



BADAN PENGAWAS OBAT DAN MAKANAN

**KEPUTUSAN KEPALA BADAN PENGAWAS OBAT DAN MAKANAN
NOMOR 433 TAHUN 2024
TENTANG
PERUBAHAN ATAS KEPUTUSAN KEPALA BADAN PENGAWAS OBAT DAN
MAKANAN NOMOR 317 TAHUN 2023 TENTANG
PENERAPAN *PILOT PROJECT E-LABELING***

DENGAN RAHMAT TUHAN YANG MAHA ESA

KEPALA BADAN PENGAWAS OBAT DAN MAKANAN,

- Menimbang** : a. bahwa ketentuan mengenai penerapan *pilot project e-labeling* sebagaimana telah ditetapkan dalam Keputusan Kepala Badan Pengawas Obat dan Makanan Nomor 317 Tahun 2023 tentang Penerapan *Pilot Project E-Labeling*, perlu disesuaikan dengan kebutuhan hukum dan kebutuhan organisasi sehingga perlu diubah;
- b. bahwa berdasarkan pertimbangan sebagaimana dimaksud dalam huruf a, perlu menetapkan Keputusan Kepala Badan Pengawas Obat dan Makanan tentang Perubahan atas Keputusan Kepala Badan Pengawas Obat dan Makanan Nomor 317 Tahun 2023 tentang Penerapan *Pilot Project E-Labeling*;
- Mengingat** : 1. Peraturan Presiden Nomor 80 Tahun 2017 tentang Badan Pengawas Obat dan Makanan (Lembaran Negara Republik Indonesia Tahun 2017 Nomor 180);
2. Peraturan Kepala Badan Pengawas Obat dan Makanan Nomor 24 Tahun 2017 tentang Kriteria dan Tata Laksana Registrasi Obat (Berita Negara Republik Indonesia Tahun 2017 Nomor 1692) sebagaimana telah beberapa kali diubah terakhir dengan Peraturan Badan Pengawas Obat dan Makanan Nomor 15 Tahun 2023 tentang Perubahan Keempat atas Peraturan Kepala Badan Pengawas Obat dan Makanan Nomor 24 Tahun 2017 tentang Kriteria dan Tata Laksana Registrasi Obat (Berita Negara Republik Indonesia Tahun 2023 Nomor 559);
3. Peraturan Badan Pengawas Obat dan Makanan Nomor 21 Tahun 2020 tentang Organisasi dan Tata Kerja Badan Pengawas Obat dan Makanan (Berita Negara Republik Indonesia Tahun 2020 Nomor 1002) sebagaimana telah diubah dengan Peraturan Badan Pengawas Obat dan Makanan Nomor 13 Tahun 2022 tentang Perubahan atas Peraturan Badan Pengawas Obat dan Makanan Nomor 21 Tahun 2020 tentang Organisasi dan Tata Kerja Badan Pengawas Obat dan Makanan (Berita Negara Republik Indonesia Tahun 2022 Nomor 629);

4. Peraturan Badan Pengawas Obat dan Makanan Nomor 22 Tahun 2022 tentang Penerapan 2D *Barcode* dalam Pengawasan Obat dan Makanan (Berita Negara Republik Indonesia Tahun 2022 Nomor 1021);
5. Peraturan Badan Pengawas Obat dan Makanan Nomor 19 Tahun 2023 tentang Organisasi dan Tata Kerja Unit Pelaksana Teknis di Lingkungan Badan Pengawas Obat dan Makanan (Berita Negara Republik Indonesia Tahun 2023 Nomor 611);
6. Keputusan Kepala Badan Pengawas Obat dan Makanan Nomor 317 Tahun 2023 tentang Penerapan *Pilot Project E-Labeling*;

MEMUTUSKAN:

- Menetapkan : KEPUTUSAN KEPALA BADAN PENGAWAS OBAT DAN MAKANAN TENTANG PERUBAHAN ATAS KEPUTUSAN KEPALA BADAN PENGAWAS OBAT DAN MAKANAN NOMOR 317 TAHUN 2023 TENTANG PENERAPAN *PILOT PROJECT E-LABELING*.
- Kesatu : Ketentuan Lampiran I dan Lampiran II Keputusan Kepala Badan Pengawas Obat dan Makanan Nomor 317 Tahun 2023 tentang Penerapan *Pilot Project E-Labeling* diubah sehingga menjadi sebagaimana tercantum dalam Lampiran I dan Lampiran II yang merupakan bagian tidak terpisahkan dari Keputusan ini.
- Kedua : Keputusan ini mulai berlaku pada tanggal ditetapkan.

Ditetapkan di Jakarta
pada tanggal 11 November 2024

KEPALA BADAN PENGAWAS OBAT DAN MAKANAN,

ttd.

TARUNA IKRAR

Salinan Sesuai Dengan Aslinya
BADAN PENGAWAS OBAT DAN MAKANAN
Kepala Biro Hukum dan Organisasi,



Agghi Perdana

LAMPIRAN I
KEPUTUSAN KEPALA BADAN PENGAWAS OBAT DAN MAKANAN
NOMOR 433 TAHUN 2024
TENTANG
PERUBAHAN ATAS KEPUTUSAN KEPALA BADAN PENGAWAS
OBAT DAN MAKANAN NOMOR 317 TAHUN 2023 TENTANG
PENERAPAN *PILOT PROJECT E-LABELING*

