



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 July 2016  
EMA/499744/2016  
Procedure Management and Business Support

## Marketing authorisations which are recommended for suspension and marketing authorisation applications which do not satisfy the criteria for authorisation as adopted by the CHMP on 21 July 2016

Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1443

Some of these medicinal products may be considered critical by the individual EU Member States. The suspension of the concerned marketing authorisation(s) may be deferred by the period for which the medicinal product is considered critical.



| <b>Member State EU/EEA</b> | <b>Marketing Authorisation Holder</b> | <b>Applicant</b>       | <b>Invented name</b>      | <b>Active Substance</b>  | <b>Strength</b>   | <b>Pharmaceutical Form</b> | <b>Route of Administration</b> |
|----------------------------|---------------------------------------|------------------------|---------------------------|--------------------------|-------------------|----------------------------|--------------------------------|
| Belgium                    |                                       | Sandoz NV              | Erlotinib Sandoz          | erlotinib                | 25 mg             | Film-coated tablet         | Oral use                       |
| Belgium                    |                                       | Sandoz NV              | Erlotinib Sandoz          | erlotinib                | 100 mg            | Film-coated tablet         | Oral use                       |
| Belgium                    |                                       | Sandoz NV              | Erlotinib Sandoz          | erlotinib                | 150 mg            | Film-coated tablet         | Oral use                       |
| Belgium                    |                                       | Teva Pharma Belgium NV | Erlotinib Ratiopharm      | erlotinib                | 25 mg             | Film-coated tablet         | Oral use                       |
| Belgium                    |                                       | Teva Pharma Belgium NV | Erlotinib Ratiopharm      | erlotinib                | 100 mg            | Film-coated tablet         | Oral use                       |
| Belgium                    |                                       | Teva Pharma Belgium NV | Erlotinib Ratiopharm      | erlotinib                | 150 mg            | Film-coated tablet         | Oral use                       |
| Belgium                    |                                       | Accord Healthcare Ltd  | Saquinavir Accord         | saquinavir               | 500 mg            | Film-coated tablet         | Oral use                       |
| Belgium                    | Teva Pharma Belgium NV                |                        | Atovaquone/Proguanil Teva | atovaquone/<br>proguanil | 62.5 mg/<br>25mg  | Film-coated tablet         | Oral use                       |
| Belgium                    | Teva Pharma Belgium NV                |                        | Atovaquone/Proguanil Teva | atovaquone/<br>proguanil | 250 mg/<br>100 mg | Film-coated tablet         | Oral use                       |
| Belgium                    | Sandoz NV                             |                        | Malaprotec                | atovaquone/<br>proguanil | 62.5 mg/<br>25mg  | Film-coated tablet         | Oral use                       |
| Belgium                    | Sandoz NV                             |                        | Malaprotec                | atovaquone/<br>proguanil | 250 mg/<br>100mg  | Film-coated tablet         | Oral use                       |
| Belgium                    | Sandoz NV                             |                        | Saquinavir Sandoz         | saquinavir               | 500 mg            | Film-coated tablet         | Oral use                       |
| Bulgaria                   |                                       | Teva B.V.              | Erlotinib Teva Pharma B.V | erlotinib                | 100 mg            | Film-coated tablet         | Oral use                       |

| <b>Member State EU/EEA</b> | <b>Marketing Authorisation Holder</b> | <b>Applicant</b>          | <b>Invented name</b>                                    | <b>Active Substance</b> | <b>Strength</b> | <b>Pharmaceutical Form</b> | <b>Route of Administration</b> |
|----------------------------|---------------------------------------|---------------------------|---|-------------------------|-----------------|----------------------------|--------------------------------|
| Bulgaria                   |                                       | Teva B.V.                 | Erlotinib Teva Pharma B.V                               | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| Bulgaria                   |                                       | Sandoz B.V.               | Erlotinib Sandoz  | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |
| Bulgaria                   |                                       | Sandoz B.V.               | Erlotinib Sandoz  | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| Bulgaria                   |                                       | Accord Healthcare Limited | Saquinavir Accord                                       | saquinavir              | 500 mg          | Film-coated tablet         | Oral use                       |
| Croatia                    |                                       | Sandoz B.V.               | Erlotinib Sandoz 25 mg filmom obložene tablete          | erlotinib               | 25 mg           | Film-coated tablet         | Oral use                       |
| Croatia                    |                                       | Sandoz B.V.               | Erlotinib Sandoz 100 mg filmom obložene tablete         | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |
| Croatia                    |                                       | Sandoz B.V.               | Erlotinib Sandoz 150 mg filmom obložene tablete         | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| Croatia                    |                                       | Teva B.V.                 | Erlotinib Pliva Hrvatska 25 mg filmom obložene tablete  | erlotinib               | 25 mg           | Film-coated tablet         | Oral use                       |
| Croatia                    |                                       | Teva B.V.                 | Erlotinib Pliva Hrvatska 100 mg filmom obložene tablete | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |
| Croatia                    |                                       | Teva B.V.                 | Erlotinib Pliva Hrvatska 150 mg filmom obložene tablete | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |

