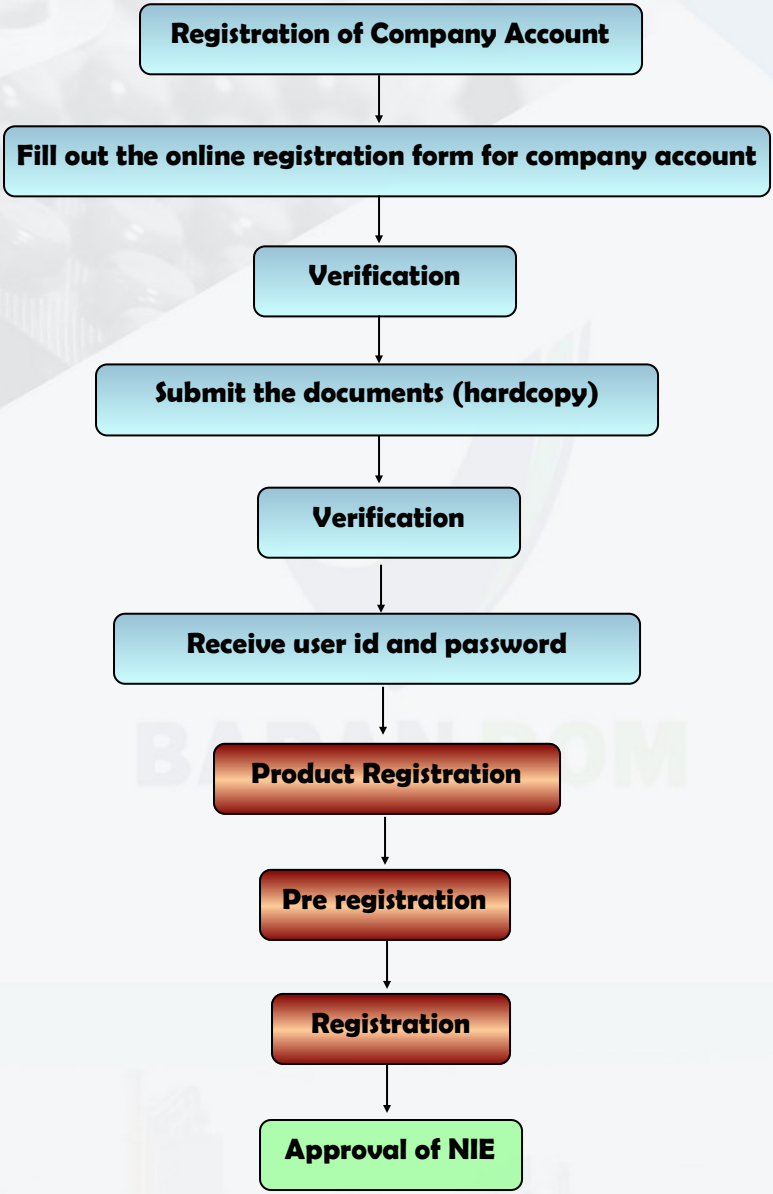
NA-DFC

GUIDANCE BOOK OF TRADITIONAL MEDICINES AND HEALTH SUPPLEMENT REGISTRATION

DIRECTORATE OF TRADITIONAL MEDICINES, HEALTH SUPPLEMENT, & COSMETIC REGISTRATION

NATIONAL AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA

Flow of Product Registration



Registration of Company Account

https://asrot.pom.go.id/asrot/

DOCUMENT REQUIRED

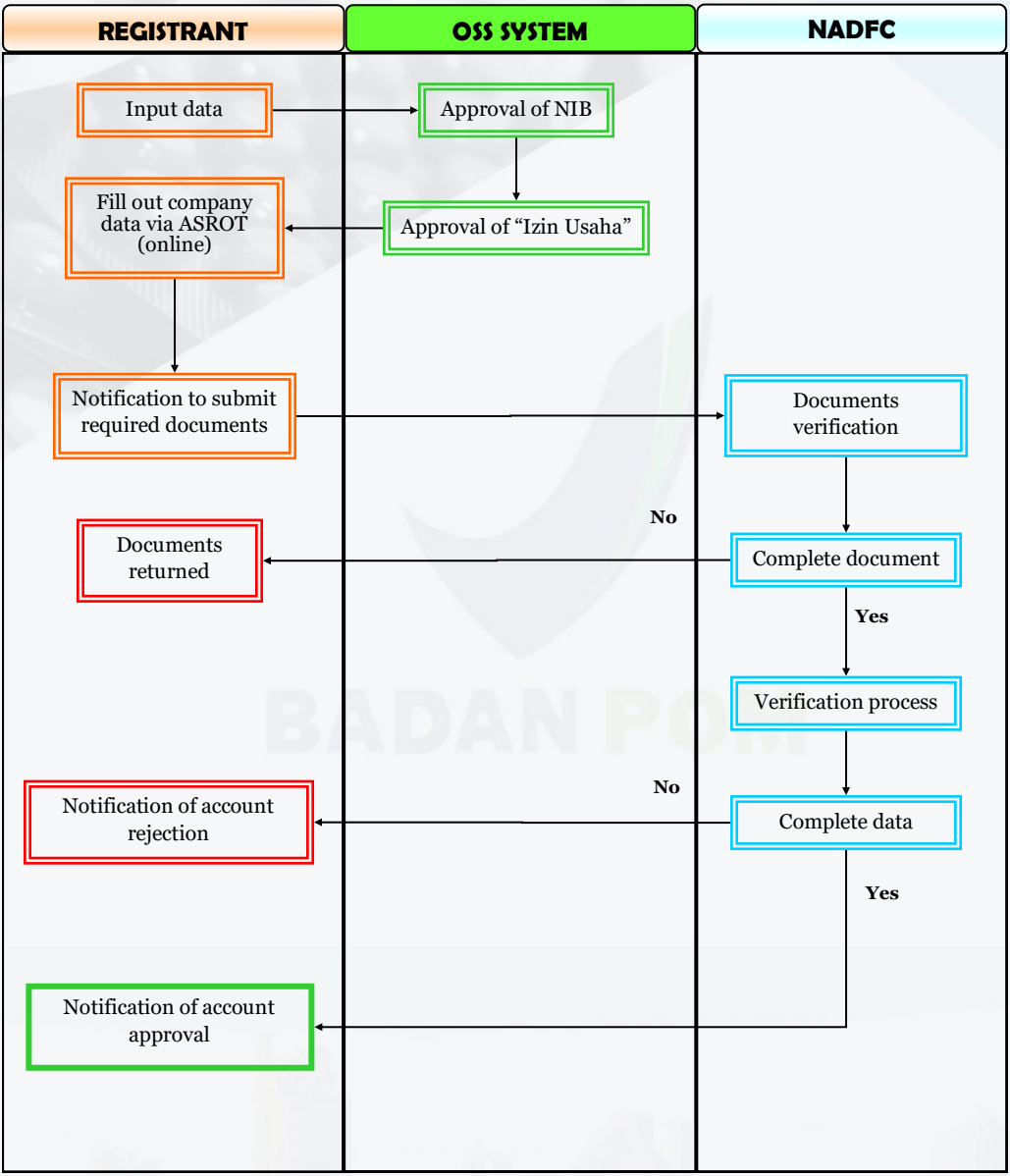
LOCAL

1. Single Business Number (*Nomor Induk Berusaha*, NIB)
2. Certificate of CPOB / CPOTB / CPPOB / Certificate of partial CPOTB
3. Individual Tax Number (*Nomor Pokok Wajib Pajak*, NPWP)
4. Notarial deed of the company
5. Letter of authorization stating person in charge of company account

IMPORTER

1. Single Business Number (Nomor Induk Berusaha, NIB)
2. Recommendations generated from the audit results of distribution facilities by Directorate of Traditional Medicine and Health Supplements Supervision or the local Balai Besar/ Balai POM
3. Single Tax Number (*Nomor Pokok Wajib Pajak*, NPWP)
4. Notarial deed of the company
5. Letter of authorization stating the person in charge of company account

Registration of Company Account



Product Registration

Divided into 3 types :

1. Registration of New Product

Registration of new product is registration of traditional medicine, health supplement, and quasi product which do not have registration number (Nomor Izin Edar, NIE) in Indonesia yet.