DAFTAR INDUSTRI FARMASI YANG MENERAPKAN
PILOT PROJECT E-LABELING

1. PT Combiphar;
2. PT Soho Industri Farmasi;
3. PT Pfizer Indonesia;
4. PT Merck Tbk;
5. PT Otsuka Indonesia;
6. PT Abbott Indonesia;
7. PT Novartis Indonesia;
8. PT Hexpharm Jaya;
9. PT Finusolprima Farma Internasional;
10. PT Global Onkolab Farmap
11. PT Aventis Pharma/PT Kalventis Sinergi Farma;
12. PT AstraZeneca Indonesia;
13. PT Glaxo Wellcome Indonesia;
14. PT Organon Pharma Indonesia;
15. PT Kalbe Farma;
16. PT Pyridam Farma;
17. PT Mega LifeSciences Indonesia;
18. PT Sejahtera Lestari Farma;
19. PT Yarindo Farmatama;
20. PT Dipa Pharmedia Intersains;
21. PT Taisho Pharmaceutical Indonesia;
22. PT Integrated Healthcare Indonesia (J&J);
23. PT Darya-Varia Laboratoria Tbk;
24. PT Dexa Medica;
25. PT Actavis Indonesia;
26. PT Sterling Products Indonesia;
27. PT Holi Pharma;
28. PT Ifars Pharmaceutical;
29. PT Genero Pharmaceuticals;
30. PT Menarini Indria Laboratories;
31. PT Meiji Indonesian Pharmaceutical Industries;
32. PT Bayer Indonesia;
33. PT Pratapa Nirmala;
34. PT Dankos Farma;
35. PT Meprofarm;

36. PT Mersifarma Tirmaku Mercusana; dan
37. PT Eisai Indonesia.

KEPALA BADAN PENGAWAS OBAT DAN MAKANAN,

ttd.

TARUNA IKRAR

LAMPIRAN II
KEPUTUSAN KEPALA BADAN PENGAWAS OBAT DAN MAKANAN
NOMOR 433 TAHUN 2024
TENTANG
PERUBAHAN ATAS KEPUTUSAN KEPALA BADAN PENGAWAS
OBAT DAN MAKANAN NOMOR 317 TAHUN 2023 TENTANG
PENERAPAN *PILOT PROJECT E-LABELING*

DAFTAR OBAT YANG TERMASUK DALAM *PILOT PROJECT E-LABELING*

A. Tahap Pertama

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
1.	Neo-K	Dus, 5 ampul @ 1 ml	DKL0604129543A1	PT. Combiphar
2.	Primperan	Dus, 6 ampul @ 2 ml	DKL7224230443A1	PT. Soho Industri Pharmasi
3.	Prevenar-13	Box, 1 prefilled syringe @ 0.5 ml	DKI1786101643A2	PT Pfizer Indonesia
4.	Zavicefta	Box, 10 vials @2.5 g	DKI2043900344A1	PT Pfizer Indonesia
5.	Ovidrel	Dus, 1 pre-filled syringe @ 0.5 mL	DKI0980501343A1	PT Merck Tbk
6.	Rebif	Dus, 3 pre-filled syringe @ 22 mcg (0.5 mL)	DKI0980500843A1	PT Merck Tbk
7.	Bfluid	Double Softbag @ 500 mL & 1000 mL	DKL1618708449A1	PT Otsuka Indonesia
8.	Asering	Softbag @ 500 mL	DKL9918705449A2	PT Otsuka Indonesia
9.	Influvac Tetra NH	Box, 1 prefilled syringe @ 0.5 ml	DKI1981601943A1	PT Abbott Indonesia
10.	Influvac Tetra SH	Box, 1 prefilled syringe @ 0.5 ml	DKI1981601843A1	PT Abbott Indonesia
11.	Simulect	Dus, 1 vial @ 20 mg + 1 ampul pelarut @ 5 ml	DKI0267503044A1	PT Novartis Indonesia

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
12.	Sandostatin LAR 30 mg	Dus, 1 vial @ 900 mg + 1 prefilled syringe @ 2 ml pelarut + 1 vial adapter + 1 safety injection needle	DKI2281602044A1	PT Novartis Indonesia
13.	Tranexamic Acid Injeksi	Dus, 2 blister @ 5 ampul @ 5 ml	GKL1108517143A1	PT Hexpharm Jaya
14.	Ceftriaxone Injeksi	Dus, 2 vial @ 1 g	GKL0208505344A1	PT Hexpharm Jaya
15.	Tutosol	Flexibag @ 500 ml	DKL2028406749A1	PT Finusolprima Farma Internasional
16.	Carboplatin	Dus, 1 vial @45ml	GKL1404428543A1	PT Global Onkolab Farma
17.	Typhim	Dus, 1 syringe @ 1 dosis (0.5 mL)	DKI2059703743A1	PT Aventis Pharma/ PT Kalventis Sinergi Farma
18.	Cordarone	Dus, 6 ampul @ 3 ml	DKI1077402943A1	PT Aventis Pharma/ PT Kalventis Sinergi Farma
19.	Imfinzi	Dus, 1 vial @ 10 ml	DKI2051303949A1	PT AstraZeneca Indonesia
20.	Vaxzevria	Dus, 10 vial @ 4 ml (8 dosis)	EUA2158600143A1	PT AstraZeneca Indonesia
21.	Zovirax Injection	Dus, 5 vial @ 250 mg	DKI0200500144A1	PT Glaxo Wellcome Indonesia
22.	Synflorix	Dus, 1 prefilled syringe @ 0.5 mg (1 dosis) + 1 jarum suntik	DKI2276703643A1	PT Glaxo Wellcome Indonesia
23.	Rituxikal	Vial 100 mg/ 10 ml	DKL2211647749A1	PT Kalbe Farma
24.		Vial 500 mg/ 50 ml		