| <b>Member State EU/EEA</b> | <b>Marketing Authorisation Holder</b> | <b>Applicant</b>      | <b>Invented name</b>                        | <b>Active Substance</b> | <b>Strength</b> | <b>Pharmaceutical Form</b> | <b>Route of Administration</b> |
|----------------------------|---------------------------------------|-----------------------|---|-------------------------|-----------------|----------------------------|--------------------------------|
| Croatia                    |                                       | Edicta Pharm d.o.o.   | Edinib 25 mg filmom obložene tablete        | erlotinib               | 25 mg           | Film-coated tablet         | Oral use                       |
| Croatia                    |                                       | Edicta Pharm d.o.o.   | Edinib 100 mg filmom obložene tablete       | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |
| Croatia                    |                                       | Edicta Pharm d.o.o.   | Edinib 150 mg filmom obložene tablete       | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| Cyprus                     |                                       | Sandoz B.V.           | Erlotinib Hydrochloride Sandoz              | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| Cyprus                     |                                       | Accord Healthcare Ltd | Saquinavir Accord                           | saquinavir              | 500 mg          | Film-coated tablet         | Oral use                       |
| Czech Republic             |                                       | Sandoz B.V.           | Erlotinib Sandoz 25 mg                      | erlotinib               | 25 mg           | Film-coated tablet         | Oral use                       |
| Czech Republic             |                                       | Sandoz B.V.           | Erlotinib Sandoz 100 mg                     | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |
| Czech Republic             |                                       | Sandoz B.V.           | Erlotinib Sandoz 150 mg                     | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| Czech Republic             |                                       | Vipharm S.A.          | Erlotinib Vipharm 25 mg potahovane tablety  | erlotinib               | 25 mg           | Film-coated tablet         | Oral use                       |
| Czech Republic             |                                       | Vipharm S.A.          | Erlotinib Vipharm 100 mg potahovane tablety | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |
| Czech Republic             |                                       | Vipharm S.A.          | Erlotinib Vipharm 150 mg potahovane tablety | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| Denmark                    |                                       | Sandoz B.V.           | Erlotinib Sandoz                            | erlotinib               | 25 mg           | Film-coated tablet         | Oral use                       |
| Denmark                    |                                       | Sandoz B.V.           | Erlotinib Sandoz                            | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |

| <b>Member State EU/EEA</b> | <b>Marketing Authorisation Holder</b> | <b>Applicant</b> | <b>Invented name</b>            | <b>Active Substance</b>  | <b>Strength</b>  | <b>Pharmaceutical Form</b> | <b>Route of Administration</b> |
|----------------------------|---------------------------------------|------------------|---------------------------------|--------------------------|------------------|----------------------------|--------------------------------|
| Denmark                    |                                       | Sandoz B.V.      | Erlotinib Sandoz                | erlotinib                | 150 mg           | Film-coated tablet         | Oral use                       |
| Denmark                    | Orifarm Generics A/S                  |                  | Atovaquone/Proguanil Orifarm    | atovaquone/<br>proguanil | 250 mg/<br>100mg | Film-coated tablet         | Oral use                       |
| Denmark                    | ratiopharm GmBH                       |                  | Atovaquone/Proguanil ratiopharm | atovaquone/<br>proguanil | 250 mg/<br>100mg | Film-coated tablet         | Oral use                       |
| Denmark                    | Sandoz A/S                            |                  | Horisto                         | atovaquone/<br>proguanil | 62.5 mg/<br>25mg | Film-coated tablet         | Oral use                       |
| Denmark                    | Sandoz A/S                            |                  | Horisto                         | atovaquone/<br>proguanil | 250 mg/<br>100mg | Film-coated tablet         | Oral use                       |
| Denmark                    | Mylan AB                              |                  | Eletriptan Mylan                | eletriptan               | 40 mg            | Film-coated tablet         | Oral use                       |
| Estonia                    |                                       | Sandoz B.V.      | Erlotinib Sandoz                | erlotinib                | 25 mg            | Film-coated tablet         | Oral use                       |
| Estonia                    |                                       | Sandoz B.V.      | Erlotinib Sandoz                | erlotinib                | 100 mg           | Film-coated tablet         | Oral use                       |
| Estonia                    |                                       | Sandoz B.V.      | Erlotinib Sandoz                | erlotinib                | 150 mg           | Film-coated tablet         | Oral use                       |
| Estonia                    |                                       | Teva B.V.        | ERLOTINIB TEVA GENERICS         | erlotinib                | 100 mg           | Film-coated tablet         | Oral use                       |
| Estonia                    |                                       | Teva B.V.        | ERLOTINIB TEVA GENERICS         | erlotinib                | 150 mg           | Film-coated tablet         | Oral use                       |
| Finland                    | ratiopharm GmbH                       |                  | Atovaquone/Proguanil ratiopharm | atovaquone/<br>proguanil | 250 mg/<br>100mg | Film-coated tablet         | Oral use                       |
| Finland                    | Sandoz A/S                            |                  | Rumbabor                        | atovaquone/<br>proguanil | 62.5 mg/<br>25mg | Film-coated tablet         | Oral use                       |

