# Check list for documents of Re-registeration biological products file

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| **Date of Submission** | |
| **Product Name** | |
| **Applicant Name** | |
| **Applicant Representative** | |
| **Biological Registration Specialist** | |

| Prepare the following items | | Check | Notes |
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| **I. Core Registration file** | | | |
| **First: Administrative data** | | | |
| **1** | **Company profile submitted & updated** | | |
| **2** | **Index** | | |
| **3** | **Covering letter on applicant head letter signed and stamped by the registration general manager for file submission for Renewal process** | | |
| **5** | **Copy of the updated pricing certificate** | | |
| **6** | **C.D. containing all content of the 3 files (core, inspection, quality)** | | |
| **7** | **A certification that all data in the file is true and accurate and updated and identical to the CD** | | |
| **8** | **Copy of all approvals or Exemptions related to the Product (technical committee, scientific committee, inspection reports, …)** | | |
| **9** | **Copy of Authorization letter for the person responsible for communication on behalf of applicant during the procedure and this letter should be certified as truly signed** | | |
| **10** | **Payment receipt (according to the last update of fees decree)** | | |
| **11** | **Original List OF variations from the MA holder** | | |
| **12** | **Application form for Renewal of biological medicinal products Signed & Stamped by the Applicant (each paper)** | | |
| **13** | **Composition Certificate** | | |
| | Original | | |
| | Authenticated & Notarized **(if not attached to CPP)** * for imported products | | |
| | On license holder letter head | | |



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| | Signed & Stamped by the license holder | | |
| | Trade name of the product is specified | | |
| | Dosage form of the product is specified | | |
| | Active ingredient (s) with its (their) quantity (ies) per unit dose is (are) specified | | |
| | inactive ingredient (s) with its (their) quantity (ies) per unit dose is (are) specified | | |
| | Specifications of Active & inactive ingredients are mentioned (e.g. in house specification , USP ,EU ,JP ,British pharmacopeia) | | |
| | The overage should be mentioned | | |
| | Identical to CPP & CTD | | |
| | API name is specified (the INN, scientific, pharmacopoeia, common name accompanied by its salt or hydrate form (if any)) | | |
| **14** | **<u>For Imported products:</u> CPP issued by Competent Authorities in Country of Origin** | | |
| | Original | | |
| | Authenticated <u>from Embassy</u> | | |
| | Valid | | |
| | The Arab Republic of Egypt is mentioned as Importing Country | | |
| | Number of product license is specified | | |
| | Date of issue is specified | | |
| | Dosage form (s) and Strength (s) are specified. | | |
| | License Holder (address, city, country) is specified | | |
| | Role of License Holder is specified | | |
| | Manufacturer of solvent should be mentioned (if different from manufacturer of the finished product) | | |
| | Product marketed in the COO | | |
| | Manufacturing sites involved in the Production of the product should be mentioned with its role (Finished product, Primary Packager, Secondary Packager, Batch releaser, Solvent manufacturer) | | |
| | Good Manufacturing Practice (GMP) of the manufacturer is specified | | |
| | Pack Presentation and pack size(s) of the Product is (are) specified (could be as an attachment) | | |
| | Active Ingredient(s) by its salt or hydrate form (if any) with its (their) quantity (ies) per unit dose is (are) specified | | |
| | Inactive Ingredient(s) with its (their) quantity (ies) per unit dose is (are) specified (could be as an attachment) | | |
| | Shelf-life of the Product is specified (could be as an attachment) | | |
| | Storage Conditions of the Product is specified (could be as an attachment) | | |
| | SPC or package insert of the product (could be as an attachment) | | |
| | If the Name of the product may change in Egypt, copy of CPP from any reference country with the name targeted to be in Egypt should be submitted (technical committee decision on 22/5/2014). | | |
| **15** | **GMP of all the manufacturers involved in the production process** **(Manufacturer of active substance, Manufacturer of finished, Manufacturer of solvent, primary packager, Secondary packager and Batch Releaser)** | | |
| | Authenticated (From Embassy) original or true copy (authentication on the certificate) | | |



