Central Administration for Pharmaceutical Products
General Administration Of Biocides Registration

Notice to applicant

Checklist of Biocides Variations

Year 2025

Code: EDREX:NP.CAPP.102
Version No: 1
Issue Date:2/2025
Effective date (if needed):2/2025

Notice to applicant body of content

Checklist of Biocides Variations

License holder (Ownership) variation

Required Documents	Comments
Variation request for biocidal products (cover letter explaining the required variation)	
Payment fees	
A copy of **the last valid registration license** & the original for viewing (If not valid, preliminary approval of re-registration is obtained)	
A copy of all **approvals**, **variations, or decisions** related to the product	
Authenticated Waiver (original) from the old product license holder with the product name, concentration, and registration number	
Manufacturing/packaging & Storage contract between the new license holder and the manufacturer/packager, attaching the agreement **annex** with the product name, concentration, and registration number (authenticated from EDA legal affairs)	
Approved **Composition** certificate (original copy) on manufacturer's papers signed by production manager or R&D manager & stamped	
The approved and stamped **layout/carton box** (and **inner leaflet** (if present) on the new license holder paper	
Declarations	
official documents of old & new license holders including Valid commercial register "with F-Toll/ toll activity in case of F-Toll/toll companies"(recently updated issuance) & Applicant tax card (valid)	
Copy of Technical operation license of the factory (latest version) issued from EDA & Manufacturing license from IDA including production line of the product.	
For imported product: 1- **Authenticated declaration letter from the old license holder states the ownership transfer** 2- **Declaration Letter from New license holder** Stating the ownership transfer 3- **Authenticated Declaration Letter from New license holder Stating** the ownership transfer ensuring that there is NO CHANGE in product composition, specification,	

manufacturing site & process, and container/closure system. The product trade Name & Reg. no. is mentioned 4- **The authorization letter/Agency agreement** between the new product license holder and the applicant 5- **Authenticated Manufacturing contract / Packaging contract** between New LH/MAH & Manufacturer/packager * If the contract is between the applicant & packager: A letter from LH/MAH authorizing the applicant to sign contracts (authenticated) & the packaging contract is authenticated from bank & EDA legal affairs. 6- Approved **Composition** certificate (original copy) signed, stamped 7- The approved and stamped **layout/carton box** (and **inner leaflet** (if present). 8- Recent & valid Certificate of a Pharmaceutical Product **(CPP) or free sale certificate containing the most updated data of the product** 9- Copy of Tax card, Commercial Register for the local company in addition to Registration card from the General Authority for export and import Control & EDA Record importing register. 10- Scientific office License & Authorization letter for the scientific office to register finished Imported products (In case the applicant of imported products is a scientific office).	

Checklist of Biocides Variations

Change name/address of License holder

Required Documents	Comments
Variation request for biocidal products (cover letter explaining the required variation)	
Payment fees	
A copy of **the last valid registration license** & the original for viewing (If not valid, preliminary approval of re-registration is obtained)	
A copy of all **approvals**, **variations, or decisions** related to the product	
Approved **Composition** certificate (original copy) on manufacturer's papers signed by production manager or R&D manager & stamped	
The approved and stamped **layout/carton box** (and **inner leaflet** if present) on the new license holder paper	
official documents with new name/address of license holder including Valid commercial register "with F-Toll/ toll activity in case of F-Toll/toll companies"(recently updated issuance) & **Tax card in which the new name is mentioned**	
Declarations	
For imported product: 1. **Authenticated declaration letter** from the product license holder and/or marketing authorization holder states the new name and/or address and that there is **no change** in the legal entity of the product license holder and/or marketing authorization holder and it does not include any change in the manufacturer 2. **Approved Composition** certificate (original copy) signed, stamped 3. The approved and stamped **layout/carton box** (and **inner leaflet** if present). 4. Recent & valid Certificate of a Pharmaceutical Product **(CPP) or free sale certificate containing the most updated data of the product** 5. Copy of Tax card, Commercial Register for the local company in addition to Registration card from the General Authority for export and import Control & EDA Record importing register. 6. Scientific office License & Authorization letter for the scientific office to register finished Imported products (In case the applicant of imported products is a scientific office).	

