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|  |  |  | <b>AGENCIA NACIONAL DE REFERENCIA REGIONAL</b> |   |  |  |                             |  |  |
| <b>DIRECCIÓN DE MEDICAMENTOS Y PRODUCTOS BIOLÓGICOS</b>                          |  |  |  |   |  |  |                             |  |  |
| <b>FUNCIÓN REGULADORA</b>  |  |  |  | <b>PUBLICACIÓN</b>  |  |  | <b>FECHA DE PUBLICACIÓN</b> |  |  |
| Laboratorio y Liberación de Lotes- Oficina de Laboratorios y Control de Calidad  |  |  |  | Liberación de lotes de Vacunas, Hemoderivados y Sueros de origen animal realizadas en Noviembre de 2016 |  |  | 2016-12-07                  |  |  |

| Distribuidor o remitente del producto               | Nombre del Producto                                   | Presentación | Producto Biológico | Productor                        | Fecha de vencimiento | No. lote del producto | Total de unidades distribuidas en el país | Fecha de Liberación o fecha oficio de no cumplimiento | Certificado de Liberación |
|---|---|--------------|--------------------|----------------------------------|----------------------|-----------------------|---|---|---------------------------|
| PAI   | VACUNA POLIOLIELITICA MULTIDOSIS (IPV)                | 2,5mL        | VACUNA             | Bilthoven Biologicals            | 2018-09              | IPV885BB              | 86230                                     | 2016-11-28  | FR-2926                   |
| PAI   | VACUNA POLIOLIELITICA MULTIDOSIS (IPV)                | 2,5mL        | VACUNA             | Bilthoven Biologicals            | 2018-09-09           | IPV885A               | 197880                                    | 2016-11-28  | FR-2941                   |
| PAI   | VACUNA ANTIPOLIOMIELITICA (ORAL) BIVALENTE TIPO 1 Y 3 | 2mL          | VACUNA             | SERUM INSTITUTE OF INDIA LTD.    | 2018-01              | 180O6006              | 450000                                    | 2016-11-02  | FR-2980                   |
| PAI   | VACUNA ANTIPOLIOMIELITICA (ORAL) BIVALENTE TIPO 1 Y 3 | 2mL          | VACUNA             | SERUM INSTITUTE OF INDIA LTD.    | 2018-01              | 180O6004              | 298200                                    | 2016-11-02  | FR-3208                   |
| PAI   | VACUNA ANTIPOLIOMIELITICA (ORAL) BIVALENTE TIPO 1 Y 3 | 2mL          | VACUNA             | SERUM INSTITUTE OF INDIA LTD.    | 2017-12              | 180O6003              | 601800                                    | 2016-11-02  | FR-3209                   |
| SANOFI PASTEUR S.A                                  | HEXAXIM   | 0,5mL        | VACUNA             | SANOFI PASTEUR S.A               | 2018-01-31           | M71235V               | 11150                                     | 2016-11-09  | PR-3338                   |
| PAI   | STAMARIL  | 5mL          | VACUNA             | SANOFI PASTEUR S.A               | 2018-05              | M53301V               | 352500                                    | 2016-11-10  | FR-3363                   |
| PAI   | VACUNA BCG  | 1mL          | VACUNA             | SERUM INSTITUTE OF INDIA LTD.    | 2017-09              | 037G5206              | 71440                                     | 2016-11-21  | FR-3367                   |
| PAI   | VACUNA BCG  | 1mL          | VACUNA             | SERUM INSTITUTE OF INDIA LTD.    | 2017-10              | 037G5231              | 314660                                    | 2016-11-18  | FR-3368                   |