B. Tahap Kedua

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
1.	Fusycorn Cream	Dus, 1 tube @ 5 gram	DKL9904124729A1	PT Combiphar
2.	Dogmatil	Dus, 10 strip @ 10 kapsul	DKL7624229901A1	PT Soho Industri Pharmasi
3.	Glufor 500 Kaplet Salut Selaput	Dus, 10 strip @ 10 kaplet salut selaput	DKL9621010309A1	PT Pyridam Farma
4.	Raost Kaplet Salut Selaput	Dus, 5 strip @ 10 kaplet salut selaput	DKL1121016809A1	PT Pyridam Farma
5.	Domperidone	Dus, 10 strip @ 10 tablet salut selaput	GKL1639203117A1	PT Mega LifeSciences Indonesia
6.	Ketorolac Trometamol	Dus, 5 strip @10 tablet salut selaput	GKL1639203317A1	PT Mega LifeSciences Indonesia
7.	Amoxicilin Tryhidrate	Dus, 10 strip @ 10 Kaplet	GKL1336703904A1	PT Sejahtera Lestari Farma
8.	Allopurinol 100	Dus, 10 strip @ 10 kaplet	GKL1536704404B1	PT Sejahtera Lestari Farma
9.	Methylprednisolone	Dus, 10 strip @10 tablet	GKL1032714110A1	PT Yarindo Farmatama
10.	Ibrance 75 mg	Dus, 1 blister @ 7 tablet salut selaput	DKI2158501617A1	PT Pfizer Indonesia
11.	Ibrance 100 mg	Dus, 1 blister @ 7 tablet salut selaput	DKI2158501617B1	PT Pfizer Indonesia
12.	Ibrance 125 mg	Dus, 1 blister @ 7 tablet salut selaput	DKI2158501617C1	PT Pfizer Indonesia
13.	Eliquis 2.5 mg	Dus, 2 blister @ 10 tablet salut selaput	DKI2190702117A1	PT Pfizer Indonesia
14.	Eliquis 5 mg	Dus, 2 blister @ 10 tablet salut selaput	DKI2190702117B1	PT Pfizer Indonesia

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
15.	Glucophage XR	Dus, 8 blister @ 15 tablet pelepasan lambat	DKL1915809314A1	PT Merck Tbk
16.	Concor	Dus, 10 blister @ 10 tablet salut selaput	DKL0215803817B1	PT Merck Tbk
17.	Samsca 15 mg	Dus, 1 blister @ 10 tablet	DKI1709700810A1	PT Otsuka Indonesia
18.	Rexulti 1 mg	Dus, 1 blister @ 10 tablet	DKI2009700917C1	PT Otsuka Indonesia
19.	Abbotc 500	Box, 3 blisters @ 10 film coated tablets	DKL0400202117A2	PT Abbott Indonesia
20.	Luvox 50	Box, 3 blisters @ 20 film coated tablets	DKI1127000417A1	PT Abbott Indonesia
21.	Galvusmet 50/500 mg	Dus, 3 strip @ 10 tablet salut selaput	DKL1930413117A1	PT Novartis Indonesia
22.	Galvusmet 50/850 mg	Dus, 3 strip @ 10 tablet salut selaput	DKL1930413117B1	PT Novartis Indonesia
23.	Tasigna 150 mg	Dus, 7 blister @ 4 kapsul	DKI2263400101B1	PT Novartis Indonesia
24.	Asam Mefenamate Kaplet	Dus, 10 strip @ 10 kaplet	GKL1308517404A1	PT Hexpharm Jaya
25.	Amoxicillin Trihydrate Kaplet	Dus, 20 strip @ 10 kaplet	GKL0308507904A1	PT Hexpharm Jaya
26.	Metformin Tablet	Dus, 20 strip @ 10 tablet	GKL0608513110A1	PT Hexpharm Jaya
27.	Simvastatin 10 Tablet	Dus, 10 blister @ 10 tablet slut selaput	GKL0108504917A1	PT Hexpharm Jaya
28.	CPG	Dus, 3 blister @ 10 tablet salut selaput	DKL0811638017A2	PT Kalbe Farma
29.	Bioplacenton	Dus, 1 tube @ 15 gram	DKL7211638828A1	PT Kalbe Farma
30.	Tamofen	Dus, 3 strip @ 10 tablet salut selaput	DKL9011603317A1	PT Global Onkolab Farma
31.	Amaryl M 2/500 mg	Dus, 3 blister @ 10 tablet salut selaput	DKL2221208617B1	PT Kalventis Sinergi Farma
32.	Amaryl M 1/250 mg	Dus, 3 blister @ 10 tablet salut selaput	DKL2221208617A1	PT Kalventis Sinergi Farma

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
33.	Amaryl 1 mg	Dus, 5 blister @ 10 tablet	DKL0521204110A1	PT Kalventis Sinergi Farma
34.	Amaryl 2 mg	Dus, 5 blister @ 10 tablet	DKL0521204110B1	PT Kalventis Sinergi Farma
35.	Amaryl 3 mg	Dus, 5 blister @ 10 tablet	DKL0521204110C1	PT Kalventis Sinergi Farma
36.	Amaryl 4 mg	Dus, 3 blister @ 10 tablet	DKL0521204110D1	PT Kalventis Sinergi Farma
37.	Calquence	Dus, 7 blister @ 8 Kapsul	DKI2151304101A1	PT AstraZeneca Indonesia
38.	Lynparza 150 mg	Dus, 7 blister @ 8 tablet salut selaput	DKI2159602717B1	PT AstraZeneca Indonesia
39.	Avamys Nasal Spray	Dus, 1 botol @ 120 spray	DKI2191601556A1	PT Glaxo Wellcome Indonesia
40.	Valtrex Tablet	Dus, 3 blister @ 14 tablet salut selaput	DKI1691601017A1	PT Glaxo Wellcome Indonesia
41.	Erleada	Dus, 1 botol plastik @ 120 tablet salut selaput	DKI2110901817A1	PT Integrated Healthcare Indonesia
42.	Invega 6 mg	Dus, 4 blister @ 7 tablet pelepasan lambat	DKI2110901714B1	PT Integrated Healthcare Indonesia
43.	Invega 9 mg	Dus, 4 blister @ 7 tablet pelepasan lambat	DKI2110901714C1	PT Integrated Healthcare Indonesia
44.	Nifural Syrup 60 ml	Botol @ 60 ml	DKL7804522537A1	PT Darya-Varia Laboratoria Tbk.
45.	Celecoxib 100 mg	Dus, 3 blister @ 10 kapsul	GKL2005065001A1	PT Dexa Medica
46.	Celenox 100 mg	Dus, 3 blister @ 10 kapsul	DKL2005065101A1	PT Dexa Medica
47.	Celecoxib 200 mg	Dus, 3 blister @ 10 kapsul	GKL2005065001B1	PT Dexa Medica
48.	Celenox 200 mg	Dus, 3 blister @ 10 kapsul	DKL2005065101B1	PT Dexa Medica