Checklist of Biocides Variations

Addition/ Change of market Authorization holder of finished pharmaceutical products (for imported finished, imported bulk & under license products)

Required Documents	Comments
Variation request for biocidal products (cover letter explaining the required variation)	
Payment fees	
A copy of **the last valid registration license** & the original for viewing (If not valid, preliminary approval of re-registration is obtained)	
A copy of all **approvals**, **variations, or decisions** related to the product	
Authenticated Declaration Letter from license holder in country of origin including Product name, reg.no. Appointing the New MAH in Egypt clarifying its full responsibilities .	
Authenticated NO CHANGE Declaration Letter from New MAH in Egypt Ensuring that there is NO CHANGE in product composition, specification, manufacturing process, and container/closure system	
Declarations	
Recent & valid Certificate of a Pharmaceutical Product **(CPP) or free sale certificate containing the most updated data of the product**	
The approved and stamped **layout/carton box** (and **inner leaflet** (if present any change in data).	

Checklist of Biocides Variations

Manufacturer Change & (Manufacturing site (or primary packaging site) change

Required Documents	Comment
Variation request for biocidal products (cover letter explaining the required variation)	
Payment fees	
A copy of **the last valid registration license** & the original for viewing (If not valid, preliminary approval of re-registration is obtained)	
A copy of all **approvals**, **variations, or decisions** related to the product	
Authenticated Waiver (original &copy) from the old manufacturer with the product name, concentration, and registration number	
Manufacturing/packaging & Storage contract between the license holder and the new manufacturer/packager, attaching the agreement **annex** with the product name, concentration, and registration number (authenticated from EDA legal affairs)	
Approved **Composition** certificate (original copy) on manufacturer's papers signed by production manager or R&D manager & stamped	
The approved and stamped **layout/carton box** (and **inner leaflet** if present) on the new manufacturer paper	
Declarations	
Copy of **official documents** of old & new manufacturers & license holders including commercial registers & Tax cards	
Copy of Technical operation license of the old and new manufacturer (latest version) issued from EDA & Manufacturing license from IDA including production line of the product.	
For imported product: 1- **Authenticated Letter of variation from product license holder stating** the required variation 2- **Authenticated Waiver** (original &copy) from the old manufacturer with the product name, concentration, and registration number or **termination letter** from the license holder to the old manufacturing /packaging site signed, stamped 3- **Valid GMP/ISO** certificate of the new manufacturer 4- **COA of finished product** from the new manufacturer 5- **Authenticated Packaging contract (for imported bulk**	

products) & manufacturing contract (for under license products) Between LH/MAH & new manufacturer/ Packager *If the contract is between the applicant & manufacturer/ Packager: A letter from LH/MAH authorizing the applicant to sign contracts. 6- Recent & valid Certificate of a Pharmaceutical Product **(CPP) or free sale certificate containing the most updated data of the product** 7- **Copy of manufacturing license of the new factory** (latest version) & confirming the presence of production line of the product **(under license products)** 8- Authenticated approved **Composition** certificate (original copy) signed, stamped 9- The approved and stamped **layout/carton box (and inner leaflet** (if present).	

Checklist of Biocides Variations

Manufacturer Addition & (Manufacturing site or primary packaging site) addition

Required Documents	Comments
Variation request for biocidal products (cover letter explaining the required variation)	
Payment fees	
A copy of **the last valid registration license** & the original for viewing (If not valid, preliminary approval of re-registration is obtained)	
A copy of all **approvals**, **variations, or decisions** related to the product	
Manufacturing/packaging & Storage contract between the license holder and the new manufacturer/packager, attaching the agreement **annex** with the product name, concentration, and registration number (authenticated from EDA legal affairs)	
Authenticated Declaration Letter from the license holder including the product trade name & reg. no. Stating: "The company takes the full legal responsibility for adding a new site without any responsibility on EDA, regarding the obligations and duties imposed under the manufacturing contract with the old factory (factories)". Names of the old factories are mentioned.	
Declarations	
Copy of **official documents** of old & new manufacturers & license holder including commercial registers & Tax cards	
Copy of Technical operation license of the old and new manufacturer (latest version) issued from EDA & Manufacturing license from IDA including production line of the product.	
For imported product: 1- **Authenticated Letter of variation from product license holder stating** the required variation 2- **Valid GMP/ISO** certificate of the added new manufacturer 3- **COA of finished product** from the added new manufacturer 4- **Authenticated Packaging contract (for imported bulk products) & manufacturing contract (for under license products)** Between LH/MAH & new manufacturer/ Packager	

