assist in the assessment of the variation by summarising both (i) the present and (ii) the proposed situations concerning the MA. In the case of consequential changes, fill in also the background explanation and justification for the consequential nature of the additional changes with respect to the main change. All differences should be clearly highlighted, e.g. italics, bold, underlined. If all the information cannot be fitted on the application form page, additional pages may be attached.
11. If this variation was applied for in the EU, submit the application in Kosovo after the approval of the variation in the EU (for type II variations) or at the time the variation can be deemed to have been accepted (for type I variations).
12. EMEA procedure number is specified in the variation assessment report from the CPMP or in the Notification on a type I variation to the terms of marketing authorisation from the EMEA.
13. If this variation was applied for in the EU, submit the application in Kosovo after the conclusion of the Mutual Recognition (Decentralised) Procedure for the variation in question
14. If this variation was applied for in an EU member state or EU accessing state submit the application in Kosovo after the approval of the variation in the reference EU member state or EU accessing state (for type II variations) or at the time the variation can be deemed to have been accepted (for type I variations).
15. Tick those sections that are relevant to the submitted application. In case of need of further clarification please contact the KMA Marketing Authorisation Department directly
16. Variation application fee payment. The schedule of fees is set out as guideline to the MA Regulation. Payment method: this should be paid to KMA, Account: Agjensioni i Kosoves per Produkte Medicinale (AKPM) 1000430070006144 BPK Prishtine, BPK Foreign Correspondent Banks: Account No. 55044937, Raiffeisen Zentralbank Oesterreich AG, Am Stadtpark 9, 1030 Wien, (Swift code RZBAATWW) and Account No. 581287000, Commerzbank AG, Filiale Frankfurt am Main, Kaiserstrasse 30, 60311 Frankfurt am Main, (Swift code COBADE33). The fee shall be paid before submission of the application. Evidence of fee payment: a copy of the bank transfer statement or cash receipt should be provided as a part of the application documentation. The marketing authorisation procedure can only proceed when the fee is paid.
17. This may be a copy of a new manufacturing authorisation, or an addendum to an existing one, or a letter from the supervising competent authority.
18. For SPC, package leaflet and labelling changes, in the proposal all differences from the approved version should be clearly highlighted or underlined. Copies of the existing versions, versions with highlighted changes and the proposed new versions should be provided.
19. This should preferably be submitted in English (if not originally available in English a translation should be provided) and approved in countries where the variation has been applied for.
20. Two samples in final immediate packaging without final labelling are sufficient.
21. In the case that the space within the boxes on the application form is not sufficient, the required information should be submitted additionally as clearly specified annexes to the application



**List of materials of animal and/or human origin contained  
or used in the manufacturing process of the medicinal product**

<b>Name of medicinal product</b>
<b>Active substance(s)</b>
<b>Applicant</b>
<i>Date of completion of table</i>

<b>1. Materials of animal origin</b>			
<b>Name of material</b>			
Source of material (tissue, plasma etc.)			
Country of origin of the source animal for the material cited			
Is the material a derivative of SRM*?			
Category of the tissue of which the material is a derivative**			
Use of material	As active substance		
	As reagent/culture medium component		
	Starting material used in manufacture of active substance		
	As excipient		
	Starting material used in manufacture of excipient		
	Other, give details		
<b>2. Materials of human origin</b>			
<b>Name of material</b>			
Source of material (tissue, plasma etc.)			
Country/ies where donation took place			
Is the material contained in a product authorised for marketing? If yes, specify states including MA numbers			
Use of material	As active substance		
	As excipient		
	Other, give details		

**Notes:**

\* **Specified risk material = SRM** = materials defined in Commission Decision 97/534/EC

- (a) the skull, including the brain and eyes, tonsils and spinal cord of  
 – bovine animals aged over 12 months  
 – ovine and caprine animals which are aged over 12 months or have a permanent incisor tooth erupted through the gum  
 (b) the spleens of ovine and caprine animals

\*\* **Categories** - specification according to the guideline CPMP/BWP/1230/98

- I High infectivity:** brain, spinal cord, (eye)  
**II Medium infectivity:** ileum, lymph nodes, proximal colon, spleen, tonsil, (dura mater, pineal gland, placenta), cerebrospinal fluid, pituitary, adrenal  
**III Low infectivity:** distal colon, nasal mucosa, peripheral nerves, bone marrow, liver, lung, pancreas, thymus  
**IV No detectable infectivity:** blood clot, faeces, heart, kidney, mammary gland, milk, ovary, saliva, salivary gland, seminal vesicle, serum, skeletal muscle, testis, thyroid, uterus, foetal tissue, (bile, bone, cartilaginous tissue, connective tissue, hair, skin, urine)

If a Ph. Eur. Certificate of Suitability for TSE is available please attach as part of the application.