2. Renewal Registration

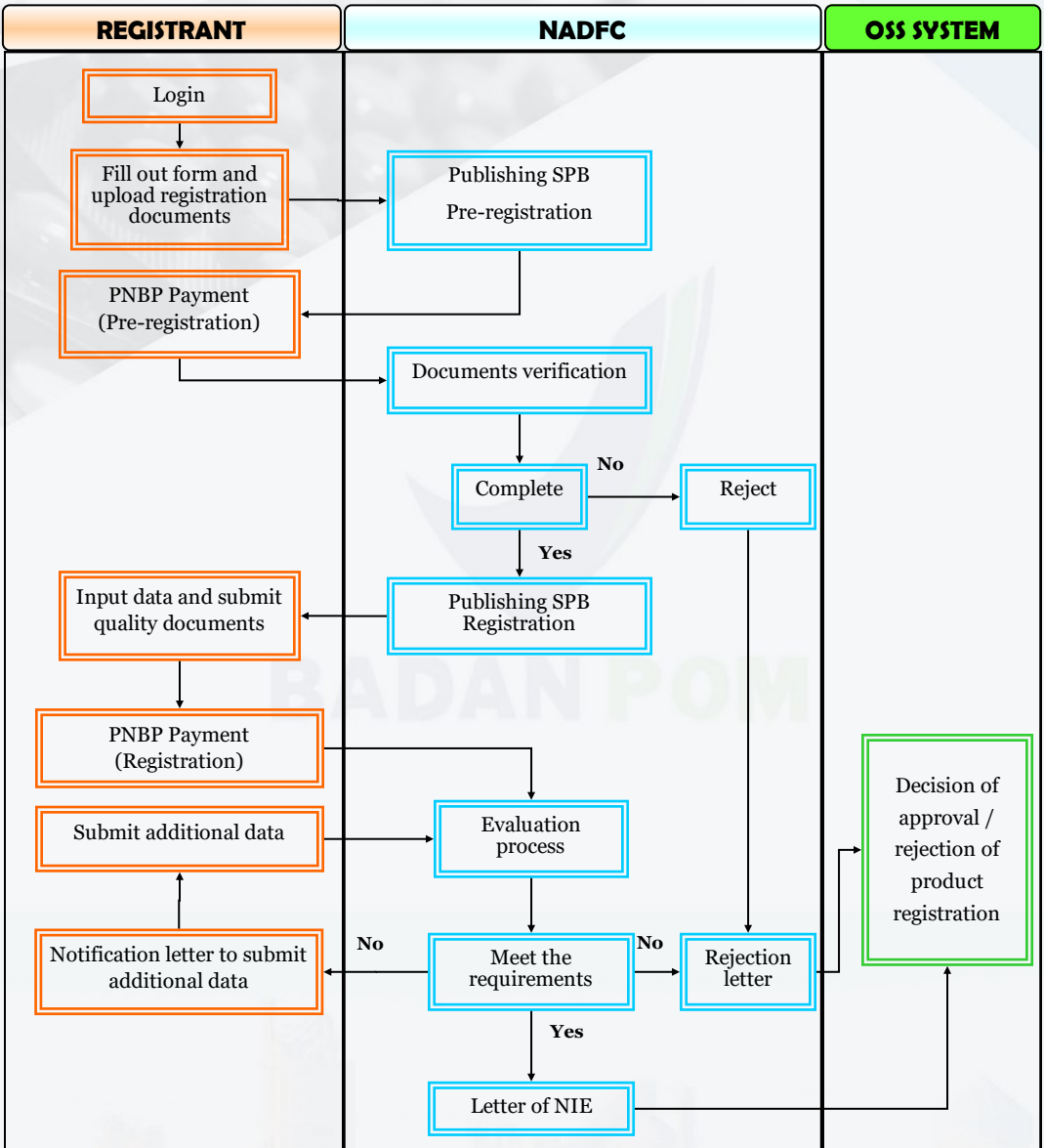
Renewal registration is registration to extend the validity period of registration number (Nomor Izin Edar, NIE).

3. Registration of Product Variation

Registration of product variation is registration of administrative and/or technical data in traditional medicine, health supplement, and quasi product which already have registration number (Nomor Izin Edar, NIE).