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|----------------------------|---------------------------------------|------------------|--|--------------------------|------------------|----------------------------|--------------------------------|
| Finland                    | Sandoz A/S                            |                  | Rumbabor                               | atovaquone/<br>proguanil | 250 mg/<br>100mg | Film-coated<br>tablet      | Oral use                       |
| Finland                    | Mylan AB                              |                  | Eletriptan Mylan                       | eletriptan               | 40 mg            | Film-coated<br>tablet      | Oral use                       |
| France                     |                                       | Sandoz B.V.      | Erlotinib Sandoz                       | erlotinib                | 25 mg            | Film-coated<br>tablet      | Oral use                       |
| France                     |                                       | Sandoz B.V.      | Erlotinib Sandoz                       | erlotinib                | 100 mg           | Film-coated<br>tablet      | Oral use                       |
| France                     |                                       | Sandoz B.V.      | Erlotinib Sandoz                       | erlotinib                | 150 mg           | Film-coated<br>tablet      | Oral use                       |
| France                     |                                       | Teva B.V.        | Erlotinib Teva Pharma                  | erlotinib                | 25 mg            | Film-coated<br>tablet      | Oral use                       |
| France                     |                                       | Teva B.V.        | Erlotinib Teva Pharma                  | erlotinib                | 100 mg           | Film-coated<br>tablet      | Oral use                       |
| France                     |                                       | Teva B.V.        | Erlotinib Teva Pharma                  | erlotinib                | 150 mg           | Film-coated<br>tablet      | Oral use                       |
| France                     |                                       | Sandoz B.V.      | SAQUINAVIR SANDOZ                      | saquinavir               | 500 mg           | Film-coated<br>tablet      | Oral use                       |
| France                     |                                       | Medipha Sante    | AMOXICILLINE MEDIPHA<br>1 g            | amoxicillin              | 1 g              | Orodispersible<br>tablet   | Oral use                       |
| France                     | Medipha Sante                         |                  | Amoxicilline Authou                    | amoxicillin              | 1 g              | Orodispersible<br>tablet   | Oral use                       |
| France                     | Sandoz                                |                  | Atovaquone/Proguanil<br>Sandoz ENFANTS | atovaquone/<br>proguanil | 62.5 mg/<br>25mg | Film-coated<br>tablet      | Oral use                       |
| France                     | Sandoz                                |                  | Atovaquone/Proguanil<br>Sandoz         | atovaquone/<br>proguanil | 250 mg/<br>100mg | Film-coated<br>tablet      | Oral use                       |

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|----------------------------|---------------------------------------|------------------|--------------------------------------|--------------------------|------------------|----------------------------|--------------------------------|
| France                     | Teva Sante                            |                  | Atovaquone/Proguanil<br>Teva ENFANTS | atovaquone/<br>proguanil | 62.5 mg/<br>25mg | Film-coated<br>tablet      | Oral use                       |
| France                     | Teva Sante                            |                  | Atovaquone/Proguanil<br>Teva         | atovaquone/<br>proguanil | 250 mg/<br>100mg | Film-coated<br>tablet      | Oral use                       |
| France                     | Venipharm                             |                  | EBACHOI                              | ebastine                 | 10 mg            | Orodispersible<br>tablet   | Oral use                       |
| France                     | Venipharm                             |                  | EBARREN                              | ebastine                 | 10 mg            | Film-coated<br>tablet      | Oral use                       |
| France                     | Biogaran                              |                  | EBASTINE BIOGARAN                    | ebastine                 | 10 mg            | Film-coated<br>tablet      | Oral use                       |
| France                     | Biogaran                              |                  | EBASTINE BIOGARAN                    | ebastine                 | 10 mg            | Orodispersible<br>tablet   | Oral use                       |
| France                     | Mylan SAS                             |                  | EBASTINE MYLAN                       | ebastine                 | 10 mg            | Orodispersible<br>tablet   | Oral use                       |
| France                     | Mylan SAS                             |                  | EBASTINE MYLAN                       | ebastine                 | 10 mg            | Film-coated<br>tablet      | Oral use                       |
| France                     | Sanofi Aventis<br>France              |                  | EBASTINE ZENTIVA                     | ebastine                 | 10 mg            | Film-coated<br>tablet      | Oral use                       |
| France                     | Sanofi Aventis<br>France              |                  | EBASTINE ZENTIVA                     | ebastine                 | 10 mg            | Orodispersible<br>tablet   | Oral use                       |
| France                     | Venipharm                             |                  | EBONDE                               | ebastine                 | 10 mg            | Film-coated<br>tablet      | Oral use                       |
| France                     | Venipharm                             |                  | EBONTAN                              | ebastine                 | 10 mg            | Orodispersible<br>tablet   | Oral use                       |
| France                     | Venipharm                             |                  | EBOUDA                               | ebastine                 | 10 mg            | Film-coated<br>tablet      | Oral use                       |