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| | Valid | | |
| | The name of plant by its address should be specified | | |
| | The date of the last inspection should be specified | | |
| | The invalidation date should be mentioned | | |
| | The production lines are specified | | |
| **16** | **Copy of Manufacturing license for all manufacturers** | | |
| | Valid | | |
| | Authenticated (From Embassy) original or true copy (authentication on the certificate) | | |
| | The name of plant by its address should be specified | | |
| | The invalidation date should be mentioned | | |
| | The production lines are specified | | |
| | Issued from the health authority of the specified country | | |
| **17** | **Outer label of the Product (1 original pack recently marketed in Egyptian market and 7 layouts)** | | |
| **18** | **Inner Label of the product (1 original label that recently marketed in Egyptian market and 7 layouts)** | | |
| **19** | **Official declaration (from scientific office or from manufacturer) stating the type of the submitted pack (COO pack , country-specific pack , international pack …..etc. ) with differences** | | |
| **20** | **Official declaration stating the relationship between Manufacturer, Importer and Distributor that Should be notarized from the chamber of commerce or its equivalent in the country of origin and Authenticated from the Egyptian embassy** | | |
| **21** | **Copy of Agency or distribution contract that Should be notarized from the chamber of commerce or its equivalent in the country of origin and Authenticated from the Egyptian embassy abroad & submit original for review** | | |
| **22** | **<u>In case of imported bulk naked vial</u>** that manufactured abroad and packed locally, the following is required:<br>- Copy of packaging contract between the importing company & local manufacturing<br>- Original Authorization letter from the abroad mother company to the importing for product registration and packaging with a local licensed packaging site (Should be notarized from the chamber of commerce or its equivalent in the country of origin and Authenticated from the Egyptian embassy abroad & submit original for review) | | |



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| 23 | Letter of Acknowledgment of full responsibility for storing the raw materials and for all stages of manufacturing and for the product's conformity with the technical specifications until the completion of distribution | | |
| 24 | Submitting a pledge acknowledging his commitment to the provisions of the Intellectual Property Protection Law No. 82 of 2002 | | |
| 25 | Submit the updated scientific office license, importer register for all importers, Updated Storage License for all Storage sites, updated Tax card & Commercial register | | |
| 26 | Copy of insert | | |
| 27 | CD containing Complete & updated Module 3 | | |
| 28 | A declaration from the license holder mentioning the product name submitted that the submitted Module 3 (version number & date) at the renewal process is the updated and complete | | |
| 29 | A declaration letter from the applicant mentioning that there are no updates in the scientific file at the renewal submission date and all updates are submitted and approved previously (or there is no updates undertaken from the product license issuance till renewal submission) | | |
| 30 | A declaration letter from the applicant mentioning that there are no updates in the stability file at the renewal submission date and all updates are submitted and approved previously (or there is no updates undertaken from the product license issuance till renewal submission) | | |
| 31 | COA for active substance & finished Product (solvent if needed) | | |
| 32 | TSE free certificate from license holder | | |
| 33 | If the materials entering in the product formulation are from blood derivatives, the following will be presented: | | |
| | Official certificates declaring plasma source (legalized in case of blood products active substance) | | |
| | HV-1, HV-2, HBsAG, HCV freedom legalized certificate for the plasma | | |
| | Copy of Certificate of release from Health authority (Drug substance only) | | |
| **File II: Inspection file** | | | |
| 1 | Site master file (for Manufacturer of active substance, Manufacturer of finished, Manufacturer of solvent, primary & secondary packager and batch releaser) including: | | |



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| | • Covering letter from the License holder declaring that the submitted SMF is the most updated and approved signed, stamped and Authorized<br>• Relevant Premises & utilities information about each site.<br>• Current status of the manufacturing site(s) with respect to current good manufacturing practice (cGMP) requirements.<br>• Legible color printouts of water treatment and air-handling systems, including pipeline and instrumentation drawings in A3 or A2 format.<br>• List of all the products and dosage forms manufactured on- the same site especially same production lines. | | |
| **2** | **GMP of all the manufacturers involved in the production process & Manufacturing license indicating production lines (Active substance, Manufacturer of finished, Manufacturer of solvent, primary packager)** | | |
| **3** | **- Latest full inspection report(s) for inspection performed by a stringent regulatory authority in the past three years and their outcomes.<br>- Last Annual product review.<br>- One completed batch manufacturing and packaging record.<br>- List of any recalls in the past three years related to products with quality defects (if found).<br>- Any warning letter or equivalent regulatory action (production-line specific) (if found).** | | |
| **4** | **CPP of the product** | | |
| **5** | **Manufacturing process for Active substance and Finished product (and solvent, if present)** | | |
| **6** | **Manufacturing validation for Active substance and Finished product (and solvent, if present)** | | |
| **7** | **Cold chain Storage & transportation procedures.** | | |
| **8** | **Copy of application form for biological products** | | |
| **9** | **List of each site where the product (Drug Substance and Drug Product), if authorized, is or would be manufactured.** | | |
| **File III: Quality file** | | | |
| **1** | **Copy of application form for biological products** | | |
| **2** | **Summary protocol (for blood products & vaccines)** | | |
| **3** | **Complete updated CTD** | | |
| **4** | **Certificate of Analysis for Drug substance & Finished product & solvent (if solvent present)** | | |
| **File IV- PV requirements** | | | |
| 5 | **إعادة تسجيل مستحضر حيوي مستورد، المستندات المطلوبة كالتالي:**<br>Soft copy searchable text PDF:<br>1. Delegation letter التفويض خطاب<br>2. Previous license of the product/s | | |