## KMA MA Form No. 3

<b>Kosovo Medicines Agency</b> <b>Agjencioni i Kosovës për Produkte Medicinale</b> Rrethi i Spitalit (OKU) 10000, Prishtinë, Kosovë Tel: +381 (38) 512 066; Fax: +381 (38) 512 243 <a href="http://www.akpm-rks.org">www.akpm-rks.org</a>	Date Received:	Protocol No:
	Application processing start date :	
	MA No:	
	MA issue date:	MA exp. date:

<b>APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION OF A MEDICINAL PRODUCT</b>	
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**Declaration and signature**

Product (invented) name:

Strength(s):

Pharmaceutical form:

Active substance(s):

Applicant:

Person authorised for communication on behalf of the applicant\*:

It is hereby confirmed that all existing data which are relevant to the quality, safety and efficacy of the medicinal product have been supplied in the dossier as appropriate and samples of the finished product, active substance(s) and excipient(s) sufficient for analysis\*\*.

It is hereby confirmed that the marketing authorisation fees have been paid to the Kosovo Medicines Agency\*\*\*.

On behalf of the applicant

Signature \_\_\_\_\_

Name \_\_\_\_\_

Function \_\_\_\_\_

Place \_\_\_\_\_ Date (yyyy-mm-dd) \_\_\_\_\_

\*\*\*Attach proof of payment as Annex 1.5 ○

**I. Type of Product and Type of Application****I.1 Type of medicinal product<sup>3</sup>**

- (i) Chemical active substance(s) ☐ (iv) Herbal ☐ (viii) Orphan / Exceptional ☐  
 (ii) Biological active substance(s) ☐ (v) Homeopathic ☐ (ix) Vitamins and minerals ☐  
 (iii) Radiopharmaceutical ☐ (vi) Advanced therapy ☐  
 (Mark relevant box(es) with X)

**I.2 Type of application**

- (i) Complete and independent (Stand alone) ☐  
 • New active substance ☐  
 • Known active substance ☐  
 (ii) New fixed combination ☐  
 (iii) Simplified procedure pursuant to:  
 (a) Well Established Medicinal Use (bibliographical) ☐  
 (b) Essential Similarity (Informed consent) ☐  
 (c) Essential Similarity (Generic) ☐  
 (d) Essential Similarity (Generic different) ☐  
 (e) Vitamins / mineral substances ☐  
 (i) Unilateral EU - Member State / EU-Accessing State recognition procedure ☐  
 (iv) Line extension ☐  
 • Reference strength and form ☐  
 (v) Herbal (traditional) medicinal product ☐  
 (vi) Homeopathic medicinal product ☐  
 (vii) Simplified procedure pursuant to Article 11 of the AI Nr.17/2013 ☐  
 (viii) EU- Centralized / EMA- CPP ☐

**2. Application particulars****2.1 Trade (invented) name of the medicinal product****2.2 Name of the active substance<sup>4</sup>****2.3 Proposed therapeutic indications<sup>5</sup>**

ATC Code:   
 (for main indication)

**2.4 Pharmaceutical form and strength<sup>6</sup>****2.5 Route(s) of administration<sup>7</sup>****2.6 Packaging and package size(s)<sup>8</sup> (attach list of Mock-ups or Samples/specimens as Annex 1.9 ○)**

(i) Immediate packaging:	(ii) Outer packaging:	(iii) Package size(s):
(iv) Shelf life (as specified in the SPC proposal):	(v) Shelf life (after first opening container):	(vi) Shelf life (after reconstitution or dilution):
(vii) Storage conditions: (as specified in the SPC proposal)		(viii) Storage conditions after first opening: (as specified in the SPC proposal)

**2.7 Summary of Product Characteristics (SPC) proposal<sup>8</sup> (attach as Annex 1.6/1.7 ○)**Albanian ☐ Serbian ☐ English ☐ Other languages (optional) ☐ (Specify):**2.8 Package Leaflet proposal<sup>9</sup> (attach as Annex 1.8 ○)**Albanian ☐ Serbian ☐ Other ☐ (Specify):**2.9 Mock-ups (immediate and outer packaging) and specimens<sup>10</sup> (attach as Annex 1.9 ○)**Albanian ☐ Serbian ☐ Other ☐ (Specify):**2.10 Description of the medicinal product<sup>11</sup>****2.9 Proposed dispensing classification (legal status) (Tick appropriate box(es) with X)**Subject to medicinal prescription ☐Not subject to medicinal prescription ☐

If subject to medicinal prescription:

(i) prescription which may be automatically renewed ☐(iv) product on restricted prescription ☐(ii) prescription which may not be automatically renewed ☐(v) product for use only in in-patient health facilities ☐(iii) product on special prescription ☐Promotion of products not subject to medicinal prescription:Promotion to health care professionals only ☐Promotion to the general public and health care professionals ☐**2.10 Qualitative and quantitative composition**(i) Qualitative and quantitative composition in terms of the active substance(s) and the excipient(s)<sup>4</sup>:

Dosage type (e.g. capsule) tablets

Name	Quantity	Unit	Reference/Monograph standard
Active substance (s)			
Excipient (s)			
Etc.			

