Special Access Scheme (SAS): Procedures and Requirements

Siti Asfijah Abdoellah, SSi, Apt, MMed Sc.

Direktorat Registrasi Obat

Badan Pengawas Obat dan Makanan

Per BPOM No. 15 Tahun 2020

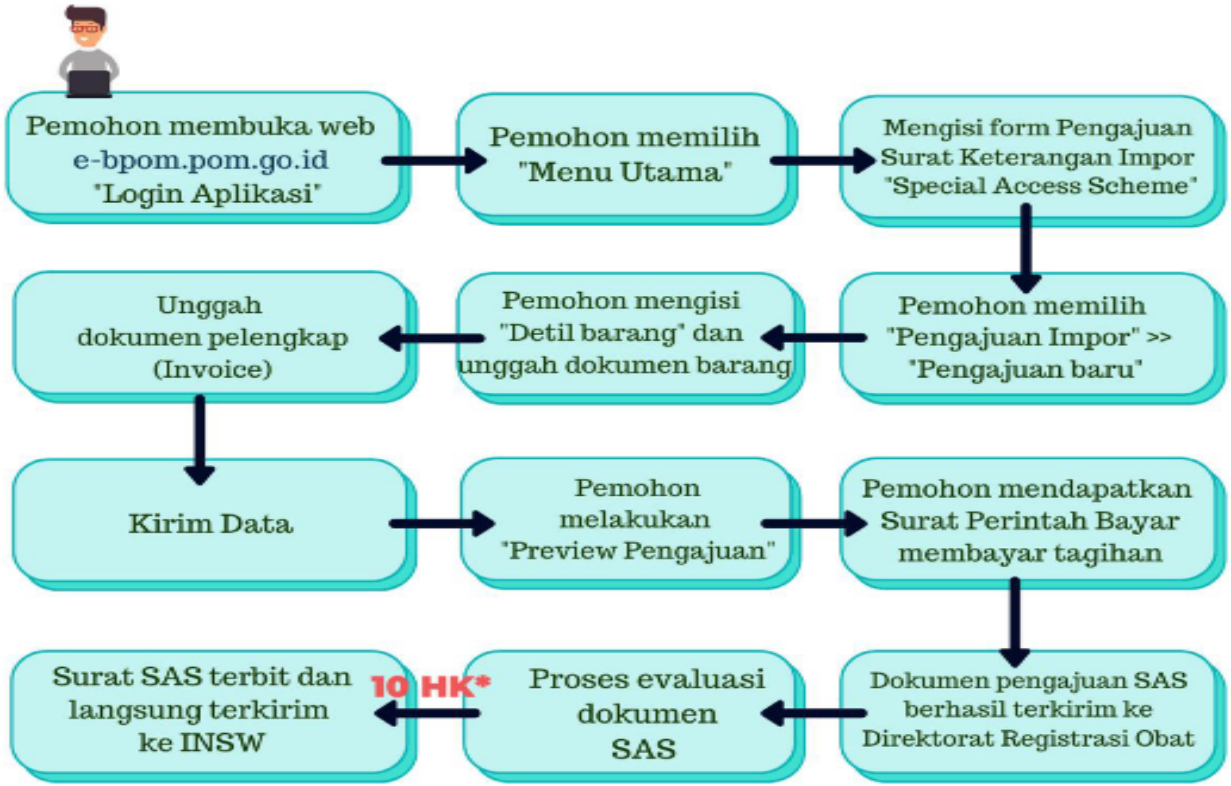
Pasal 28:

(1) Dikecualikan dari ketentuan sebagaimana diatur dalam Peraturan Badan ini bagi Obat dan Makanan tanpa Izin Edar Badan Pengawas Obat dan Makanan, dapat dimasukkan ke dalam wilayah Indonesia.

(2) Obat dan Makanan sebagaimana dimaksud pada ayat (1) merupakan Obat dan Makanan yang pemasukannya ditujukan untuk:

a. penggunaan sendiri/pribadi berdasarkan pertimbangan tenaga kesehatan atau tanpa pertimbangan tenaga kesehatan;
b. penelitian;
c. pengembangan produk dan/atau ilmu pengetahuan;
d. donasi;
e. sampel untuk registrasi/pendaftaran Izin Edar;
f. uji klinik untuk persyaratan pendaftaran, pengembangan produk, dan/atau ilmu pengetahuan;
g. program pemerintah;
h. kepentingan nasional yang mendesak;
i. penggunaan khusus untuk pelayanan kesehatan yang belum dapat diproduksi dalam negeri; dan
j. pameran.