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|----------------------------|---------------------------------------|---------------------------|--|-------------------------|-----------------|----------------------------|--------------------------------|
| France                     | Mylan SAS                             |                           | Eletriptan Mylan                       | eletriptan              | 20 mg           | Film-coated tablet         | Oral use                       |
| France                     | Mylan SAS                             |                           | Eletriptan Mylan                       | eletriptan              | 40 mg           | Film-coated tablet         | Oral use                       |
| France                     | Medipha Sante                         |                           | Tramadol/Paracétamol Nialex            | tramadol/paracetamol    | 37.5 mg/325mg   | Film-coated tablet         | Oral use                       |
| France                     | Zydus France                          |                           | Tramadol/Paracétamol Zydus France      | tramadol/paracetamol    | 37.5 mg/325mg   | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Pharma Resources GmbH     | Etoricoxib PhaRes 30 mg Filmtabletten  | etoricoxib              | 30 mg           | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Pharma Resources GmbH     | Etoricoxib PhaRes 60 mg Filmtabletten  | etoricoxib              | 60 mg           | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Pharma Resources GmbH     | Etoricoxib PhaRes 90 mg Filmtabletten  | etoricoxib              | 90 mg           | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Pharma Resources GmbH     | Etoricoxib PhaRes 120 mg Filmtabletten | etoricoxib              | 120 mg          | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Bristol Laboratories Ltd. | Celecoxib axcount 100 mg Hartkapseln   | celecoxib               | 100 mg          | Capsule, hard              | Oral use                       |
| Germany                    |                                       | Bristol Laboratories Ltd. | Celecoxib axcount 200 mg Hartkapseln   | celecoxib               | 200 mg          | Capsule, hard              | Oral use                       |
| Germany                    |                                       | Micro Labs GmbH           | Amoxicillin Micro Labs 250 mg          | amoxicillin             | 250 mg          | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Micro Labs GmbH           | Amoxicillin Micro Labs 500 mg          | amoxicillin             | 500 mg          | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Micro Labs GmbH           | Amoxicillin Micro Labs 750 mg          | amoxicillin             | 750 mg          | Film-coated tablet         | Oral use                       |



| Member State EU/EEA | Marketing Authorisation Holder | Applicant          | Invented name  | Active Substance                | Strength        | Pharmaceutical Form | Route of Administration |
|---------------------|--------------------------------|--------------------|--|---------------------------------|-----------------|---------------------|-------------------------|
| Germany             |                                | Micro Labs GmbH    | Amoxicillin Micro Labs 1000 mg   | amoxicillin                     | 1000 mg         | Film-coated tablet  | Oral use                |
| Germany             |                                | Micro Labs GmbH    | Rasagilin Micro Labs 1 mg Tabletten                                      | rasagiline                      | 1 mg            | Film-coated tablet  | Oral use                |
| Germany             |                                | Lupin (Europe) Ltd | Duloxetine-Hormosan 60 mg magensaftresistente Hartkapseln                | duloxetine                      | 60 mg           | Capsule, hard       | Oral use                |
| Germany             |                                | Lupin (Europe) Ltd | Duloxetine-Hormosan 40 mg magensaftresistente Hartkapseln                | duloxetine                      | 40 mg           | Capsule, hard       | Oral use                |
| Germany             |                                | Lupin (Europe) Ltd | Duloxetine-Hormosan 30 mg magensaftresistente Hartkapseln                | duloxetine                      | 30 mg           | Capsule, hard       | Oral use                |
| Germany             |                                | Lupin (Europe) Ltd | Duloxetine-Hormosan 20 mg magensaftresistente Hartkapseln                | duloxetine                      | 20 mg           | Capsule, hard       | Oral use                |
| Germany             |                                | Micro Labs GmbH    | Irbesartan / Hydrochlorothiazide Micro Labs 150 mg/12.5 mg Filmtabletten | irbesartan/ hydrochlorothiazide | 150 mg/ 12.5mg  | Film-coated tablet  | Oral use                |
| Germany             |                                | Micro Labs GmbH    | Irbesartan / Hydrochlorothiazide Micro Labs 300 mg/12.5 mg Filmtabletten | irbesartan/ hydrochlorothiazide | 300 mg/ 12.5 mg | Film-coated tablet  | Oral use                |