Details of any overages should not be included in the formulation columns but stated below:

• active substance(s): \_\_\_\_\_

• excipient(s): \_\_\_\_\_





<b>2.12 Marketing authorisation holder / contact persons / company</b>
<b>(i) Applicant :</b> Company name: Address: Country: Tel: Fax: E-mail:
<b>(ii) Authorised person in Kosovo<sup>12</sup> :</b> Name: Company name: Address: Tel: Fax: E-mail:
<b>(iii) Qualified person for Pharmacovigilance<sup>13</sup> :</b> Name: Company name: Address: Tel: Fax: E-mail: • Attach CV of qualified person for pharmacovigilance if different from the first MA
<b>2.13 Manufacturer(s)</b>
<b>(i) Authorised manufacturer(s) (or importer) responsible for batch release (as shown in the package leaflet and where applicable in the labeling):</b> Company name: Address: Country: Tel: Fax: E-mail:
<b>For Blood Products and Vaccines:</b> Details of the state laboratory or laboratory designated for that purpose (OMCL) where the official batch release takes place: Name: Address: Country: Tel: Fax: E-mail:



**(ii) Manufacturer(s) of the medicinal product and site(s) of manufacture <sup>14</sup>:**

Company name:  
 Address:  
 Country:  
 Tel:  
 Fax:  
 E-mail:

**(iii) Manufacturer of the active substance(s) <sup>15</sup>:**

Substance:  
 Company name:  
 Address:  
 Country:  
 Tel:  
 Fax:  
 E-mail:

**(iv) Contract companies used for bioavailability / bioequivalence or used for the validation of blood product manufacturing processes**

Manufacturer name:  
 Address:  
 Tel:  
 Fax:  
 E-mail:  
 Duty performed according to contract:

Location of performance of analytical tests and clinical data collection:

**3. Marketing authorisations of the same medicinal product in other countries <sup>16</sup>** (i.e. from applicants/MAHs belonging to the same mother company or group of companies OR which are 'licensees') Provide information in accordance with the following scheme and attach as 5.21 in the list of Annexed documents ☐
**(i) Renewal in country of origin**

Country:  
 Date of authorisation (yyyy-mm-dd):  
 Invented name:  
 Authorisation number:  
 • Attach copy of renewal of a marketing authorisation in Annex 5.22 ☐

**(ii) Pending**

Country:  
 Date of submission (yyyy-mm-dd):

**(iii) Refused**

Country:  
 Date of refusal (yyyy-mm-dd):  
 Reason for refusal:

**(iv) Withdrawn (by applicant before authorisation)**

Country:  
 Date of withdrawal (yyyy-mm-dd):  
 Reason for withdrawal:

**(v) Withdrawn (by applicant after authorisation)**

Country:  
 Date of withdrawal (yyyy-mm-dd):  
 Invented name:  
 Authorisation number:  
 Reason for withdrawal:

**(vi) Suspended/revoked (by competent authority)**

Country:  
 Date of suspension/revocation (yyyy-mm-dd):  
 Invented name:  
 Reason for suspension/revocation:

**4. Other information**(i) EAN code<sup>17</sup>: 

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(iii) Intellectual property protection to be applied for in Kosovo<sup>18</sup>:

- Product composition ☐ No ☐ Yes (if applicable, attach declaration of originality as Annex 5.24 ☐)
- Trade name ☐ No ☐ Yes (if applicable, attach declaration of originality as Annex 5.24 ☐)



**DOCUMENTS APPENDED TO THIS APPLICATION**

<b>Module 1:</b>	
<input type="checkbox"/> 1.0	Cover Letter
<input type="checkbox"/> 1.1	Comprehensive table of content
<input type="checkbox"/> 1.2	Renewal Application Form with the following annexes:
<input type="checkbox"/> 1.2.1	Copy of MA Certificate of a product that shall apply for renewal procedure
<input type="checkbox"/> 1.4	Declaration of the Variation of the medicinal product ,if they have, and attach a copy of notification including „extension“ and last renewal
<input type="checkbox"/> 1.5	Evidence of fee payment,
<input type="checkbox"/> 1.6	SPC proposal (in Albanian, Serbian languages) - hard copy and CD.
<input type="checkbox"/> 1.7	SPC in English language last update- hard copy and CD.
<input type="checkbox"/> 1.8	Package leaflet / PIL / Package insert proposal (in Albanian, Serbian languages) - hard copy and CD.
<input type="checkbox"/> 1.9	Mock-ups (immediate and outer packaging) or samples/specimens attached to the application (in Albanian, Serbian). 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' and 'computer generated version'. A 'specimen' should be interpreted as referring to a sample of the actual printed inner and outer packaging and package insert
<input type="checkbox"/> 1.10	Statement from competent authority that conducted last GMP inspection or declaration from qualified person for batch release
<input type="checkbox"/> 1.11	PSUR (Periodic Safety Update Report and Summary Bridging Report if applicable)