Alur Pengajuan SAS melalui e-BPOM



*Untuk SAS yang ditujukan untuk penanganan COVID-19, *timeline* proses evaluasi dokumen adalah 2 HK

SAS for Biological Products

1. Cover Letter
2. Applicant's Declaration
   - as a commitment to be responsible for the safety and quality aspects of the product as well as storage, distribution and use, in accordance with the provision of laws and regulations
3. Statement Letter
   - of having cold chain facilities/infrastructure for product storage & distribution with adequate capacity
4. Product Information
5. Details of Product usage plan
   - list of hospital or health care facility and doctor/HCPs
6. Recommendation Letter from Ministry of Health

7 Donation statement from the donor (applicable for donation)

8 Certificate of Analysis

9 Valid GMP Certificate of the manufacturer

10 Invoice & packing list

11 Airway Bill (if available)

12 Informed consent form

- if the product have not been approved for marketing authorization or EUA in any country

KONTAK KAMI:

BADAN POM

Jika Anda memiliki pertanyaan
terkait pengajuan SAS,
silakan hubungi kontak kami

(021) 4244691 ext. 1338
0822-3825-3347 (Asfy)
0812-8160-177 (Sari)
Petugas Loket:
0896-3597-2354 (Ajis)

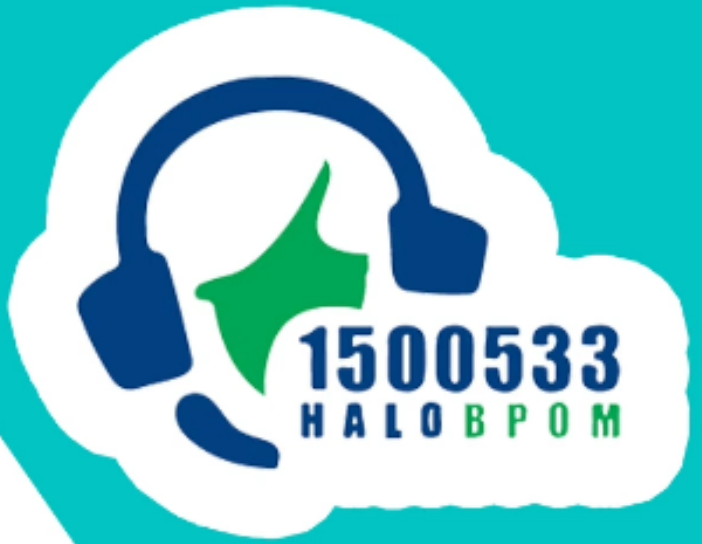
sas_obat@pom.go.id
clinicaltrial@pom.go.id

- Direktorat Registrasi Obat
  Gedung F Barat lantai 5
- Pelayanan Publik Direktorat Registrasi Obat
  Gedung B lantai 1

Jl. Percetakan Negara no. 23
Jakarta Pusat

BADAN POM

THANK YOU
TERIMA KASIH



SATU TINDAKAN UNTUK MASA DEPAN, BACA LABEL SEBELUM MEMBELI

halobpom@pom.go.id www.pom.go.id @bpom_ri Bpom RI

SAS for Vaccine

1. Cover Letter
2. Applicant's Declaration
   - as a commitment to be responsible for the safety and quality aspects of vaccines as well as storage, distribution and use of vaccines in accordance with the provision of laws and regulations
3. Statement Letter
   - of having cold chain facilities/infrastructure for vaccine storage & distribution with adequate capacity
4. Product Information
5. Details of vaccine usage plan
   - list of hospital or health care facility, list of vaccine recipients and doctor in charge of vaccination
6. Recommendation Letter from Ministry of Health
   - for vaccines used in health programs

7 Donation statement from the donor

8 Certificate of Analysis

9 Valid GMP Certificate of the manufacturer of vaccine

10 Lot release certificate

- from the responsible National Regulatory Authority (NRA)/ National Control Laboratory (NCL) in the country of origin

11 Summary batch protocol of production and testing from 3 consecutives batches

12 Invoice & packing list

13 Airway Bill (if available)

14 Informed consent form

- if the vaccine have not been approved for marketing authorization or EUA in any country