*If the contract is between the applicant & manufacturer/packager: A letter from LH/MAH authorizing the applicant to sign contracts. 5- Recent & valid Certificate of a Pharmaceutical Product **(CPP) or free sale certificate containing the most updated data of the product** 6- **Copy of manufacturing license of the new factory** (latest version) & confirming the presence of production line of the product **(under license products)** 7- **Authenticated Declaration Letter from the license holder** including the product trade name & reg. no. Stating: "The company takes the full legal responsibility for adding a new site without any responsibility on EDA, regarding the obligations and duties imposed under the manufacturing contract with the old factory (factories)". Names of the old factories are mentioned.	

Checklist of Biocides Variations

Change name of Manufacturer (Manufacturing site)

Required Documents	Comments
Variation request for biocidal products (cover letter explaining the required variation)	
Payment fees	
A copy of **the last valid registration license** & the original for viewing (If not valid, preliminary approval of re-registration is obtained)	
A copy of all **approvals**, **variations, or decisions** related to the product	
Last Updated Factory License Released from EDA "Stating the New Name of the Manufacturing site	
Approved **Composition** certificate (original copy) on manufacturer's papers signed by production manager or R&D manager & stamped	
The approved and stamped **layout/carton box** (and **inner leaflet** (if present) on the new manufacturer name)	
Declarations	
official documents of old & new manufacturer name including Valid commercial register (recently updated issuance) & Applicant tax card (valid)	
Copy of Technical operation license of the manufacturer (old name and new name) issued from EDA & Manufacturing license from IDA including production line of the product.	
official documents of license holder including Valid commercial register "with F-Toll/ toll activity in case of F-Toll/toll companies"(recently updated issuance)& Applicant tax card (valid)	
For imported product: 1. **Letter of variation** from the product license holder stating the required variation for approval to change the name of the place of manufacture for the product stating the name of the product, its concentration, registration number, and the name of the owner, explaining that the change does not include the place of manufacture, the method of manufacture, or the quality of the product.	

2. **Declaration of the registered place of manufacture** and its new name & authenticated from Chamber of Commerce/Notary, Egyptian Consulate/Embassy. 3. **No Change Declaration** Letter from LH Stating that there's NO Change in the physical location of the manufacturing site, manufacturing process, quality & composition of the product (Authenticated from Chamber of Commerce/Notary, Egyptian Consulate/Embassy) 4. **Valid GMP/ISO** certificate of the manufacturer in which the new name/ address is mentioned. **5.** Recent & valid Certificate of a Pharmaceutical Product **(CPP) or free sale certificate containing the most updated data of the product** 6. Approved **Composition** certificate (original copy) signed, stamped & authenticated 7. The approved and stamped **layout/carton box** and **inner leaflet** (if present). 8. **Certificate of analysis** of the product from the factory with the new name.	

Checklist of Biocides Variations

Applicant change (change agent)

Required Documents	Comments
Variation request for biocidal products (cover letter explaining the required variation)	
Payment fees	
A copy of **the last valid registration license** & the original for viewing (If not valid, preliminary approval of re-registration is obtained)	
A copy of all **approvals**, **variations, or decisions** related to the product	
Termination letter from the license holder of the product terminating the agency for the old agent, authenticated by the Chamber of Commerce and the Egyptian Embassy abroad.	
Agency agreement/ Authorization letter from the license holder of the product for the new agent to register the product, authenticated by the Chamber of Commerce and the Egyptian Embassy abroad	
Approved **Composition** certificate (original copy) on manufacturer's papers signed by production manager or R&D manager & stamped	
The approved and stamped **layout/carton box** (and **inner leaflet** if present)	
Recent & valid Certificate of a Pharmaceutical Product **(CPP) or free sale certificate containing the most updated data of the product**	
Declarations	

Checklist of Biocides Variations

API manufacturing site change/Addition (API Supplier change/Addition)