<b>Module 2</b>	
<input type="checkbox"/> 2.3	Quality Overall Summary (Quality Expert Bridging Report)

All documentation:	submitted / not submitted
All pages and volumes present and marked:	yes / no
Documentation:	accepted / not accepted
Documentation not accepted for reasons :	
Signature of KMA officer:	
Date:	(KMA to fill out)



### Instructions for the applicant

The application form may be completed by typewriter or computer. If there is insufficient space to complete any part of the application form, please use additional pages, which then will become an integral part of the application. In the appropriate part, specify that there is an additional appendix. References to already submitted documentation are not permitted. The application should be completed in compliance with valid KMA guidelines or other documents that are referred to. All guidelines can be found on the KMA web site ([www.akpm-rks.org](http://www.akpm-rks.org)) or are obtainable directly from the KMA premises.

1. Any legal or physical entity, authorised by the applicant to communicate with KMA is considered as the authorised person. This person submits to KMA the officially verified authorisation by the applicant. Each applicant without a permanent residence or a registered office in Kosovo has a duty to authorise an authorised person with an address in Kosovo to submit the application and to communicate with KMA. The following documents should be provided:

\* a letter of authorisation to communicate on behalf of the applicant (MAH) and original of agency agreement or a legally attested copy of the agency agreement between the applicant/MAH and the authorised person (attach as Annex 5.1 to the application);

\* proof of the legal establishment of the authorised person in Kosovo, e.g. certificate of registration of a legal entity with the relevant competent authority in Kosovo (attach to the application as Annex 5.2).

2. Renewal for Marketing Authorisation fee payment is the half price of the MA fee. Regulation. Payment method: this should be paid to KMA Account: Agjensioni i Kosoves per Produkte Medicinale (AKPM) 1000430070006144 BPK Prishtine, BPK Foreign Correspondent Banks: Account No. 55044937, Raiffeisen Zentralbank Oesterreich AG, Am Stadpark 9, 1030 Wien, (Swift code RZBAATWW) and Account No. 581287000, Commerzbank AG, Filiale Frankfurt am Main, Kaiserstrasse 36, 60311 Frankfurt am Main, (Swift code COBADE33). The fee shall be paid before submission of the application. Evidence of fee payment: a copy of the bank transfer statement should be provided as a part of the application documentation. The marketing authorisation procedure can only proceed when the fee is paid.

3. A product can fall into more than one category simultaneously. Biological active substance(s) includes medicinal products derived from blood and plasma and immunological products. Advanced therapy medicinal products means any medicinal product based on processes focused on various gene transfer-produced bio-molecules, and biologically advanced therapeutic modified cells and tissues as active substances or part of active substances. Orphan applies to medicinal products defined by the EMEA as possessing orphan status and exceptional applies to medicinal products for which a MA may be granted under exceptional circumstances.

4. Only one name should be given in the following order of priority: INN\*, Ph.Eur., National Pharmacopoeia, common name, scientific name.

\* the active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant (for further details consult WHO Cumulative List No. 10 of International Nonproprietary Names (INN) for pharmaceutical substances).

5. Specify a broad therapeutic indication group (e.g. antihypertensives, diuretics) and indicate the ATC code for the main therapeutic indication. If the ATC code is not assigned, propose it and state that it is a proposal. The ATC code will be assigned during the marketing authorisation procedure according to the latest WHO ATC classification code valid for the authorisation period. This item is for information purposes only and does not affect the outcome of the authorisation decision-making process.

6. An application for authorisation of one dosage form and one strength of the medicinal product should be made on each application form except for homeopathics, where more dilution degrees can be included in an application. If the active substance is present as a salt, hydrate etc., it must be clearly and unambiguously stated whether the strength refers to the molecular substance or the active entity of the molecule. Use the list of standard Ph.Eur. terms.

7. In the case of parenteral products specify all proposed routes of administration, e.g. intravenous, intra-arterial, intramuscular, subcutaneous and as specified in the SPC proposal.

8. Summary of Product Characteristics (SPC). The SPC should be submitted in Albanian/Serbian languages and follow the structure set out in English language in KMA guideline KMAG2.1.V1 10/05 on CTD Module 1 – Administrative information or KMA guideline KMAG2.2.V1 10/05 on Part 1 – Summary of the dossier.

9. Package leaflet. The package leaflet proposal shall be provided in Albanian, Serbian languages and in conformance with KMA guideline KMAG2.1.V1 10/05 on CTD Module 1 – Administrative information or KMA guideline KMAG2.2.V1 10/05 on Part 1 – Summary of the dossier.

10. This table should be completed in such a way, that it is clear which immediate and outer packaging belong to a single package size, and should be unambiguous how many product presentations are included in this application. Include administration devices where applicable. A list of mock-ups\* or samples/specimens\*\* sent with the application should be attached.

\* 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 insert.

11. Provide a detailed description of the dosage form appearance (colour, shape, dimensions, imprint, markings, consistency, flavour etc.).