| PAI   | VACUNA BCG  | 1mL          | VACUNA             | SERUM INSTITUTE OF INDIA LTD.    | 2017-11              | 037G5240              | 213900                                    | 2016-11-21  | FR-3369                   |
| NISSI S.A.S   | OCTANINE F 1000 UI                                    | 10mL         | HEMODERIVADO       | OCTAPharma PHARMAZEUTIKA         | 2019-03              | K615B2203             | 220                                       | 2016-11-16  | PR-3372                   |
| NISSI S.A.S   | OCTANINE F 500 UI                                     | 5mL          | HEMODERIVADO       | OCTAPharma PHARMAZEUTIKA         | 2019-03              | K616B2203             | 280                                       | 2016-11-16  | PR-3373                   |
| NISSI S.A.S   | OCTANINE F 250 UI                                     | 5mL          | HEMODERIVADO       | OCTAPharma PHARMAZEUTIKA         | 2018-10              | A548E2204             | 48  | 2016-11-16  | PR-3374                   |
| LABORATORIOS BAXTER S.A.                            | FACTOR HUMANO ANTIHEMOFILICO METODO M HEMOFIL M       | 10mL         | HEMODERIVADO       | BAXTER A.G.                      | 01/05/2018           | THA15262AC            | 506                                       | 2016-11-02  | PR-3375                   |
| PAI   | GARDASIL  | 0,5mL        | VACUNA             | Merck Sharp & Dohme Corp.        | 2017-11-24           | M027495               | 50000                                     | 2016-11-16  | FR-3380                   |
| LABORATORIOS DELTA                                  | VACUNA ANTITETÁNICA                                   | 0,5mL        | VACUNA             | INSTITUTO FINLAY                 | 2019-05              | 608T                  | 103151                                    | 2016-11-18  | PR-3385                   |
| LABORATORIOS BAXTER S.A.                            | FLEXBUMIN 20%   | 50mL         | HEMODERIVADO       | BAXTER A.G.                      | 2018-06              | LB031682              | 16272                                     | 2016-11-18  | PR-3387                   |
| PAI   | VACUNA ANTIPOLIOMIELITICA (ORAL) BIVALENTE TIPO 1 Y 3 | 2mL          | VACUNA             | SERUM INSTITUTE OF INDIA LTD.    | 2018-05              | 180O6088              | 67440                                     | 2016-11-02  | FR-3396                   |
| LABORATORIOS BAXTER S.A.                            | IMMUNINE 600 UI                                       | 5mL          | HEMODERIVADO       | BAXTER A.G.                      | 2018-02              | VNC1R006AS            | 432                                       | 2016-11-16  | PR-3406                   |
| GlaxoSmithKline Colombia S.A.                       | VAMMRIX   | 0,5mL        | VACUNA             | GlaxoSmithKline Biologicals S.A. | 2017-09              | A71CB109A             | 5600                                      | 2016-11-18  | PR-3407                   |
| FIAC S.A.S Farmaceutica Internacional de alto costo | IG VENA 5g/100mL                                      | 100mL        | HEMODERIVADO       | KEDRION                          | 2019-01              | 168002                | 150                                       | 2016-11-17  | PR-3422                   |
| FIAC S.A.S Farmaceutica Internacional de alto costo | IMMUNORHO 300mcg                                      | 5mL          | HEMODERIVADO       | KEDRION                          | 2018-11              | G12F77143             | 2000                                      | 2016-11-17  | PR-3423                   |