Required Documents	Comments
Variation request for biocidal products (cover letter explaining the required variation)	
Payment fees	
A copy of **the last valid registration license** -approval & the original for viewing (If not valid, preliminary approval of re-registration is obtained)	
A copy of all **approvals**, **variations, or decisions** related to the product	
Valid GMP/ISO mentions the name of the raw material	
An approved declaration declares the suppliers of the active raw materials used in manufacturing, stating the following: The name of the product and its concentration The name of the raw material used in manufacturing The name of the factory and its country of origin, the name of the supplier and its country of origin	
Declarations	
COA of the raw material analysis certificate for each API manufacturing site, signed and sealed with the company's seal abroad.	
official documents of license holder including Valid commercial register "with F-Toll/ toll activity in case of F-Toll/toll companies"(recently updated issuance) & Applicant tax card (valid)	
For Under License Products: A declaration letter is submitted from the LH stating approval to add or change the source of the active raw material.	
For pesticides Products 1. **A copy of the impurities certificate** and the material handling certificate shall be submitted. 2. **free sale of API** "valid and authenticated" signed by responsible governmental authority in the country of origin	

3. **Authorization letter** from the manufacturer for the active substance, stating the degree of purity TC and the original for review, to be documented by the Chamber of Commerce and the Egyptian embassy in the country of origin 4. **Declaration of API supplier** (if there is a difference between the API manufacturer and API supplier, provide a declaration letter with the relation between them).	

Checklist of Biocides Variations

API manufacturing site name change (API Supplier name change)

Required Documents	Comments
Variation request on LH ,supplier, approved and stamped by it, explaining the company's variation request to approve changing the name of sources of active raw materials (indicating the old name and new name of sources) only without a change in the place of manufacture (manufacturing site the same)	
Payment fees	
A copy of **the last valid registration license** & the original for viewing (If not valid, preliminary approval of re-registration is obtained)	
A copy of all **approvals**, **variations, or decisions** related to the product	
GMP/ISO of old name mentions the name of the raw material	
Valid GMP/ISO of the new name indicating the same manufacturing place contains the active substance	
Declarations	
COA of the raw material analysis certificate for each API manufacturing site, signed and sealed with the company's seal abroad.	
official documents of license holder including Valid commercial register "with F-Toll/ toll activity in case of F-Toll/toll companies"(recently updated issuance)& Applicant tax card (valid)	

Checklist of Biocides Variations

Changing the purity (TC) of the active substance of pesticides

Required Documents	Comments
A declaration letter on the LH, approved and stamped by it, explaining the company's request to approve changing the purity of the active raw materials (indicating the old and new sources to be added or changed to them)	
Payment fees	
A copy of **the last valid registration license- approval** & the original for viewing (If not valid, preliminary approval of re-registration is obtained)	
A copy of all **approvals**, **variations, or decisions** related to the product	
Declaration from the LH indicating suppliers of the active raw materials used in manufacturing, stating the following: - The name of the product and its concentration - The name of the raw material used in manufacturing - The name of the factory and its country of origin, the name of the supplier and its country of origin	
Valid GMP/ISO of the suppliers of the active raw materials	
Certificate of impurities and Free sale of API "valid and authenticated" signed by responsible governmental authority in the country of origin	
Declarations	
official documents of license holder including Valid commercial register "with F-Toll/ toll activity in case of F-Toll/toll companies"(recently updated issuance) & Applicant tax card (valid)	
Authorization letter stating the degree of impurity, TC, and the original for review that they are documented by the Chamber of Commerce and the Egyptian embassy in the country of origin	
Approved **Composition** certificate (original copy) on manufacturer's papers signed by production manager or R&D manager & stamped	
The approved and stamped **layout/carton box** (and **inner leaflet** if present)	

Checklist of Biocides Variations

Changing the target pest of pesticides

Required Documents	Comments
Variation request for biocidal products (cover letter explaining the required variation)	
Payment fees	
A copy of **the last valid registration license** & the original for viewing (If not valid, preliminary approval of re-registration is obtained)	
A copy of all **approvals**, **variations, or decisions** related to the product	
A copy of the WHO scientific reference indicating the target pest and the active substance of the pesticide	
official documents of license holder including Valid commercial register "with F-Toll/ toll activity in case of F-Toll/toll companies"(recently updated issuance)& Applicant tax card (valid)	
Declarations	
The new stamped **layout/carton box** (and **inner leaflet** if present) of new target pest.	