12. The responsible person is the person making the application on behalf of the applicant and is the same person as described in Note 1 above.

13. The qualified person responsible for pharmacovigilance should hold a university degree in pharmacy or human medicine

14. All manufacturing steps and the site of manufacture must be indicated. It is a legal requirement for the applicant to notify the Kosovo Medicines Agency of any alteration to the manufacturing sites and processes to that stated in this application.

15. Only the final manufacturer of the active substance(s) should be mentioned. The quality control certificate of the active ingredient(s) must be submitted. This should be a notified copy of the original

16. The same product means the same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form.

17. Specify the EAN bar code, if available. This item is for information purposes only and does not affect the marketing authorisation decision-making process.

18. If the medicinal product is currently protected by intellectual property rights conventions in terms of either its trade name or composition and the applicant wishes to apply these rights in the territory of Kosovo this has to be clearly stated. The existing rights should be clearly stated in Annex 5.21 to this application at the discretion of the applicant. The Annex should state the nature of the patent(s), under which jurisdiction(s) and when the patent(s) were issued, expiry dates of patent(s) and registration and expiry of registered trade names. For medicinal products authorised in Kosovo that have the granted status of 'innovative medicinal products', a period of data exclusivity shall apply in accordance with applicable EU procedures





Anex 4	Anex 4	Anex 4
<p><b>Kontrata per fabrikim dhe analiza</b></p>	<p><b>Contract Manufacture and Analysis</b></p>	<p><b>Ugovor za fabrikaciju i analiza</b></p>
<p>Ky kre shqyrton përgjegjësitë e fabrikuesit kundrejt Autoriteve Kompetente lidhur me Autorizimin e Fabrikimit dhe Autorizimin e Tregtimit të lëshuar.</p>	<p>This Chapter deals with the responsibilities of manufacturers towards the Competent Authorities with respect to the granting of marketing and manufacturing authorisations.</p>	<p>Ovo poglavlje razmatra odgovornosti proizvođača prema kompetentnim organima u odnosu davanja dozvole za marketing i proizvodnju.</p>
<p><b>1.1. Të përgjithshme</b></p>	<p><b>1.1. General</b></p>	<p><b>1.1. Opšte</b></p>
<p>Kontrata për fabrikim dhe analiza duhet të përcaktohet në mënyrë korrekte, që të shmangen keqkuptimet të cilat mund të rezultojnë në një produkt ose një punë jocalësore. Duhet të ketë një kontratë me shkrim midis Dhënësit të Kontratës dhe Pranuesit të Kontratës, e cila në mënyrë të qartë përcakton detyrimet e secilës palë. Kontrata duhet të paraqesë qartë mënyrën nëpërmjet së cilës Personi i Kualifikuar ushtron përgjegjësinë e tij të plotë në lejimin/lirimin e çdo numri serie të barit (produktit) për efekt shitjeje. Të gjitha marrëveshjet në lidhje me kontratën për fabrikim dhe analiza, përfshirë këtu dhe ndonjë ndryshim të propozuar për marrëveshjen teknike apo të tjera, duhet të jenë në përputhje me autorizimin e tregtimit për produktin në fjalë.</p>	<p>The contract for the fabrication and analysis must be correctly defined, to avoid misunderstandings which could result in a poor quality product or work. There must be a written contract between the Contract Providers and recipients of Contract, which clearly defines the obligations of each party. The contract should clearly present the manner in which the qualified person exercises his full responsibility in allowing/releasing of each number of medicine series (product) for the purpose of sale. All agreements regarding the contract for fabrication and analysis, including any proposed changes to technical or other agreement, should be in accordance with the marketing authorization for the product in question.</p>	<p>Ugovor za izradu i analizu mora biti tačno definisan, da bi se izbegli nesporazumi koji bi mogli dovesti do lošeg kvaliteta proizvoda ili rada. Mora da postoji pisani ugovor između Davaoca Ugovora i Primaoca Ugovora, koji jasno definiše obaveze svake strane. Ugovor mora da jasno predstavi način na koji kvalifikovano lice vrši svoju punu odgovornost za dozvoljavanje/oslobađanje svakog broja serije leka (proizvoda) u svrhu prodaje. Svi sporazumi vezani za ugovor o izradivanju i analizama, uključujući sve predložene izmene tehničkih ili drugih sporazuma, mora da bude u skladu sa autorizacijom za promet za proizvod u pitanju.</p>