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|----------------------------|---------------------------------------|------------------|---|---------------------------------|-----------------|----------------------------|--------------------------------|
| Germany                    |                                       | Micro Labs GmbH  | Irbesartan / Hydrochlorothiazide Micro Labs 300 mg /25 mg Filmtabletten | irbesartan/ hydrochlorothiazide | 300 mg / 25mg   | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Sandoz B.V.      | Erlotinib HEXAL 25 mg Filmtabletten                                     | erlotinib                       | 25 mg           | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Sandoz B.V.      | Erlotinib HEXAL 100 mg Filmtabletten                                    | erlotinib                       | 100 mg          | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Sandoz B.V.      | Erlotinib HEXAL 150 mg Filmtabletten                                    | erlotinib                       | 150 mg          | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Sandoz B.V.      | Erlotinib - 1 A Pharma 25 mg Filmtabletten                              | erlotinib                       | 25 mg           | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Sandoz B.V.      | Erlotinib - 1 A Pharma 100 mg Filmtabletten                             | erlotinib                       | 100 mg          | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Sandoz B.V.      | Erlotinib - 1 A Pharma 150 mg Filmtabletten                             | erlotinib                       | 150 mg          | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Teva B.V.        | Erlotinib-ratiopharm 25 mg Filmtabletten                                | erlotinib                       | 25 mg           | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Teva B.V.        | Erlotinib-ratiopharm 100 mg Filmtabletten                               | erlotinib                       | 100 mg          | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Teva B.V.        | Erlotinib-ratiopharm 150 mg Filmtabletten                               | erlotinib                       | 150 mg          | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Teva B.V.        | Erlotinib-ratiopharm 25 mg Filmtabletten                                | erlotinib                       | 25 mg           | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Teva B.V.        | Erlotinib-ratiopharm 100 mg Filmtabletten                               | erlotinib                       | 100 mg          | Film-coated tablet         | Oral use                       |

| <b>Member State EU/EEA</b> | <b>Marketing Authorisation Holder</b> | <b>Applicant</b> | <b>Invented name</b>   | <b>Active Substance</b> | <b>Strength</b> | <b>Pharmaceutical Form</b> | <b>Route of Administration</b> |
|----------------------------|---------------------------------------|------------------|--|-------------------------|-----------------|----------------------------|--------------------------------|
| Germany                    |                                       | Teva B.V.        | Erlotinib-ratiopharm 150 mg Filmtabletten                                | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Teva B.V.        | Erlotinib-ratiopharm 25 mg Filmtabletten                                 | erlotinib               | 25 mg           | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Teva B.V.        | Erlotinib-ratiopharm 100 mg Filmtabletten                                | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |
| Germany                    |                                       | Teva B.V.        | Erlotinib-ratiopharm 150 mg Filmtabletten                                | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| Germany                    | Hexal Aktiengesellschaft              |                  | Saquinavir HEXAL 500 mg Filmtabletten                                    | saquinavir              | 500 mg          | Film-coated tablet         | Oral use                       |
| Germany                    | ratiopharm GmbH                       |                  | Atovaquon/Proguanilhydrochlorid-ratiopharm 62,5 mg/25 mg Filmtabletten   | atovaquone/proguanil    | 62.5 mg/25mg    | Film-coated tablet         | Oral use                       |
| Germany                    | ratiopharm GmbH                       |                  | Atovaquon/Proguanilhydrochlorid-ratiopharm 250 mg/100 mg Filmtabletten   | atovaquone/proguanil    | 250 mg/100mg    | Film-coated tablet         | Oral use                       |
| Germany                    | 1A Pharma GmbH                        |                  | Atovaquon/Proguanilhydrochlorid - 1 A Pharma 250 mg/100 mg Filmtabletten | atovaquone/proguanil    | 250 mg/100mg    | Film-coated tablet         | Oral use                       |
| Germany                    | 1A Pharma GmbH                        |                  | Atovaquon/Proguanilhydrochlorid - 1 A Pharma 62,5 mg/25 mg Filmtabletten | atovaquone/proguanil    | 62.5 mg/25mg    | Film-coated tablet         | Oral use                       |
| Germany                    | Hexal Aktiengesellschaft              |                  | Malacomp HEXAL   | atovaquone/proguanil    | 250 mg/100mg    | Film-coated tablet         | Oral use                       |
| Germany                    | Hexal Aktiengesellschaft              |                  | Malacomp HEXAL junior  | atovaquone/proguanil    | 62.5 mg/25mg    | Film-coated tablet         | Oral use                       |