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
49.	Ticagrelor	Dus, 3 strip @ 10 tablet salut selaput	GKL2005063917A2	PT Dexa Medica
50.	Briclot	Dus, 3 blister @ 10 tablet salut selaput	DKL2005063817A1	PT Dexa Medica
51.	Levetiracetam 250 mg Tablet salut selaput	Dus, 3 strip @ 10 tablet salut selaput	GKL1905519017A1	PT Actavis Indonesia
52.	Levetiracetam 500 mg Tablet salut selaput	Dus, 3 strip @ 10 tablet salut selaput	GKL1905519017B1	PT Actavis Indonesia
53.	Gabapentin 100 Kapsul	Dus, 5 blister @ 10 kapsul	GKL1905518901A1	PT Actavis Indonesia
54.	Gabapentin 300 Kapsul	Dus, 5 blister @ 10 kapsul	GKL1905518901B1	PT Actavis Indonesia

C. Tahap Ketiga

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
1.	OBH Anak Rasa Madu	Dus, 1 botol plastik @ 60 ml	DTL0604129337B1	PT. Combiphar
2.	Tantum	Dus, 2 strip @ 6 tablet hisap	DTL7224216312A1	PT. Soho Industri Pharmasi
3.	Sohobion 5000	Dus, 10 strip @ 10 tablet salut selaput	DBL0624222417B1	PT. Soho Industri Pharmasi
4.	Atorvastatin Calcium	Dus, 10 strip @ 10 kaplet salut selaput	GKL1902506709A1	PT. Dipa Pharmalab Intersains
5.	Calcium Polystyrene Sulfonate	Dus, 20 sachet @ 5 g	GKL1902506823A1	PT. Dipa Pharmalab Intersains
6.	Mycostatin	Dus, botol plastik @ 12 ml	DKL1124400233A1	PT. Taisho Pharmaceutical Indonesia
7.		Dus, botol plastik @ 30 ml		

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
8.	Myco-Z	Dus, tube @ 10 g	DKL1124402330A1	PT. Taisho Pharmaceutical Indonesia
9.	Cetirizine Hydrochloride	Dus, 10 amplop @ 1 blister @ 10 kaplet	GTL1639203204A1	PT. Mega LifeSciences Indonesia
10.		Dus, 20 amplop @ 1 blister @ 10 kaplet		
11.	Tablet Tambah Darah	Dus, 10 amplop @ 1 blister @ 10 tablet salut selaput	GBL2039204617A1	PT. Mega LifeSciences Indonesia
12.		Dus, 20 amplop @ 1 blister @ 30 tablet salut selaput		
13.	Paracetamol	Dus, 10 amplop @ 1 strip @ 10 kaplet	GBL0936702304A1	PT. Sejahtera Lestari Farma
14.	Panadol	Dus, 10 blister @ 10 kaplet	DBL9624502804A1	PT Sterling Products Indonesia
15.	Panadol Extra	Dus, 10 blister @ 10 kaplet	DBL9424502004A1	PT Sterling Products Indonesia
16.	Panadol Cold and Flu	Dus, 10 blister @ 10 kaplet	DTL9424502404A1	PT Sterling Products Indonesia
17.	Panadol Flu dan Batuk	Dus, 10 blister @ 10 kaplet	DTL1124503604A1	PT Sterling Products Indonesia
18.	Pedialyte Solution	Box, plastic bottle @ 500 ml	DBL1000203835A1	PT Abbott Indonesia
19.	Pedialyte Bubble Gum	Box, plastic bottle @ 500 ml	DBL1000203935A1	PT Abbott Indonesia
20.	Dulcolax 10 mg	Dus, 1 strip @ 5 suppositoria	DTL1921208253B1	PT Aventis Pharma
21.	Telfast 60 mg	Dus, 1 blister @ 10 tablet salut selaput	DTL1121205217A1	PT Kalventis Sinergi Farma
22.	Plavix	Dus, 2 blister @ 14 tablet salut selaput	DKL1321205717A1	PT Kalventis Sinergi Farma
23.	Guaifenesin 100 mg	Dus, 10 strip @ 10 Tablet	GTL2117115010A1	PT Holi Pharma

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
24.	Folic Acid 1 mg	Dus, 10 Amplop @ 1 blister @ 10 tablet	GBL2017114710A1	PT Holi Pharma
25.	Paratusin PE Syrup 60 ml	Dus, Botol 60 ml	DTL1604525137A1	PT Darya-Varia Laboratoria Tbk.
26.	Naprex Susp 60 ml	Dus, 1 Botol Plastik @ 60 ml	DBL0304518633A1	PT Darya-Varia Laboratoria Tbk.
27.	Nifural Syrup 60 ml	Botol @ 60 ml	DKL7804522537A1	PT Darya-Varia Laboratoria Tbk.
28.	Decolgen Liquid	Dus, 1 botol @ 60 ml	DTL1504523437A1	PT Darya-Varia Laboratoria Tbk.
29.	Decolsin Syrup	Dus, 1 botol plastik @ 60 ml	DTL1504522937A1	PT Darya-Varia Laboratoria Tbk.
30.	Disudrin-ped Drops	Dus, 1 botol @ 10 ml	DTL1904529336A1	PT Darya-Varia Laboratoria Tbk.
31.	Naprex Drops	Dus, botol plastik @ 15 ml	DBL0204518236A1	PT Darya-Varia Laboratoria Tbk.
32.	Cohistan Expectorant 60 ml	Dus, 1 botol @ 60 ml	DTL2004530137A1	PT Darya-Varia Laboratoria Tbk.
33.	Cohistan Expectorant 100 ml	Dus, 1 botol @ 100 ml	DTL2004530137A1	PT Darya-Varia Laboratoria Tbk.
34.	Daryazinc Drops	Dus, 1 botol @ 15 ml	DTL1204520936A1	PT Darya-Varia Laboratoria Tbk.
35.	Daryazinc Syrup	Dus, botol @ 60 ml	DTL1204521037A1	PT Darya-Varia Laboratoria Tbk.
36.	ARCALION	Dus, 10 strip @ 6 tablet salut gula	DKL1704525616A1	PT Darya-Varia Laboratoria Tbk.
37.	Bioprexum 5	Dus, 1 botol plastik @ 30 tablet salut selaput	DKI1631600617A1	PT Darya-Varia Laboratoria Tbk.