Registration of New Product

Traditional Medicine and Health Supplement



SPB: *Surat Perintah Bayar* (Payment warrant); NIE: *Nomor Izin Edar* (Product registration number)

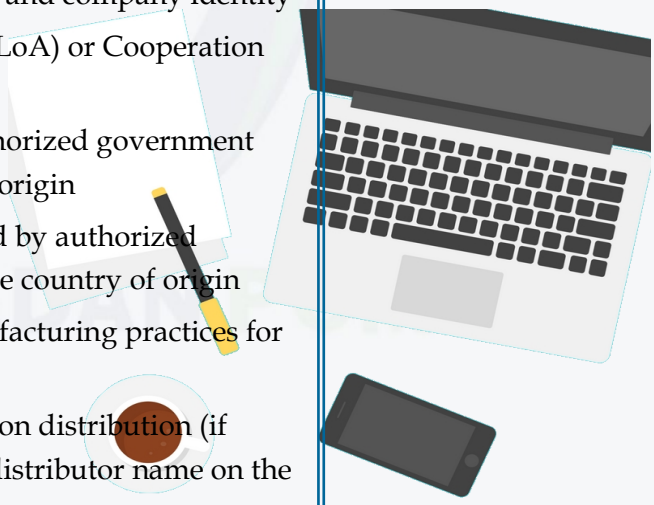
Administrative Documents for Registration of New Product

Local / Contract Product

1. Form of product identity and company identity
2. Certificate of good manufacturing practices *)
3. Cooperation Agreement on contract/toll manufacturing (if any)
4. Cooperation Agreement on distribution (if registrant intend to put distributor name on the label)

Imported / Licensed Product

1. Form of product identity and company identity
2. Letter of Authorization (LoA) or Cooperation Agreement on Licensing
3. CFS/ CPP issued by authorized government agency in the country of origin
4. Certificate of GMP issued by authorized government agency in the country of origin
5. Certificate of good manufacturing practices for Licensee *)
6. Cooperation Agreement on distribution (if registrant intend to put distributor name on the label)



(*) Note :

- For local traditional medicine, in the form of CPOTB certificate or partial CPOTB certificate for UKOT and/or UMOT
- For imported and licensed traditional medicine, in the form of CPOTB certificate
- For health supplement, in the form of : (i) CPOB certificate and joint facility approval for health supplement with non-drug composition, (ii) CPOTB certificate, (iii) CPPOB certificate

Technical Documents for Registration of New Product

Formula and Manufacturing Process

1. Complete formula in metric unit
2. Sum of each ingredient for one production batch
3. Detail of manufacturing process

Method to check the quality of raw material

1. Certificate of analysis and specification raw material
2. Identification raw matrerial

Method to check the quality of finished good

1. Certificate of analysis finished good stating specification, analytical method, and result
2. Protocol and result of stability test
3. Stability data from packaging factory if the products are packed (repacking) in indonesia

Quality and Safety Test

1. Physical and chemical tests
2. Marker compound or group compound test for Standardized Herbal Medicine (Obat Herbal Terstandar, OHT) and Fitofarmaka
3. Microbiology test (TPC, TYMC, Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella sp., Shigella sp.)
4. Heavy metal test (Pb, Hg, Cd, As)
5. Alcohol test for oral liquid (not more than 1%)
6. Benzyl piperazine test for product containing Cayenne extract
7. Caffeine test for product containing caffeine and plant drug containing caffeine such as Yerba Mate, Guarana, Coffee
8. Toxicity test for Ganoderma/Lingzhi/Maitake/Shitake and other materials with unknown safety and efficacy
9. Chloramphenicol test for product containing honey and other honey-derived materials
10. Certificate of analysis gelatine, origin of gelatine, Bovine Spongiform Encephalopathy (BSE) free certificate and halal certificate from authorized institution
11. Lovastatin test for Monascus sp (Red Yeast), not more than 1 % and citrinin-free
12. Origin dan manufacturing process for certain material in accordance to applicable provision

Others

1. Claim of efficacy, direction of use and batch numbering system
2. Sample in original packaging (if needed)
3. Full colour labelling design (packaging design)
4. Other supporting datas regarding special information such as halal logo, iradiation, organic logo, etc.