| FIAC S.A.S Farmaceutica Internacional de alto costo | EMOCLOT 500 UI  | 10mL         | HEMODERIVADO       | KEDRION                          | 2019-01              | 451605                | 2041                                      | 2016-11-18  | PR-3424                   |
| AMAREY NOVA MEDICAL S.A                             | PENTAGLOBIN x 50 mL                                   | 50mL         | HEMODERIVADO       | BIOTEST PHARMA GMBH              | 2018-04-30           | B146226               | 58  | 2016-11-18  | PR-3436                   |
| FIAC S.A.S Farmaceutica Internacional de alto costo | UMAN ALBUMIN 200g/L                                   | 50mL         | HEMODERIVADO       | KEDRION                          | 2018-11              | 152944                | 3000                                      | 2016-11-04  | PR-3444                   |
| PAI   | VARIVAX   | 0,5mL        | VACUNA             | Merck Sharp & Dohme Corp.        | 2018-06-08           | M028706               | 37850                                     | 2016-11-28  | FR-3459                   |
| PAI   | VARIVAX   | 0,5mL        | VACUNA             | Merck Sharp & Dohme Corp.        | 2018-06-08           | M028707               | 37650                                     | 2016-11-28  | FR-3460                   |

|                          |   |       |              |                               |            |            |        |            |            |
|--------------------------|---|-------|--------------|-------------------------------|------------|------------|--------|------------|------------|
| PAI                      | VARIVAX   | 0,5mL | VACUNA       | Merck Sharp & Dohme Corp.     | 2018-06-08 | M028708    | 37430  | 2016-11-28 | FR-3461    |
| PAI                      | VARIVAX   | 0,5mL | VACUNA       | Merck Sharp & Dohme Corp.     | 2018-06-08 | M028710    | 36940  | 2016-11-28 | FR-3462    |
| PAI                      | VARIVAX   | 0,5mL | VACUNA       | Merck Sharp & Dohme Corp.     | 2018-06-08 | M028415    | 33230  | 2016-11-28 | FR-3463    |
| PAI                      | VARIVAX   | 0,5mL | VACUNA       | Merck Sharp & Dohme Corp.     | 2018-07-21 | M033928    | 16900  | 2016-11-28 | FR-3464    |
| PAI                      | TETADIF   | 5mL   | VACUNA       | BB-NCIPD.LTD                  | 2018-09    | D2296      | 54200  | 2016-11-23 | FR-3466-R1 |
| PAI                      | TETADIF   | 5mL   | VACUNA       | BB-NCIPD.LTD                  | 2018-09    | D2299      | 504700 | 2016-11-23 | FR-3467    |
| PAI                      | TETADIF   | 5mL   | VACUNA       | BB-NCIPD.LTD                  | 2018-10    | D2300      | 141100 | 2016-11-23 | FR-3468    |
| BAKER & MCKENZIE         | EVICEL SELLANTE DE FIBRINA HUMANA x 2 ml                        | 2mL   | HEMODERIVADO | OMRIX BIOPHARMACEUTICALS LTD  | 2018-03    | V30F10J    | 492    | 2016-11-02 | PR-3487    |
| SANOFI PASTEUR S.A       | STAMARIL  | 0,5mL | VACUNA       | SANOFI PASTEUR S.A            | 2017-09    | L54383V    | 20000  | 2016-11-16 | PR-3489    |
| SANOFI PASTEUR S.A       | VERORAB   | 0,5mL | VACUNA       | SANOFI PASTEUR S.A            | 2018-10    | M16541V    | 3000   | 2016-11-30 | PR-3491    |
| SANOFI PASTEUR S.A       | TYPHIM VI   | 0,5mL | VACUNA       | SANOFI PASTEUR S.A            | 2018-02    | M00656M    | 4100   | 2016-11-18 | PR-3492    |
| NISSI S.A.S              | OCTANATE 1000 UI  | 10mL  | HEMODERIVADO | OCTAPHARMA AB                 | 2018-04    | M619D1202  | 995    | 2016-11-02 | PR-3493    |