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
38.	Bioprexum 10	Dus, 1 botol plastik @30 tablet salut selaput	DKI1631600617B1	PT Darya-Varia Laboratoria Tbk.
39.	BioprexumPlus	Dus, 1 botol plastik @30 tablet salut selaput	DKI1631600517A1	PT Darya-Varia Laboratoria Tbk.
40.	Coralan 5	Dus, 4 blister @14 tablet salut selaput	DKI1668601317A1	PT Darya-Varia Laboratoria Tbk.
41.	Coralan 7,5	Dus, 4 blister @14 tablet salut	DKI1668601317B1	PT Darya-Varia Laboratoria Tbk.
42.	Coveram 5/5	Dus, 1 botol plastik @30 tablet	DKI1631600710A1	PT Darya-Varia Laboratoria Tbk.
43.	Coveram 5/10	Dus, 1 botol plastik @30 tablet	DKI1631600710C1	PT Darya-Varia Laboratoria Tbk.
44.	Coveram 10/5	Dus, 1 botol plastik @30 tablet	DKI1631600710B1	PT Darya-Varia Laboratoria Tbk.
45.	Coveram 10/10	Dus, 1 botol plastik @30 tablet	DKI1631600710D1	PT Darya-Varia Laboratoria Tbk.
46.	Diamicron Mr60	Dus, 2 blister @ 15 tablet pelepasan lambat	DKI1768601214A1	PT Darya-Varia Laboratoria Tbk.
47.	Diamicron 80	Dus, 12 strip @ 10tablet	DKL1604524910A1	PT Darya-Varia Laboratoria Tbk.
48.	Natrilix Sr	Dus, 3 strip @ 10tablet salut pelepasan lambat	DKL1704527296A1	PT Darya-Varia Laboratoria Tbk.
49.	Natexam 1,5/5	Dus, 6 blister @ 5 tablet pelepasan lambat	DKI1768601614A1	PT Darya-Varia Laboratoria Tbk.
50.	Natexam 1,5/10	Dus, 6 blister @ 5 tablet pelepasan lambat	DKI1768601614B1	PT Darya-Varia Laboratoria Tbk.
51.	Stablon	Dus, 3 strip @ 10 tablet salut gula	DKL1704524816A1	PT Darya-Varia Laboratoria Tbk.

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
52.	Trizedon MR 35	Dus, 2 blister @ 30 tablet salut selaput pelepasan lambat	DKL1604524514A1	PT Darya-Varia Laboratoria Tbk.
53.	Valdoxan	Dus, 2 blister @14 tablet salut selaput	DKI1668601517A1	PT Darya-Varia Laboratoria Tbk.
54.	Elsiron Kaplet	Dus, 10 amplop @ 1 strip @10 kaplet	DTL9509204804A1	PT Ifars Pharmaceutical
55.	Acifar 200 Kaplet	Dus, 10 strip @ 10 kaplet	DKL9709207204A1	PT Ifars Pharmaceutical
56.	Dumin Kaplet	Dus, 10 blister @ 10 kaplet & Dus, 100 blister @ 10 kaplet	DBL8305501304A1	PT Actavis Indonesia
57.	Dumin Syrup	Dus, 1 botol @ 60 ml	DBL8505505137A1	PT Actavis Indonesia
58.	Dumin Enema	Dus, 5 alubag @ 1 rectal tube@ 2.5 ml	DBL0105510758A1	PT Actavis Indonesia
59.		Dus, 5 alubag @ 1 rectal tube@ 4 ml	DBL0105510758B1	
60.	Keytruda	Dus, 1 vial @ 4 ml	DKI2287102549A1	PT Organon Pharma Indonesia
61.	Floxonase Aqueous Nasal Spray	Dus, botol 120 doses	DKI1091600456A1	PT Glaxo Wellcome Indonesia
62.	Keppra Tablet 250 mg	Dus, 3 blister @ 10 tablet salut selaput	DKI1083901017A1	PT Glaxo Wellcome Indonesia
63.	Infanrix-Hexa	Dus, 1 pre-filled syringe @0,5 ml + 1 vial @ 0,5 ml	DKI2176703044A1	PT Glaxo Wellcome Indonesia
64.	Havrix 720	Dus, 1 pre-filled syringe @0,5 ml	DKI2176702843A1	PT Glaxo Wellcome Indonesia
65.	Rotarix	Dus, 1 tube @ 1,5 ml	DKI2276703933A1	PT Glaxo Wellcome Indonesia