<p><b>1.2. Dhënësi i kontratës</b></p> <p>a) Dhënësi i Kontratës është përgjegjës për vlerësimin e kompetencës të pranuesit të kontratës me qëllim të kryerjes së suksesshme të punës së kërkuar dhe për sigurimin nëpërmjet saj, që do të zbatohen parimet dhe udhëzimet e PMF-se të barnave ashtu siç janë parashikuar në këtë udhëzues.</p> <p>b) Dhënësi i Kontratës duhet të pajisë Pranuesin e Kontratës me të gjithë informacionin e nevojshëm për kryerjen në mënyrë korrekte të operacioneve të kontraktuara, në përputhje me Autorizimin e Tregtimit apo ndonjë kërkesë tjetër ligjore. Dhënësi i Kontratës duhet të sigurojë që Pranuesi i Kontratës është tërësisht i informuar për çdo problem me produktin/barin ose me punën e cila mund të paraqesë ndonjë rrezik për ambientet e tij, paisjet, personelin, materialet ose produktet e tjera.</p> <p>c) Dhënësi i Kontratës duhet të sigurohet që të gjitha produktet e përpunuara dhe materialet e dorëzuara (furnizuara) atij nëpërmjet Pranuesit të Kontratës,</p>	<p><b>1.2. The Contract Giver</b></p> <p>a) The Contract Giver is responsible for assessing the competence of the Contract Acceptor to carry out successfully the work required and for ensuring by means of the contract that the principles and guidelines of GMP as interpreted in this Guide are followed.</p> <p>b) The Contract Giver should provide the Contract Acceptor with all the information necessary to carry out the contracted operations correctly in accordance with the marketing authorisation and any other legal requirements. The Contract Giver should ensure that the Contract Acceptor is fully aware of any problems associated with the product or the work which might pose a hazard to his premises, equipment, personnel, other materials or other products.</p> <p>c) The Contract Giver should ensure that all processed products and materials delivered to him by the Contract Acceptor comply with their specifications or that</p>	<p><b>1.2. Davaoc Ugovora</b></p> <p>a) Davaac ugovora je odgovoran za procenu kompetentnosti primaoca ugovora, za uspešno obavljanje potrebnog posla i da putem ugovora obezbedi da se principi i uputstva za DPP naglašenih u ovom uputstvu primenjuju.</p> <p>b) Davaac Ugovora treba da obezbedi Primaocu Ugovora sve potrebne informacije za ispravno obavljanje ugovorenih poslova u skladu sa autorizacijom marketinga i svim drugim zakonskim obavezama. Davaac Ugovora treba da obezbedi da je Primaoc Ugovora potpuno svestan svih problema u vezi sa proizvodom ili radom, koji bi mogli predstavljati opasnost za njegove prostorije, opremu, osoblje i drugih materijala ili proizvoda.</p> <p>c) Davaac Ugovora treba da obezbedi da svi obrađeni proizvodi i materijali dostavljeni od strane Primaoca Ugovora budu u skladu sa njihovim specifikacijama ili da su proizvodi i da</p>
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<p>janë në përputhje me specifikimet e tyre dhe që produktet janë lejuar/liruar nga një Person i Kualifikuar.</p>	<p>the products have been released by a Qualified Person.</p>	<p>su proizvodi dozvoljeni/pušteni od strane kvalifikovane osobe</p>
<p><b>1.3. Pranuesi i Kontratës</b></p> <p>a) Pranuesi i Kontratës duhet të ketë në zotërim ambientet dhe paisjet e duhura, njohuri dhe eksperiencë, personel kompetent për kryerjen në mënyrë të suksesshme të punës së përcaktuar nga Dhënësi i Kontratës. Kontrata për fabrikim mund të ndërmerret vetëm nga një fabrikues, i cili është mbajtës i një autorizimi fabrikimi.</p> <p>b) Pranuesi i Kontratës duhet të sigurojë që të gjitha produktet apo materialet e dorëzuara (furnizura) atij janë të përshtatshme për qëllimin e synuar.</p> <p>c) Pranuesi i Kontratës nuk do të kalojë drejt një pale të tretë ndonjë punë të besuar atij sipas kontratës, pa vlerësimin paraprak të Dhënësit të Kontratës dhe aprovimit të marrëveshjeve. Marrëveshjet e bëra midis Pranuesit të Kontratës dhe çdo palë të tretë duhet të sigurojnë që fabrikimi dhe informacioni analitik është bërë i mundur në të njëjtën mënyrë sikurse midis Dhënësit dhe Pranuesit fillestar të Kontratës.</p>	<p><b>1.3. The Contract Acceptor</b></p> <p>a) The Contract Acceptor must have adequate premises and equipment, knowledge and experience, and competent personnel to carry out satisfactorily the work ordered by the Contract Giver. Contract manufacture may be undertaken only by a manufacturer who is the holder of a manufacturing authorisation.</p> <p>b) The Contract Acceptor should ensure that all products or materials delivered to him are suitable for their intended purpose.</p> <p>c) The Contract Acceptor should not pass to a third party any of the work entrusted to him under the contract without the Contract Giver's prior evaluation and approval of the arrangements. Arrangements made between the Contract Acceptor and any third party should ensure that the manufacturing and analytical information is made available in the same way as between the original Contract Giver and Contract</p>	<p><b>1.3. Primaoc Ugovora</b></p> <p>a) Primaoc Ugovora mora posedovati odgovarajuće objekte, opremu, znanje i iskustvo, i stručna lica za uspešno obavljanje posla određenog od strane Davaoca Ugovora. Ugovor za izradu može se preduzeti od strane samo jednog proizvođača koji je nosilac dozvole za proizvodnju.</p> <p>b) Primaoc Ugovora treba da obezbedi da svi proizvodi ili materijali koji mu se isporučuju budu pogodni za svrhu za koju su namenjeni.</p> <p>c) Primaoc Ugovora ne sme preneti bilo koji posao koji je prema ugovoru poveren njemu, trećem licu, bez prethodnog ocenjivanja od strane Davaoca Ugovora i odobrenja ugovora. Ugovori između Primaoca Ugovora i trećeg lica moraju osiguravati da proizvodnja i analitičke informacije budu dostupne na isti način kao i između Davoca Ugovora i prvobitnog Primaoca Ugovora.</p>