| <b>Member State EU/EEA</b> | <b>Marketing Authorisation Holder</b>                 | <b>Applicant</b> | <b>Invented name</b>                   | <b>Active Substance</b> | <b>Strength</b> | <b>Pharmaceutical Form</b> | <b>Route of Administration</b> |
|----------------------------|---|------------------|--|-------------------------|-----------------|----------------------------|--------------------------------|
| Germany                    | Hormosan Pharma Gesellschaft mit beschränkter Haftung |                  | Pregabalin-Hormosan 25 mg Hartkapseln  | pregabalin              | 25 mg           | Capsule, hard              | Oral use                       |
| Germany                    | Aristo Pharma GmbH                                    |                  | Eprosartan Aristo 600 mg Filmtabletten | eprosartan              | 600 mg          | Film-coated tablet         | Oral use                       |
| Germany                    | Glenmark Arzneimittel GmbH                            |                  | Celecoxib Glenmark 200 mg Hartkapseln  | celecoxib               | 200 mg          | Capsule, hard              | Oral use                       |
| Germany                    | Glenmark Arzneimittel GmbH                            |                  | Celecoxib Glenmark 100 mg Hartkapseln  | celecoxib               | 100 mg          | Capsule, hard              | Oral use                       |
| Greece                     |   | Genepharma SA    | ERLOTINIB/GENEPHARM                    | erlotinib               | 25 mg           | Film-coated tablet         | Oral use                       |
| Greece                     |   | Genepharma SA    | ERLOTINIB/GENEPHARM                    | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |
| Greece                     |   | Genepharma SA    | ERLOTINIB/GENEPHARM                    | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| Hungary                    |   | Vipharm S.A.     | ERLOTINIB VIPHARM 100 mg filmtabletta  | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |
| Hungary                    |   | Vipharm S.A.     | ERLOTINIB VIPHARM 150 mg filmtabletta  | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| Hungary                    |   | Vipharm S.A.     | ERLOTINIB VIPHARM 25 mg filmtabletta   | erlotinib               | 25 mg           | Film-coated tablet         | Oral use                       |
| Hungary                    |   | Sandoz B.V.      | ERLOTINIB Sandoz 25 mg filmtabletta    | erlotinib               | 25 mg           | Film-coated tablet         | Oral use                       |

| Member State EU/EEA | Marketing Authorisation Holder | Applicant          | Invented name                          | Active Substance         | Strength         | Pharmaceutical Form | Route of Administration |
|---------------------|--------------------------------|--------------------|--|--------------------------|------------------|---------------------|-------------------------|
| Hungary             |                                | Sandoz B.V.        | ERLOTINIB Sandoz 100 mg filmtabletta   | erlotinib                | 100 mg           | Film-coated tablet  | Oral use                |
| Hungary             |                                | Sandoz B.V.        | ERLOTINIB Sandoz 150 mg filmtabletta   | erlotinib                | 150 mg           | Film-coated tablet  | Oral use                |
| Hungary             |                                | Lupin (Europe) Ltd | Pregabalin Merck 25 mg kemény kapszula | pregabalin               | 25 mg            | Capsule, hard       | Oral use                |
| Iceland             | Lyfis ehf.                     |                    | Celecoxib LYFIS                        | celecoxib                | 100 mg           | Capsule, hard       | Oral use                |
| Iceland             | Lyfis ehf.                     |                    | Celecoxib LYFIS                        | celecoxib                | 200 mg           | Capsule, hard       | Oral use                |
| Ireland             |                                | Sandoz B.V.        | Erlotinib Rowex                        | erlotinib                | 25 mg            | Film-coated tablet  | Oral use                |
| Ireland             |                                | Sandoz B.V.        | Erlotinib Rowex                        | erlotinib                | 100 mg           | Film-coated tablet  | Oral use                |
| Ireland             |                                | Sandoz B.V.        | Erlotinib Rowex                        | erlotinib                | 150 mg           | Film-coated tablet  | Oral use                |
| Italy               |                                | Teva B.V.          | ERLOTINIB TEVA                         | erlotinib                | 25 mg            | Film-coated tablet  | Oral use                |
| Italy               |                                | Teva B.V.          | ERLOTINIB TEVA                         | erlotinib                | 100 mg           | Film-coated tablet  | Oral use                |
| Italy               |                                | Teva B.V.          | ERLOTINIB TEVA                         | erlotinib                | 150 mg           | Film-coated tablet  | Oral use                |
| Italy               |                                | Sandoz B.V.        | ERLOTINIB SANDOZ                       | erlotinib                | 100 mg           | Film-coated tablet  | Oral use                |
| Italy               |                                | Sandoz B.V.        | ERLOTINIB SANDOZ                       | erlotinib                | 150 mg           | Film-coated tablet  | Oral use                |
| Italy               | Sandoz S.p.A.                  |                    | ATOVAQUONE E PROGUANILE SANDOZ         | atovaquone/<br>proguanil | 250 mg/<br>100mg | Film-coated tablet  | Oral use                |