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
66.	Zovirax Tablet	Dus, 5 blister @5 tablet	DKI1691601310A1	PT Glaxo Wellcome Indonesia
67.	Trelegy Ellipta	Dus, 1 ellipta @30 dosis	DKI2275705167A1	PT Glaxo Wellcome Indonesia
68.	Seretide Diskus 50 mcg/100 mcg	Dus, 1 diskus @ 60 dosis	DKI1991500167A1	PT Glaxo Wellcome Indonesia
69.	Mucosta	Dus, 10 blister @ 10 tablet salut selaput	DKL0518707017A1	PT Otsuka Indonesia
70.	Meptin	Dus, 10 blister @ 10 tablet	DKL8118700110A1	PT Otsuka Indonesia
71.	Meptin Mini	Dus, 10 blister @ 10 tablet	DKL8518700110B1	PT Otsuka Indonesia
72.	Meptin	Dus, 28 vial (plastic unit) @ 0,3 mL	DKI1156101468A1	PT Otsuka Indonesia
73.	Meptin	Dus, 28 vial (plastic unit) @ 0,5 mL	DKI1156101468A1	PT Otsuka Indonesia
74.	Mycoral 200 mg Tablet	Dus, 5 blister @ 10 tablet	DKL8711605817A1	PT Kalbe Farma
75.	Divoltar 50 mg Tablet	Dus, 5 strip @ 10 tablet	DKL8811606915B1	PT Kalbe Farma
76.	Kalnex 500 mg Tablet	Dus, 10 strip @ 10 tablet	DKL9111614210A1	PT Kalbe Farma
77.	Zypraz 0,5 mg Tablet	Dus, 5 strip @ 10 tablet	DPL0111632810B1	PT Kalbe Farma
78.	Zypraz 1 mg Tablet	Dus, 5 strip @ 10 tablet	DPL0111632810C1	PT Kalbe Farma
79.	Kalxetin 10 mg Kapsul	Dus, 3 strip @ 10 kapsul	DKL0111618501B1	PT Kalbe Farma
80.	Kalxetin 20 mg Kapsul	Dus, 3 strip @ 10 kapsul	DKL0111618501A1	PT Kalbe Farma
81.	Kalmethasone Tablet	Dus, 20 Blister @ 10 tablet	DKL8311601510A2	PT Kalbe Farma
82.	Kalcirol N Cream/5 G	Dus, 1 tube @ 5 gram	DKL7211642929A1	PT Kalbe Farma
83.	Paxus 30 mg	Dus, 1 vial @ 5 ml	DKL1411643643A1	PT Kalbe Farma
84.	Paxus 100 mg	Dus, 1 vial @ 16,7 ml	DKL1411643643A1	PT Kalbe Farma
85.	Curacil	Dus, 1 vial @ 10 ml	DKL 8711605743A1	PT Kalbe Farma
86.	Kalmoxilin	Dus, 10 strip	DKL7811607404A1	PT Kalbe Farma

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
		@ 10 kaplet		
87.	Bactesyn Oral	Dus, 3 strip @ 10 kaplet	DKL9411620604A1	PT KalbeFarma
88.	Metrix 1 mg	Dus, 5 strip @ 10 tablet	DKL0311636210A1	PT KalbeFarma
89.	Metrix 2 mg	Dus, 5 strip @ 10 tablet	DKL0311636210B1	PT KalbeFarma
90.	Metrix 3 mg	Dus, 5 strip @ 10 tablet	DKL0311636210C1	PT KalbeFarma
91.	Metrix 4 mg	Dus, 2 blister @ 15 tablet	DKL0511636210D1	PT KalbeFarma
92.	Neuralgin RX	Dus, 10 blister @ 10kaplet	DKL2311647804A1	PT Kalbe Farma
93.	Ticage	Dus, 6 blister @ 10 tablet salut selaput	DKL2311647917A1	PT KalbeFarma
94.	Metronidazole	Flexibag@100 ml	GKL0228403449A1	PT Finusolprima Farma International
95.	Docetaxel 20 mg/vial	Dus, 1 vial@2ml	GKL2044300643A1	PT Global Onkolab Farma
96.	Docetaxel 80 mg/vial	Dus, 1 vial@8ml	GKL2044300643A1	PT Global Onkolab Farma
97.	Brexel 20 mg/vial	Dus, 1 vial@2ml	DKL2044300543A1	PT Global Onkolab Farma
98.	Brexel 80 mg/vial	Dus, 1 vial@8ml	DKL2044300543A1	PT Global Onkolab Farma
99.	Calcium Folate	Dus, 1 vial@5ml	GKL2044300243A1	PT Global Onkolab Farma

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
100.	Paracetamol	Flexybag @ 100 ml	GKL1508518449A1	PT HexpharmJaya Laboratories
101.	Ciprofloxacin lactate	Flexibag@100 ml	GKL0808515349A2	PT HexpharmJaya Laboratories
102.	Omeprazole 20mg	Dus, 20 strip @ 10 kapsultunda	GKL0508512603A1	PT HexpharmJaya Laboratories
103.	Lansoprazole 30 mg	Dus, 10 strip @ 10 kapsultunda	GKL0308508603A1	PT HexpharmJaya Laboratories
104.	Pantoprazole Sodium 40 mg	Dus, 1 vial @40 mg	GKL1508518544A1	PT HexpharmJaya Laboratories
105.	Cefotaxime Sodium 1000 mg	Dus, 2 vial @1 g	GKL0208505944B1	PT HexpharmJaya Laboratories
106.	Meropenem Trihydrate 1 g	Dus, 1 vial @1 g	GKL1108516844A1	PT HexpharmJaya Laboratories
107.	Citicoline Sodium 125 mg	Dus, 1 blister @ 5 ampul @4 mL	GKL0708513843B1	PT HexpharmJaya Laboratories
108.	Ranitidine HCL 25 mg	Dus, 2 blister @ 5 ampul @2 mL	GKL0608513443A1	PT HexpharmJaya Laboratories
109.	Meloxicam 7,5 mg	Dus, 10 strip @ 10 tablet	GKL1208517310A1	PT HexpharmJaya Laboratories
110.	Meloxicam 15 mg	Dus, 10 strip @ 10 tablet	GKL1208517310B1	PT HexpharmJaya Laboratories
111.	Danasone 0,5 mg	Dus, 20 strip @ 10 tablet	DKL0208505710A1	PT HexpharmJaya Laboratories
112.	Loratadine 10 mg	Dus, 10 strip @ 10 tablet	GTL0408510510A1	PT HexpharmJaya Laboratories
113.	Simvastatin 20 mg	Dus, 10 blister @ 10 tablet salut selaput	GKL1008504917B1	PT HexpharmJaya Laboratories