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| | 3. Updated Cover letter (on the company paper of the PV representative/agent/scientific office) clarifying the Date of the submission (not exceeding 2 days before the submission)/ Directed to the Manager of General Administration of Pharmaceutical Vigilance/ Name of the product /Name of the Active substance/ context of submission/ Name of the MAH/ Content of the submission/ Actual signature of the QPPV or LSR "signature by QPPV or LSR (not print screen)"- "Accepted Digital/Electronic signature"/company stamp<br>4. صورة ضوئية من أصل ايصال سداد + "pink receipt" صورة ضوئية من أصل ايصال سداد "yellow receipt" لكل **(File number)** مقابل الخدمات المقدمة من الادارة المركزية للرعاية الصيدلية مختوم ا بختم اليقظة بقيمة 1000 جنيه مصري" لا تشمل ضريبة القيمة المضافة "عن طلب تقييم ملحق تحديث المعلومات الإكلينيكية المقدم في إطار إعادة التسجيل(ACO) طبقا لقرار السيد الاستاذ الدكتور رئيس الهيئة رقم / 99 ،2022<br>5. صورة ضوئية من أصل ايصال سداد + "pink receipt" صورة ضوئية من أصل ايصال سداد "yellow receipt" لكل **(File number)** مقابل الخدمات المقدمة من الادارة المركزية للرعاية الصيدلية مختوم ا بختم اليقظة بقيمة 1000 جنيه مصري" لا تشمل ضريبة القيمة المضافة "عن طلب تقييم خطة إدارة المخاطر (RMP) طبقا لقرار السيد الاستاذ الدكتور رئيس الهيئة رقم2021 / 6<br>(موضحا بالايصال اسم المستحضر/المادة الفعالة/التركيز – الشكل الصيدلي/اطار التقديم / اسم الشركة صاحبة المستحضر)<br>6. Confirmation e-mail by PSMF reception portal (as an evidence of submission of the PSMF of the company to EPVC) **or** Latest released valid PSMF assessment report "for all concerned parties"<br>7. Updated version of Summary of PSMF(s)/PSSF<br>8. In case of submission by PV representative or agent, the PV rep./agent should submit an authorized and authenticated (by all concerned parties) PV agreement between the MAH & the service provider covering all the PV activities<br>9. The Addendum to clinical overview (ACO): covering the period since the initial marketing authorization or since the last renewal until 90 days prior to renewal submission.<br>10. The most updated "EU/Global/Core-Risk Management Plan (RMP)"of the product.<br>11. The Egyptian display of EU-RMP | | |
| 6 | **<u>بالنسبة لإعادة تسجيل مستحضر حيوي محلي المستندات المطلوبة</u>**<br>Soft copy searchable text PDF:<br>1. Delegation letter تفويض خطاب<br>2. Previous license of the product/s<br>3. Updated Cover letter (on the company paper of the PV representative/agent/scientific office) clarifying the Date of the submission (not exceeding 2 days before the submission)/ Directed to | | |



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| | the Manager of General Administration of Pharmaceutical Vigilance/ Name of the product /Name of the Active substance/ context of submission/ Name of the MAH/ Content of the submission/ Actual signature of the QPPV “signature by QPPV (not print screen)”/company stamp<br>4. صورة ضوئية من أصل ايصال سداد “yellow receipt” + "pink receipt” لكل **(File number)** مقابل الخدمات المقدمة من الادارة المركزية للرعاية الصيدلية مختوم ا بختم اليقظة بقيمة 1000 جنيه مصري "لا تشمل ضريبة القيمة المضافة "عن طلب تقييم ملحق تحديث المعلومات الإكلينيكية المقدم في إطار إعادة التسجيل (ACO) طبقا لقرار السيد الاستاذ الدكتور رئيس الهيئة رقم 99 / 2022 ،<br>5. صورة ضوئية من أصل ايصال سداد “yellow receipt + pink receipt” لكل **(File number)** مقابل الخدمات المقدمة من الادارة المركزية للرعاية الصيدلية مختوم ا بختم اليقظة بقيمة 500 جنيه مصري" لا تشمل ضريبة القيمة المضافة "عن طلب تقييم خطة إدارة المخاطر (RMP) طبق ا لقرار السيد الاستاذ الدكتور رئيس الهيئة رقم / 6 2021 (موضحا بالايصال اسم المستحضر/المادة الفعالة/التركيز – الشكل الصيدلي/اطار التقديم /اسم الشركة صاحبة المستحضر)<br>6. Confirmation e-mail by PSMF reception portal (as an evidence of submission of the PSMF of the company to EPVC) or Latest released valid PSMF assessment report “all concerned parties”<br>7. Updated version of Summary of PSMF(s)/PSSF<br>8. In case of submission by PV representative, the PV rep should submit an authorized and authenticated (by all concerned parties) PV agreement between the MAH & the service provider covering all the PV activities<br>9. The Addendum to clinical overview (ACO): covering the period since the initial marketing authorization or since the last renewal until 90 days prior to renewal submission.<br>10. Egyptian-Risk Management Plan (RMP) of the product. | | |



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