| Member State EU/EEA | Marketing Authorisation Holder | Applicant                                | Invented name                                    | Active Substance         | Strength         | Pharmaceutical Form | Route of Administration |
|---------------------|--------------------------------|--|--|--------------------------|------------------|---------------------|-------------------------|
| Italy               | Sandoz S.p.A.                  |  | ATOVAQUONE E PROGUANILE SANDOZ                   | atovaquone/<br>proguanil | 62.5 mg/<br>25mg | Film-coated tablet  | Oral use                |
| Italy               | Sandoz S.p.A.                  |  | SAQUINAVIR SANDOZ                                | saquinavir               | 500 mg           | Film-coated tablet  | Oral use                |
| Italy               | Mylan S.p.A.                   |  | ELETRIPTAN MYLAN                                 | eletriptan               | 20 mg            | Film-coated tablet  | Oral use                |
| Italy               | Mylan S.p.A.                   |  | ELETRIPTAN MYLAN                                 | eletriptan               | 40 mg            | Film-coated tablet  | Oral use                |
| Latvia              |                                | PharmaSwiss<br>Česká republika<br>s.r.o. | Erlotinib PharmaSwiss 25 mg film-coated tablets  | erlotinib                | 25 mg            | Film-coated tablet  | Oral use                |
| Latvia              |                                | PharmaSwiss<br>Česká republika<br>s.r.o. | Erlotinib PharmaSwiss 100 mg film-coated tablets | erlotinib                | 100 mg           | Film-coated tablet  | Oral use                |
| Latvia              |                                | PharmaSwiss<br>Česká republika<br>s.r.o. | Erlotinib PharmaSwiss 150 mg film-coated tablets | erlotinib                | 150 mg           | Film-coated tablet  | Oral use                |
| Latvia              |                                | Sandoz B.V.                              | Erlotinib Sandoz 25 mg film-coated tablets       | erlotinib                | 25 mg            | Film-coated tablet  | Oral use                |
| Latvia              |                                | Sandoz B.V.                              | Erlotinib Sandoz 100 mg film-coated tablets      | erlotinib                | 100 mg           | Film-coated tablet  | Oral use                |
| Latvia              |                                | Sandoz B.V.                              | Erlotinib Sandoz 150 mg film-coated tablets      | erlotinib                | 150 mg           | Film-coated tablet  | Oral use                |
| Latvia              |                                | Accord Healthcare Ltd                    | Saquinavir Accord 500 mg film-coated tablets     | saquinavir               | 500 mg           | Film-coated tablet  | Oral use                |