Renewal Registration

When does registrant start to do renewal registration process ?

D-60 hingga D-10 before expiration of NIE (registration number)

Renewal Registration is conducted online via ASROT

Required Documents

Local

1. Formula in metric unit
2. Approval letter and all variations which have been previously approved
3. The last packaging design which has been previously approved
4. Letter of declaration stating the product are still freely marketed along with the last batch number
5. Newest full colour packaging design

Import

1. Formula in metric unit
2. Approval Letter and all variations which have been previously approved
3. The last packaging design which has been previously approved
4. Letter of Declaration stating the product are still freely marketed along with the last Certificate of Imported Product (Surat Keterangan Impor, SKI)
5. Newest full colour packaging design
6. Applicable Letter of Authorization / Appointment (LoA)

Toll Manufacturing/ Licensed Product

Plus current toll manufacturing / license agreement

Registration of Product Variation

Minor Variation by Notification

1. Changes of packaging design, such as but not limited to colour of packaging design, images or product information layout, type or size of the writing, company logo, removal of foreign language, shape and/or dimension of packaging without changes in specification and size of packaging
2. Changes of batch numbering system
3. Changes or addition of imprint bossing or other marking on tablet; changes or addition of printing and/or ink on capsule
4. Changes of analytical method for raw material and/or finished good which do not change specification and quality of the raw material and/or finished good
5. Changes or addition of raw material manufacturer which do not alter specification and quality of raw material and/or finished good