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
114.	Amlodipine Besilate 5 mg	Dus, 10 strip @ 10 tablet	GKL0708513910A1	PT HexpharmJaya Laboratories
115.	Amlodipine Besilate 10 mg	Dus, 10 strip @ 10 tablet	GKL0708513910B1	PT HexpharmJaya Laboratories
116.	Glimepiride 1 mg	Dus, 10 strip @ 10 tablet	GKL0508512710A1	PT HexpharmJaya Laboratories
117.	Glimepiride 2 mg	Dus, 10 strip @ 10 tablet	GKL0508512710B1	PT HexpharmJaya Laboratories
118.	Glimepiride 3 mg	Dus, 10 strip @ 10 tablet	GKL0508512710C1	PT HexpharmJaya Laboratories
119.	Glimepiride 4 mg	Dus, 10 strip @ 10 tablet	GKL0608512710D1	PT HexpharmJaya Laboratories
120.	Atorvastatin Calcium 10 mg	Dus, 5 blister @ 10 tablet salut selaput	GKL1408517817A1	PT HexpharmJaya Laboratories
121.	Atorvastatin Calcium 20 mg	Dus, 5 blister @ 10 tablet salut selaput	GKL1408517817B1	PT HexpharmJaya Laboratories
122.	Bisoprolol Fumarate 2.5 mg	Dus, 10 blister @ 10 tablet salut selaput	GKL2008513317B1	PT HexpharmJaya Laboratories
123.	Bisoprolol Fumarate 5 mg	Dus, 10 blister @ 10 tablet salut selaput	GKL0608513317A1	PT Hexpharm Jaya Laboratories
124.	Allopurinol 100 mg	Dus, 10 blister @ 10 tablet	GKL0708514410A1	PT HexpharmJaya Laboratories
125.	Allopurinol 300 mg	Dus, 10 blister @ 10 tablet	GKL0708514410B1	PT HexpharmJaya Laboratories
126.	Ranitidine HCl	Dus, 10 strip @ 10 tablet salut selaput	GKL0308509017A1	PT HexpharmJaya Laboratories
127.	Methyl prednisolone 4 mg	Dus, 10 blister @ 10 tablet	GKL0508512310A1	PT HexpharmJaya Laboratories

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
128.	Candesartan 16	Dus, 10 strip @ 10 tablet	GKL2208520810A1	PT HexpharmJaya Laboratories
129.	ClopidogrelBisulfate	Dus, 5 strip @ 10 tablet salut selaput	GKL1008516517A1	PT HexpharmJaya Laboratories
130.	Ciprofloxacin HCl	Dus, 10 strip @ 10 tablet salut selaput	GKL0208505117A1	PT HexpharmJaya Laboratories
131.	AmoxicillinTrihydrate	Dus, 1 botol @ 60 ml	GKL0308507838A1	PT HexpharmJaya Laboratories
132.	LevofloxacinHemihydrate	Dus, 5 strip @ 10 kaplet salut selaput	GKL1408518009A1	PT HexpharmJaya Laboratories
133.	Bintamox	Dus, 1 botol @ 60 ml	DKL0308508438A1	PT HexpharmJaya Laboratories
134.	Hexalgin	Dus, 10 strip @ 10 kaplet	DKL2208521204A1	PT HexpharmJaya Laboratories
135.	Metisol 4	Dus, 10 blister @ 10 tablet	DKL0608513610A1	PT HexpharmJaya Laboratories
136.	Vomina	Dus, 10 strip @ 10 Tablet	DKL2208521110A1	PT HexpharmJaya Laboratories
137.	Glimetic 2	Dus, 10 strip @ 10 tablet	DKL0908515810A1	PT HexpharmJaya Laboratories
138.	Girabloc	Dus, 10 strip @ 10 tablet salut selaput	DKL0208506617A1	PT HexpharmJaya Laboratories
139.	Ticagrelor 90 mg	Dus, 3 blister @ 10 tablet salut selaput	GKL2308521317A1	PT HexpharmJaya Laboratories
140.	Salbutamol 2	Dus, 10 strip @ 10 tablet	GKL9832707710A1	PT Yarindo Farmatama
141.	Salbutamol 4	Dus, 10 strip @ 10 tablet	GKL9832707710B1	PT Yarindo Farmatama

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
142.	Digoxin	Dus, 10 blister @ 10 tablet	GKL9832705210A1	PT Yarindo Farmatama
143.	Brilinta FCT 60 mg	Dus, 4 blister @ 14 tablet salut selaput	DKI1751303217A1	PT AstraZeneca Indonesia
144.	Brilinta FCT 90 mg	Dus, 4 blister @ 14 tablet salut selaput	DKI1635301117A1	PT AstraZeneca Indonesia
145.	Brilinta ODT	Dus, 7 blister @ 8 tablet orodispersible	DKI2351304481A1	PT AstraZeneca Indonesia
146.	Tezspire	Dus, 1 pre-filled pen @1,91 ml	DKI2451304743A2	PT AstraZeneca Indonesia
147.	Enhertu	Dus, 1 Vial @100 mg	DKI2468100144A1	PT AstraZeneca Indonesia
148.	Imjudo	Dus, 1 vial @ 15 ml	DKI2451304849B1	PT AstraZeneca Indonesia
149.	Nurtec	Dus, 1 blister @ 2 tabletcepat larut	DKI2346200181A1	PT Pfizer Indonesia
150.	Staquis	Dus, 1 tube @ 30 g	DKI2472101230A1	PT Pfizer Indonesia
151.	Aromasin	Dus, 2 blister @ 15 tablet salut gula	DKI0254200316A1	PT Pfizer Indonesia
152.	Provera 10 mg	Dus, 3 blister @ 10 tablet	DKI0054200210C1	PT Pfizer Indonesia
153.	Provera100 mg	Dus, 10 blister @10 tablet	DKI0054200210D1	PT Pfizer Indonesia
154.	Concor 1.25 mg	Dus, 3 blister @ 10 tablet salut selaput	DKL1015803817C1	PT Merck Tbk
155.	Concor 10 mg	Dus, 3 blister @ 10 tablet salut selaput	DKL9115803817B1	PT Merck Tbk
156.	Concor 5 mg	Dus, 10 blister @ 10 tablet salut selaput	DKL9115803817A1	PT Merck Tbk