| LABORATORIOS BAXTER S.A. | FLOSEAL x 5 ml  | 5mL   | HEMODERIVADO | BAXTER HEALTHCARE CORPORATION | 2018-02-28 | HA160849   | 312    | 2016-11-02 | PR-3496    |
| BIOSPIFAR S.A            | OCTAPLEX 500 UI   | 20mL  | HEMODERIVADO | OCTAPHARMA                    | 2018-04    | L619A2611  | 700    | 2016-11-02 | PR-3504    |
| NISSI S.A.S              | OCTANATE 500 UI   | 10mL  | HEMODERIVADO | OCTAPHARMA AB                 | 2018-04    | M620B1202  | 1600   | 2016-11-02 | PR-3505    |
| LABORATORIOS DELTA       | VACUNA ANTITETÁNICA   | 0,5mL | VACUNA       | INSTITUTO FINLAY              | 2019-05    | 609T       | 104962 | 2016-11-04 | PR-3506    |
| BAXALTA COLOMBIA S.A.S.  | IMMUNINE 600 UI   | 5mL   | HEMODERIVADO | BAXTER A.G.                   | 2018-02    | VNC1R006AT | 247    | 2016-11-11 | PR-3507    |
| BAXALTA COLOMBIA S.A.S.  | FEIBA 500 U   | 20mL  | HEMODERIVADO | BAXTER A.G.                   | 2018-03    | VNF2R044AD | 1080   | 2016-11-11 | PR-3508    |
| PAI                      | STAMARIL MULTIDOSIS   | 5mL   | VACUNA       | SANOFI PASTEUR S.A            | 2018-10-31 | M56051V    | 500000 | 2016-11-17 | FR-3511    |
| PAI                      | VACUNA ADSORBIDA CONTRA DIFTERIA, TÉTANO Y PERTUSSIS MULTIDOSIS | 5mL   | VACUNA       | SERUM INSTITUTE OF INDIA LTD. | 2018-06    | 282P6011   | 200000 | 2016-11-17 | FR-3517    |
| PAI                      | DIFTET  | 5mL   | VACUNA       | BB-NCIPD.LTD                  | 2019-05    | C2114      | 1000   | 2016-11-22 | FR-3523    |
| BAXALTA COLOMBIA S.A.S.  | IMMUNINE 600 UI   | 5mL   | HEMODERIVADO | BAXTER A.G.                   | 2018-05    | VNC1R016AH | 941    | 2016-11-02 | PR-3527    |
| LABORATORIOS BAXTER S.A. | TISSEEL LYO X 10mL  | 10mL  | HEMODERIVADO | BAXTER A.G.                   | 2018-07    | VNT5R029AC | 60     | 2016-11-10 | PR-3528    |
| LABORATORIOS BAXTER S.A. | TISSEEL LYO X 4mL   | 4mL   | HEMODERIVADO | BAXTER A.G.                   | 2018-05    | VNT5R024AD | 435    | 2016-11-10 | PR-3529    |
| LABORATORIOS BAXTER S.A. | TISSEEL LYO X 2 ml  | 2mL   | HEMODERIVADO | BAXTER A.G.                   | 2018-06    | VNT5R026AL | 260    | 2016-11-10 | PR-3530    |
| AMAREY NOVA MEDICAL S.A  | INTRATECT X 50mL  | 50mL  | HEMODERIVADO | BIOTEST PHARMA GMBH           | 2018-05-31 | B791756    | 108    | 2016-11-18 | PR-3531    |
| BAXALTA COLOMBIA S.A.S.  | FEIBA 1000 U  | 20mL  | HEMODERIVADO | BAXTER A.G.                   | 2018-05    | VNF2R052AJ | 432    | 2016-11-10 | PR-3532    |
| BIOTOSCANA FARMA S.A     | HEPAVAX GENE TF 20 mcg  | 1mL   | VACUNA       | BERNA BIOTECH KOREA CORP      | 2019-06-06 | 1434026    | 50000  | 2016-11-02 | PR-3533-R1 |
| AMAREY NOVA MEDICAL S.A  | PENTAGLOBIN x 10 mL   | 10mL  | HEMODERIVADO | BIOTEST PHARMA GMBH           | 2016-05-31 | B146256    | 70     | 2016-11-10 | PR-3534-R2 |
| BAXALTA COLOMBIA S.A.S.  | FLEXBUMIN 20%   | 50mL  | HEMODERIVADO | BAXTER A.G.                   | 2018-07    | LB032110   | 14040  | 2016-11-10 | PR-3538    |
| LABORATORIOS BAXTER S.A. | TISSEEL LYO X 2 ml  | 2mL   | HEMODERIVADO | BAXTER A.G.                   | 2017-09    | VNT5Q027AD | 65     | 2016-11-10 | PR-3539    |
| SANOFI PASTEUR S.A       | TETRAXIM  | 0,5mL | VACUNA       | SANOFI PASTEUR S.A            | 2018-08    | M02401M    | 6850   | 2016-11-21 | PR-3540    |
| BIOTOSCANA FARMA S.A     | SANDOGLOBULINA 6g   | 200mL | HEMODERIVADO | CSL BEHRING AG                | 2019-07-31 | 4340200176 | 1879   | 2016-11-10 | PR-3537    |
| AMAREY NOVA MEDICAL S.A  | HEPATECT CP X 2mL   | 2mL   | HEMODERIVADO | BIOTEST PHARMA GMBH           | 2018-05-31 | B793096    | 150    | 2016-11-11 | PR-3541    |