<p>d) Pranuesi i Kontratës duhet të shmangët nga çdo lloj aktiviteti i cili mund të ndikojë negativisht në cilësinë e produktit të fabrikuar dhe/ose të analizuar për Dhënësin e Kontratës.</p>	<p>Acceptor.</p> <p>d) The Contract Acceptor should refrain from any activity which may adversely affect the quality of the product manufactured and/or analysed for the Contract Giver.</p>	<p>d) Primaoc Ugovora treba izbegavati svaku aktivnost koja može negativno uticati na kvalitet proizvoda koji je fabrikovan i/ili analiziran za Davaoca Ugovora.</p>
<p><b>1.4. Kontrata</b></p> <p>a) Një kontratë duhet të hartohet midis Dhënësit të Kontratës dhe Pranuesit të Kontratës, e cila specifikon përgjegjësitë respektive të tyre lidhur me fabrikimin dhe kontrollin e produktit. Aspektet teknike të kontratës duhet të përcaktohen nga persona kompetentë, zotërues të mirë të teknologjisë farmaceutike, analizave dhe PMF-së të barnave. Të gjitha marrëveshjet për fabrikimin dhe analizat duhet të jenë në përputhje me Autorizimin e Tregtimit, rënë dakort midis dy palëve.</p> <p>b) Kontrata duhet të specifikojë mënyrën se si Personi i Kualifikuar lejon/liron serinë për shitje, siguron që çdo seri ka qenë e fabrikuar dhe verifikuar në përputhjen me kërkesat e Autorizimit të Tregtimit.</p> <p>c) Kontrata duhet të përshkruajë në mënyrë të qartë se kush është</p>	<p><b>1.4. The Contract</b></p> <p>a) A contract should be drawn up between the Contract Giver and the Contract Acceptor which specifies their respective responsibilities relating to the manufacture and control of the product. Technical aspects of the contract should be drawn up by competent persons suitably knowledgeable in pharmaceutical technology, analysis and Good Manufacturing Practice. All arrangements for manufacture and analysis must be in accordance with the marketing authorisation and agreed by both parties.</p> <p>b) The contract should specify the way in which the Qualified Person releasing the batch for sale ensures that each batch has been manufactured and checked for compliance with the requirements of Marketing Authorisation.</p> <p>c) The contract should describe clearly who is responsible for</p>	<p><b>1.4. Ugovor</b></p> <p>a) Između Primaoca Ugovora i Davaoca Ugovora mora se pripremiti ugovor koji će određivati njihove respektivne odgovornosti koji se odnose na proizvodnju i kontrolu proizvoda. Tehnički aspekti ugovora će se utvrditi od strane kompetentnih lica koji su eksperti u polju farmaceutske tehnologije analize i DPP lekova. Svi sporazumi za proizvodnju i analizu moraju biti u skladu sa autorizacijom trgovine, dogovoreno između obe strane.</p> <p>b) Ugovor bi trebalo da odredi način na koji kvalifikovano lice dozvoljava/izdaje serju za prodaju, obezbeđuje da je svaka serija bila proverena i proizvedena u skladu sa zahtevima Autorizacije Trgovine.</p> <p>c) Ugovor bi trebalo da jasno opisuje ko je odgovoran za</p>