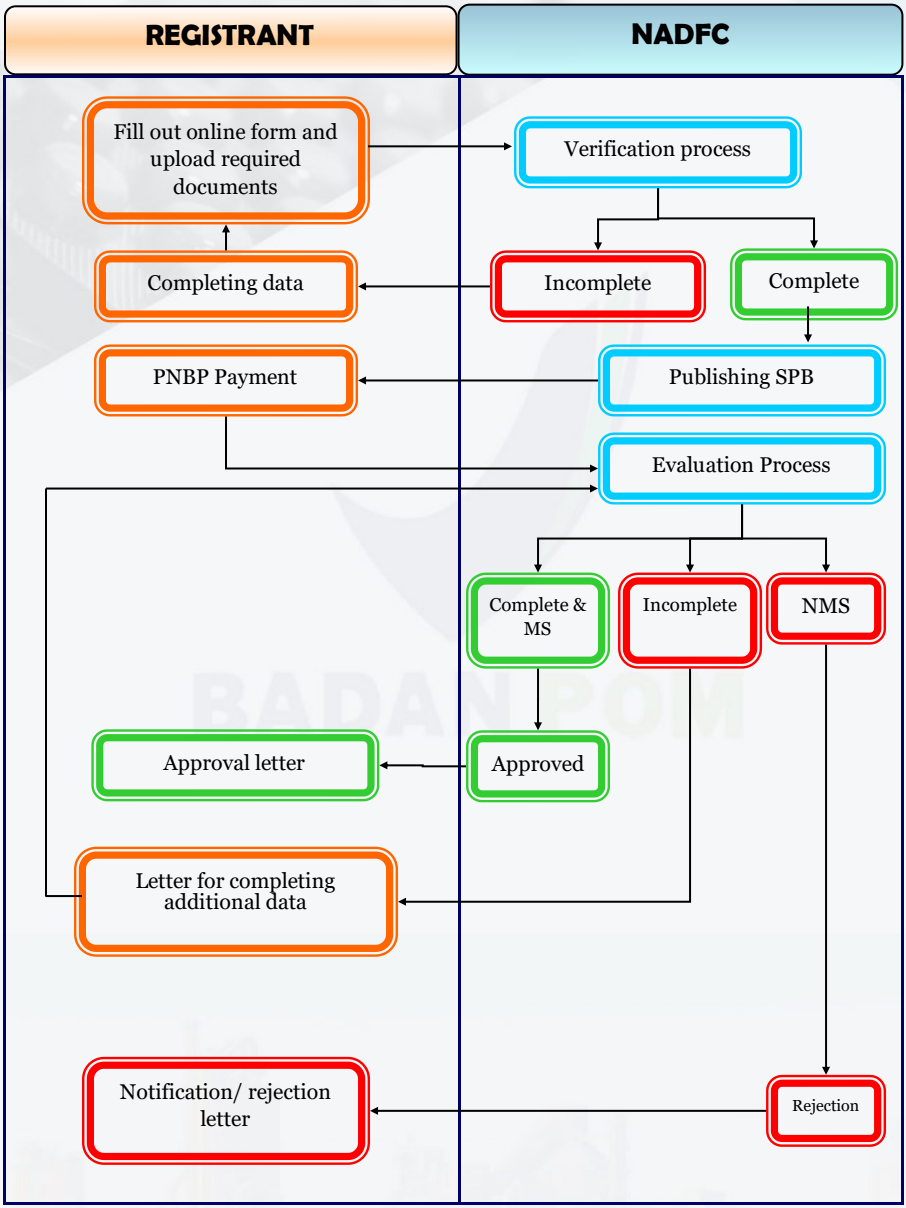
Minor Variation by Approval

1. Changes of product name
2. Changes of packaging design, such as but not limited to images, non-company logo; addition of product information in English or other languages, tag line which does not affect product efficacy
3. Changes or addition of secondary packaging and/or brosur/leaflet
4. Changes or addition of packaging size
5. Changes of name/addreses of registrant, manufacturer, and/or license provider without location change
6. Changes or addition secondary packaging factory
7. Special package request

Major Variation

1. Changes of raw material and/or finished good specification
2. Changes of product composition which do not affect product safety and efficacy
3. Changes of efficacy claim and/or posology which affects efficacy
4. Changes of type and specification of packaging material
5. Changes of product stability regarding expired date
6. Changes of production technology
7. Changes or addition of production location and/or primary packaging location
8. Changes of registrant name along with changes of ownership status

Flow of Renewal Registration & Registration of Product Variation



SPB: *Surat Perintah Bayar* (Payment warrant)

LIST OF ABBREVIATIONS

API	: Angka Pengenal Importir
ASROT	: Aplikasi Sistem e-Registrasi Obat Tradisional dan Suplemen Kesehatan
BKO	: Bahan Kimia Obat
BSE	: Bovine Spongiform Encephalopathy
CFS	: Certificate of Free Sale
CoA	: Certificate of Analysis
COD	: Cairan Obat Dalam
CPP	: Certificate of Pharmaceutical Products
CPOB	: Cara Pembuatan Obat yang Baik
CPOTB	: Cara Pembuatan Obat Tradisional yang Baik
CPPB	: Cara Produksi Pangan yang Baik
GMO	: Genetically Modified Organisms
GMP	: Good Manufacturing Practice
MS	: Memenuhi Syarat
NIB	: Nomor Induk Berusaha
NIE	: Nomor Izin Edar
NPWP	: Nomor Pokok Wajib Pajak
OSS	: Online Single Submission
PNBP	: Penerimaan Negara Bukan Pajak
Prareg	: Pra registrasi
Reg	: Registrasi
SIKA	: Surat Izin Kerja Apoteker
SIUP	: Surat Izin Usaha Perdagangan
SKI	: Surat Keterangan Impor

PRODUCT REGISTRATION SERVICE

Public Service Building (Building B), 2nd Floor

Directorate of Traditional Medicines, Health Supplement & Cosmetic Registration

National Agency of Drug and Food Control

Jl. Percetakan Negara No. 23, Jakarta Pusat 10560

1. **Correspondence Desk**

   Monday - Friday 08.30 - 15.30

2. **Document Reception Desk**

   Monday - Thursday 08.30 - 16.00

3. **Duty Manager Consultation Desk**

   Monday - Thursday 09.00- 16.00

4. **IT Consultation Desk**

   Monday - Thursday 09.00 - 16.00

(021) 4244691 / 424819

penilaianot_sm@yahoo.com

penilaian_ot@pom.go.id

penilaian_sm_kuasi@pom.go.id

https://asrot.pom.go.id/asrot/

In accordance to PP 32 Tahun 2017 Tentang Jenis dan Tarif Atas Jenis PNBP yang Berlaku Pada Badan Pengawas Obat dan Makanan