| AMAREY NOVA MEDICAL S.A  | PENTAGLOBIN x 100 mL  | 100mL | HEMODERIVADO | BIOTEST PHARMA GMBH           | 2018-06-30 | B146336    | 250    | 2016-11-17 | PR-3542    |

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|-------------------------|--|-------|--------------|------------------------------|------------|------------|--------|------------|------------|
| SANOFI PASTEUR S.A      | MENACTRA                                 | 0,5mL | VACUNA       | SANOFI PASTEUR S.A           | 2018-02-08 | U5506AB    | 19700  | 2016-11-17 | PR-3543    |
| SANOFI PASTEUR S.A      | AVAXIM 80                                | 0,5mL | VACUNA       | SANOFI PASTEUR S.A           | 2017-08    | L74591V    | 5000   | 2016-11-02 | PR-3544    |
| AMAREY NOVA MEDICAL S.A | INTRATECT X 50mL                         | 50mL  | HEMODERIVADO | BIOTEST PHARMA GMBH          | 2018-05-31 | B791796    | 400    | 2016-11-17 | PR-3545    |
| AMAREY NOVA MEDICAL S.A | HEPATECT CP X 40mL                       | 40mL  | HEMODERIVADO | BIOTEST PHARMA GMBH          | 2018-04-30 | B793076    | 25     | 2016-11-17 | PR-3546-R1 |
| AMAREY NOVA MEDICAL S.A | PENTAGLOBIN x 10 mL                      | 10mL  | HEMODERIVADO | BIOTEST PHARMA GMBH          | 2018-06-30 | B146286    | 80     | 2016-11-17 | PR-3549    |
| AMAREY NOVA MEDICAL S.A | INTRATECT X 50mL                         | 50mL  | HEMODERIVADO | BIOTEST PHARMA GMBH          | 31/05/2018 | B791796    | 300    | 2016-11-17 | PR-3550-R1 |
| NISSI S.A.S             | OCTANATE 1000 UI                         | 10mL  | HEMODERIVADO | OCTAPHARMA AB                | 2018-03    | M614C1205  | 91     | 2016-11-11 | PR-3551    |
| NISSI S.A.S             | OCTANATE 500 UI                          | 10mL  | HEMODERIVADO | OCTAPHARMA AB                | 2018-02    | M611E1201  | 1861   | 2016-11-11 | PR-3552    |
| PAI                     | STAMARIL MULTIDOSIS                      | 5mL   | VACUNA       | SANOFI PASTEUR S.A           | 2018-11    | M5623      | 500000 | 2016-11-28 | FR-3555    |
| BIOSPIFAR S.A           | GAMMANORM X 20 mL                        | 20mL  | HEMODERIVADO | OCTAPHARMA AB                | 2019-08    | M636A860C  | 450    | 2016-11-22 | PR-3556    |
| SANOFI PASTEUR S.A      | TETAVAX                                  | 0,5mL | VACUNA       | SANOFI PASTEUR S.A           | 2018-06-30 | M72873V    | 5961   | 2016-11-28 | PR-3557    |
| SANOFI PASTEUR S.A      | TETAVAX                                  | 0,5mL | VACUNA       | SANOFI PASTEUR S.A           | 2018-06-30 | M72747V    | 4339   | 2016-11-28 | PR-3558    |
| BAKER & MCKENZIE        | EVICEL SELLANTE DE FIBRINA HUMANA x 1 ml | 1mL   | HEMODERIVADO | OMRIX BIOPHARMACEUTICALS LTD | 2018-05    | V30F110A   | 288    | 2016-11-30 | PR-3566    |
| BAXALTA COLOMBIA S.A.S. | KIOVIG 5g                                | 50mL  | HEMODERIVADO | BAXTER S.A                   | 2016-06    | LE12R237AC | 6259   | 2016-11-23 | PR-3569    |
| BIOTOSCANA FARMA S.A    | RHOPHYLAC 300                            | 2mL   | HEMODERIVADO | CSL BEHRING AG               | 2019-05    | 4345900019 | 600    | 2016-11-22 | PR-3578    |
| SANOFI PASTEUR S.A      | PENTAXIM                                 | 0,5mL | VACUNA       | SANOFI PASTEUR S.A           | 2017-11    | N0A131V    | 923    | 2016-11-30 | PR-3604-R3 |
| BIOTOSCANA FARMA S.A    | RHOPHYLAC 300                            | 2mL   | HEMODERIVADO | CSL BEHRING AG               | 31/05/2019 | 4345900019 | 1200   | 2016-11-24 | PR-3605-R1 |