<p>përgjegjës për blerjen e materialeve, analizën dhe lejimin/lirimin e materialeve/lendëve, ndërmarrjen e kontrolleve mbi prodhimin dhe cilësinë, duke përfshirë kontrollet në proces dhe se kush ka përgjegjësinë mbi marrjen e mostrave dhe analizat. Në rastin e kontraktimit të analizave, kontrata duhet të deklarojë nëse Pranuesi i Kontratës duhet të marrë apo jo mostra në ambientet e fabrikuesit.</p> <p>d) Dokumentet mbi fabrikimin, analizën dhe shpërndarjen si dhe mostrat referencë duhet të mbahen ose të jenë të disponueshme të Dhënësi i Kontratës. Në rast ankesash ose një defekti të dyshuar çdo dokument që ka lidhje me vlerësimin e cilësisë së një produkti duhet të jetë i disponueshëm dhe i specifikuar në procedurat e defekt/tërheqjes të Dhënësit të Kontratës.</p> <p>e) Kontrata duhet të lejojë Dhënësin e Kontratës për të vizituar paisjet e Pranuesit të Kontratës.</p> <p>f) Në rast kontraktimi të analizave, Pranuesi i Kontratës duhet të nënkuptojë që ai është subjekt inspektimi nga autoritetet kompetente.</p>	<p>purchasing materials, analyzing and admitting/releasing materials/substances, undertaking production and quality controls, including in-process controls, and who has responsibility for sampling and analysis. In the case of contract analysis, the contract should state whether or not the Contract Acceptor should take samples at the premises of the manufacturer.</p> <p>d) Manufacturing, analytical and distribution records, and reference samples should be kept by, or be available for, the Contract Giver. Any records relevant to assessing the quality of a product in the event of complaints or a suspected defect must be accessible and specified in the defect/recall procedures of the Contract Giver.</p> <p>e) The contract should permit the Contract Giver to visit the facilities of the Contract Acceptor.</p> <p>f) In the case of analysis contract, the Contract Acceptor should understand that he is subject to Inspection by the competent Authorities.</p>	<p>nabavku materijala, analizu i dozvoljavanje / odobravanje materijala / substance, kontrolisanje proizvodnje i kvaliteta, uključujući kontrole u procesu, a ko ima odgovornost za uzimanje uzoraka i analiza. U slučaju ugovora analiza, ugovor bi trebalo da deklarise da li Primaoc Ugovora treba da uzme ili ne uzorke u prostorijama proizvođača.</p> <p>d) Dokumenti o proizvodnji, analizi i distribuciji i referentni uzorci treba da se čuvaju ili budu dostupni kod Davaoca Ugovora. U slučaju žalbe ili sumnje za defekt, svaki dokument vezan za procenu kvaliteta proizvoda mora biti dostupan i specifikovan u procedurama za defekt/povlačenje Davaoca Ugovora.</p> <p>e) Ugovor bo trebalo da dozvoljava Davaocu Ugovora da poseti postrojenja Primaoca Ugovora.</p> <p>f) U slučaju ugovora analiza, Primaoc Ugovora treba da bude svestan da je predmet inspekcije kompetentnih organa.</p>
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## Aneksi 8-Tarifat e DAM/ tariffs in the DAM/ tarife odelenja AM

## SCHEDULE OF FEES FOR MARKETING AUTHORISATIONS

An applicant must pay the marketing authorisation fee (including expert examination costs) according to the following fee schedule.

TYPE OF APPLICATION	Fee (Euros)
<b>A. Marketing Authorisation (5 years)</b>	
1. Original medicinal product under <b>complete and independent procedure</b> (for each strength and form)	2,000
1.1 for each additional form	750
1.2 for each additional strength	500
1.3 for each additional package	250
2. Medicinal product under <b>EU- Centralised procedure EMA-CPP</b> (for each strength and form)	2,000
2.1 for each additional form	750
2.2 for each additional strength	500
2.3 for each additional package	250
3. Medicinal product under <b>EU- Decentralised procedure</b> (for each strength and form)	
3.1 NCE/NBE	2,000
3.2 Generic	1,000
3.3 for each additional form	750
3.4 for each additional strength	500
3.5 for each additional package	250
4. Medicinal product under <b>Unilateral recognition procedure</b> (for each strength and form)	2,000
4.1 for each additional form	750
4.2 for each additional strength	500
4.3 for each additional package	250
5. Medicinal product under <b>Well Established Medicinal Use (bibliographic) procedure</b> (for each strength and form)	1000
5.1 for each additional form	750
5.2 for each additional strength	500
5.3 for each additional package	250
6. Medicinal product under <b>Essential Similarity (Informed consent) procedure</b> (for each strength and form)	1,000
6.1 for each additional form	750
6.2 for each additional strength	500
6.3 for each additional package	250
7. Medicinal product under <b>Essential Similarity (Generic and Generic different) procedure</b> (for each strength and form)	1,000
7.1 for each additional form	750
7.2 for each additional strength	500
7.3 for each additional package	250



## Kosovo Medicines Agency

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<b>8. Line extension (Reference strength and form)</b>	1000
8.1 for each additional form	750
8.2 for each additional strength	500
8.3 for each additional package	250
<b>9. Traditional Herbal medicinal product</b>	1000
9.1 for each additional form	750
9.2 for each additional strength	500
9.3 for each additional package	250
<b>10. Medicinal product under Simplified procedure pursuant to Article 11 of the AI Nr.17/2013 (for each strength and form)</b>	2000
10.1 for each additional form	750
10.2 for each additional strength	500
10.3 for each additional package	250
<b>11.CPP Certificate</b>	1000
<b>12. Regulatory or Scientific advice to applicant</b>	50
<b>13.Variations</b>	
	200
13.1.Type I variation	400
13.2. Type II variation	

## 14. Renewal

**Renewal fee will be the half of payment from the fee which has been paid depending on the type of application for Marketing Authorization.**

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