Checklist of Biocides Variations

Changing the composition of inactive raw materials

Required Documents	Comments
Variation request for biocidal products (cover letter explaining the required variation)	
Payment fees	
A copy of **the last valid registration license** & the original for viewing (If not valid, preliminary approval of re-registration is obtained)	
A copy of all **approvals**, **variations, or decisions** related to the product	
Old Composition approved by the EDA lab Drug Control (in the case of registered products)	
A statement of the old composition on the factory paper stamped by the production manager or the R & D manager	
A statement of the new composition on the factory paper stamped by the production manager or the R & D manager	
official documents of license holder including Valid commercial register "with F-Toll/ toll activity in case of F-Toll/toll companies"(recently updated issuance) & Applicant tax card (valid)	
Declarations	
For Imported Finished Products/Imported Bulk/ Under license Products: 1. Original and **copy of a letter** from the company that owns the product abroad with the required change in the formulation statement) or **a certificate of a product Pharmacist (C.P.P)** from a health authority /responsible governmental authority in the country of origin (authenticated from the chamber of commerce & Egyptian Consulate/embassy in the country of origin) 2. An approved, stamped, and documented **composition** from the Chamber of Commerce and the Egyptian Consulate abroad on the factory paper abroad.	

Checklist of Biocides Variations

Changing the pack type

Required Documents	Comments
Variation request for biocidal products (cover letter explaining the required variation) to approve the Change in the type of the package indicating the name of the preparation and its concentration (and its registration number) and the type of registered package and the one to be changed to.	
Payment fees	
A copy of **the last valid registration license-approval** & the original for viewing (If not valid, preliminary approval of re-registration is obtained)	
A copy of all **approvals**, **variations, or decisions** related to the product	
official documents of license holder including Valid commercial register "with F-Toll/ toll activity in case of F-Toll/toll companies"(recently updated issuance)& Applicant tax card (valid)	
Declarations	
For Imported Finished Products/Imported Bulk/ Under license Products: An **Authenticated original packaging letter** and a copy from the license holder with the required change (authenticated from the chamber of commerce & Egyptian Consulate/embassy in the country of origin)	

Checklist of Biocides Variations

Changing or Adding the size of the package / adding a package

Required Documents	Comments
Variation request for biocidal products (cover letter explaining the required variation) to approve an addition or Change in the size of the package indicating the name of the preparation and its concentration (and its registration number) and the type of registered package and the one to be added.	
Payment fees	
A copy of **the last valid registration license-approval** & the original for viewing (If not valid, preliminary approval of re-registration is obtained)	
A copy of all **approvals**, **variations, or decisions** related to the product	
official documents of license holder including Valid commercial register "with F-Toll/ toll activity in case of F-Toll/toll companies"(recently updated issuance)& Applicant tax card (valid)	
Declarations	
For Imported Finished Products/Imported Bulk/ Under license Products: An **Authenticated original packaging letter** and a copy from the license holder with the required change (authenticated from the chamber of commerce & Egyptian Consulate/embassy in the country of origin)	

Checklist of Biocides Variations

Approving or changing an outer label/leaflet for the product

Required Document	Comment
Variation request for biocidal products (cover letter explaining the required variation	
Payment fees	
A copy of **the last valid registration license** & the original for viewing (If not valid, preliminary approval of re-registration is obtained)	
A copy of all **approvals**, **variations, or decisions** related to the product	
The internal label or leaflet / the new outer label shows the complete data and attaches an approved **scientific reference** for the data to be requested. Stamped with the company's seal.	
official documents of license holder including Valid commercial register "with F-Toll/ toll activity in case of F-Toll/toll companies"(recently updated issuance)& Applicant tax card (valid)	
Declarations	
For Imported Finished Products/Imported Bulk/ Under license Products: An original letter and a copy from the license holder with the required change (authenticated from the chamber of commerce & Egyptian Consulate/embassy in the country of origin)	

Checklist of Biocides Variations

Changing the shelf life/storage conditions of the product

Required Documents	Comments
Variation request for biocidal products (cover letter explaining the required variation(**A declaration letter on the paper of the LH**, approved and stamped by it, explaining the company's request indicating the company's request to approve an extension of the Expiry date/storage conditions of the product, the name of the product, its concentration and its registration number are mentioned.)	
Payment fees	
A copy of **the last valid registration license** & the original for viewing (If not valid, preliminary approval of re-registration is obtained)	
A copy of all **approvals**, **variations, or decisions** related to the product	
official documents of license holder including Valid commercial register "with F-Toll/ toll activity in case of F-Toll/toll companies"(recently updated issuance)& Applicant tax card (valid)	
Declarations	
The approval of the Stability Department stating the shelf life of the product or the new storage conditions.	