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
157.	Glucophage XR750 mg	Dus, 8 blister @ 15 tablet pelepasan lambat	DKL1915809314B1	PT Merck Tbk
158.	Glucophage XR1000 mg	Dus, 12 blister @ 10 tablet pelepasan lambat	DKL2215809314C1	PT Merck Tbk
159.	Cosyrel 5/5	Dus, 1 botol plastik @30 tablet salut selaput	DKI2068601817A1	PT Genero Pharmaceuticals
160.	Cosyrel 5/10	Dus, 1 botol plastik @30 tablet salut selaput	DKI2068601817B1	PT Genero Pharmaceuticals
161.	Triplixam 5/1,25/5	Dus, 1 botol plastik @30 tablet salut selaput	DKI2131600817A1	PT Genero Pharmaceuticals
162.	Triplixam 5/1,25/10	Dus, 1 botol plastik @30 tablet salut selaput	DKI2131600817B1	PT Genero Pharmaceuticals
163.	Triplixam 10/2,5/10	Dus, 1 botol plastik @30 tablet salut selaput	DKI2131600817D1	PT Genero Pharmaceuticals
164.	Trizedon 80 MGOD	Dus, 5 strip @ 6 kapsul pelepasan lambat	DKL1806103003A1	PT Eisai Indonesia
165.	Avastin	Dus, 1 vial @ 4 ml	DKI2157508643A1	PT Menarini Indria Laboratories
166.	Phesgo	Dus, 1 vial @ 600 mg/600 mg/10 ml	DKI2257511243B1	PT Menarini Indria Laboratories
167.	Perjeta	Dus, 1 vial 420 mg/14 ml	DKI2157508549A1	PT Menarini Indria Laboratories
168.	Nipe Drop	1 botol @ 15 ml	DKL9832205736A1	PT Menarini Indria Laboratories

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
169.	Procaine Penicillin-G Meiji	Dus, 100 vial @ 3 g	DKL7215302544A1	PT Meiji Indonesian Pharmaceutical Industries
170.	Fosmicin	Dus, 10 vial @ 1 g	DKL9715302444A1	PT Meiji Indonesian Pharmaceutical Industries
171.	Fosmicin	Dus, 10 vial @ 2 g	DKL9715302444B1	PT Meiji Indonesian Pharmaceutical Industries
172.	Sulfasalazine	Dus, 3 Strip @ 10 Kaplet Salut Enterik	GKL2131548307A1	PT Pratapa Nirmala
173.	Neostigmine Methylsulfate	Dus, 5 Ampul @ 1 mL	GKL2031545643A1	PT Pratapa Nirmala
174.	Farmadol 100	Dus, 1 Vial @ 100 mL	DKL0931528849A1	PT Pratapa Nirmala
175.	Paclitaxel 30 mg	Dus, 1 vial @ 5 ml	GKL1404428443A1	PT Dankos Farma
176.	Paclitaxel 100 mg	Dus, 1 vial @ 16,7ml	GKL1404428443A1	PT Dankos Farma
177.	Rheu-Trex	Dus, 5 strip @ 10 tablet	DKL1704429910A1	PT Dankos Farma
178.	Sucralfate Suspensi	Botol plastik @ 100 ml	GKL1615624733A2	PT Meprofarm
179.	Ketorolac Trometamol Injeksi	Dus, 10 ampul @ 1 ml	GKL1815627143A1	PT Meprofarm
180.	Ranitidine HCl Injeksi	Dus, 10 ampul @ 2 ml	GKL1815626543A1	PT Meprofarm
181.	Dexamethasone Sodium Phosphate Injeksi	Dus, 10 ampul @ 1 ml	GKL1615625643A1	PT Meprofarm
182.	Mucifat Suspensi	Dus, 1 botol plastik @ 100 ml	DKL1615624633A2	PT Meprofarm

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
183.	Ursodeoxycholic Acid Kapsul	Dus, 10 strip @ 10kapsul	GKL1815626801A1	PT Meprofarm
184.	Allopurinol 100	Dus, 10 blister @10 tablet	GKL1633313410A1	PT Mersifarma Tirmaku Mercusana
185.	Allopurinol 300	Dus, 3 blister @10 tablet	GKL1733314610A1	PT Mersifarma Tirmaku Mercusana
186.	Amlodipine 5	Dus, 10 strip @ 10tablet	GKL1933316910A1	PT Mersifarma Tirmaku Mercusana
187.	Amlodipine 10	Dus, 10 strip @ 10tablet	GKL1933316910B1	PT Mersifarma Tirmaku Mercusana
188.	Amoxicillin 500	Dus, 10 strip @ 10tablet	GKL0133303804A1	PT Mersifarma Tirmaku Mercusana
189.	Cotrimoxazole Suspensi	Botol plastik @60 ml	GKL1733314833A1	PT Mersifarma Tirmaku Mercusana
190.	DHP Frimal	Dus, 1 blister @9 tablet salut selaput	DKI1340100217A1	PT Mersifarma Tirmaku Mercusana
191.	Ketorolac Trometamol Injeksi	Dus, 12 ampul @1ml	GKL1933316643A1	PT Mersifarma Tirmaku Mercusana
192.	Mefenamic Acid 500	Dus, 10 blister @10 kaplet salut selaput	GKL1633313009A2	PT Mersifarma Tirmaku Mercusana
193.	Mersibion 5000 Injeksi	Dus, 10 ampul @3ml	DKL0233304243A1	PT Mersifarma Tirmaku Mercusana
194.	Metronidazole Infus	Dus, 1 botol @100ml	GKL1833316249A1	PT Mersifarma Tirmaku Mercusana
195.	Paracetamol Infus	Botol @100ml	GKL1733314449A1	PT Mersifarma Tirmaku Mercusana
196.	Ranitidine Injeksi	Dus, 10 ampul @2ml	GKL1833315643A1	PT Mersifarma Tirmaku Mercusana

No.	Nama Produk	Kemasan	Nomor Izin Edar	Pemilik Izin Edar
197.	Risperidone 2	Dus, 5 strip @ 10 tablet salut selaput	GKL1133310317A1	PT Mersifarma Tirmaku Mercusana
198.	Trihexyphenidyl 2	Dus, 10 blister @10 tablet	GKL1433312410A1	PT Mersifarma Tirmaku Mercusana
199.	Elevit	Dus, 5 strip @ 6 tablet salut selaput	DBL2302009917A1	PT Bayer Indonesia

KEPALA BADAN PENGAWAS OBAT DAN MAKANAN,

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TARUNA IKRAR