| Member State EU/EEA | Marketing Authorisation Holder | Applicant                                | Invented name  | Active Substance                   | Strength           | Pharmaceutical Form | Route of Administration |
|---------------------|--------------------------------|--|--|------------------------------------|--------------------|---------------------|-------------------------|
| Lithuania           |                                | PharmaSwiss<br>Česká republika<br>s.r.o. | Erlotinib PharmaSwiss  | erlotinib                          | 25 mg              | Film-coated tablet  | Oral use                |
| Lithuania           |                                | PharmaSwiss<br>Česká republika<br>s.r.o. | Erlotinib PharmaSwiss  | erlotinib                          | 100 mg             | Film-coated tablet  | Oral use                |
| Lithuania           |                                | PharmaSwiss<br>Česká republika<br>s.r.o. | Erlotinib PharmaSwiss  | erlotinib                          | 150 mg             | Film-coated tablet  | Oral use                |
| Lithuania           |                                | Sandoz B.V.                              | Erlotinib Sandoz   | erlotinib                          | 25 mg              | Film-coated tablet  | Oral use                |
| Lithuania           |                                | Sandoz B.V.                              | Erlotinib Sandoz   | erlotinib                          | 100 mg             | Film-coated tablet  | Oral use                |
| Lithuania           |                                | Sandoz B.V.                              | Erlotinib Sandoz   | erlotinib                          | 150 mg             | Film-coated tablet  | Oral use                |
| Lithuania           |                                | Teva B.V.                                | Erlotinib Teva Generics  | erlotinib                          | 150 mg             | Film-coated tablet  | Oral use                |
| Lithuania           |                                | Accord Healthcare Ltd                    | Saquinavir Accord 500 mg plėvele dengtos tabletės                        | saquinavir                         | 500 mg             | Film-coated tablet  | Oral use                |
| Luxembourg          |                                | Sandoz S.A.                              | Saquinavir   | saquinavir                         | 500 mg             | Film-coated tablet  | Oral use                |
| Luxembourg          |                                | Micro Labs GmbH                          | Irbesartan / Hydrochlorothiazide Micro Labs 150 mg/12.5 mg Filmtabletten | irbesartan/<br>hydrochlorothiazide | 150 mg/<br>12.5 mg | Film-coated tablet  | Oral use                |

| Member State EU/EEA | Marketing Authorisation Holder | Applicant       | Invented name  | Active Substance               | Strength       | Pharmaceutical Form | Route of Administration |
|---------------------|--------------------------------|-----------------|--|--------------------------------|----------------|---------------------|-------------------------|
| Luxembourg          |                                | Micro Labs GmbH | Irbesartan / Hydrochlorothiazide Micro Labs 300 mg/12.5 mg Filmtabletten | irbesartan/hydrochlorothiazide | 300 mg/12.5 mg | Film-coated tablet  | Oral use                |
| Luxembourg          |                                | Micro Labs GmbH | Irbesartan / Hydrochlorothiazide Micro Labs 300 mg /25 mg Filmtabletten  | irbesartan/hydrochlorothiazide | 300 mg / 25mg  | Film-coated tablet  | Oral use                |
| Luxembourg          |                                | Teva B.V.       | Erlotinib-ratiopharm 25 mg Filmtabletten                                 | erlotinib                      | 25 mg          | Film-coated tablet  | Oral use                |
| Luxembourg          |                                | Teva B.V.       | Erlotinib-ratiopharm 100 mg Filmtabletten                                | erlotinib                      | 100 mg         | Film-coated tablet  | Oral use                |
| Luxembourg          |                                | Teva B.V.       | Erlotinib-ratiopharm 150 mg Filmtabletten                                | erlotinib                      | 150 mg         | Film-coated tablet  | Oral use                |
| Luxembourg          |                                | Teva B.V.       | Erlotinib Ratiopharm   | erlotinib                      | 25 mg          | Film-coated tablet  | Oral use                |
| Luxembourg          |                                | Teva B.V.       | Erlotinib Ratiopharm   | erlotinib                      | 100 mg         | Film-coated tablet  | Oral use                |
| Luxembourg          |                                | Teva B.V.       | Erlotinib Ratiopharm   | erlotinib                      | 150 mg         | Film-coated tablet  | Oral use                |
| Luxembourg          |                                | Micro Labs GmbH | Rasagilin Micro Labs 1 mg Tabletten                                      | rasagiline                     | 1 mg           | Film-coated tablet  | Oral use                |
| Luxembourg          | Sandoz S.A.                    |                 | Malaprotec   | atovaquone/proguanil           | 62.5 mg/25mg   | Film-coated tablet  | Oral use                |
| Luxembourg          | Sandoz S.A.                    |                 | Malaprotec   | atovaquone/proguanil           | 250 mg/100mg   | Film-coated tablet  | Oral use                |



| <b>Member State EU/EEA</b> | <b>Marketing Authorisation Holder</b> | <b>Applicant</b> | <b>Invented name</b>   | <b>Active Substance</b> | <b>Strength</b> | <b>Pharmaceutical Form</b> | <b>Route of Administration</b> |
|----------------------------|---------------------------------------|------------------|--|-------------------------|-----------------|----------------------------|--------------------------------|
| Luxembourg                 | ratiopharm GmbH                       |                  | Atovaquon/Proguanilhydrochlorid-ratiopharm 62,5 mg/25 mg Filmtabletten | atovaquone/proguanil    | 62.5 mg/25mg    | Film-coated tablet         | Oral use                       |
| Luxembourg                 | ratiopharm GmbH                       |                  | Atovaquon/Proguanilhydrochlorid-ratiopharm 250 mg/100 mg Filmtabletten | atovaquone/proguanil    | 250 mg/100mg    | Film-coated tablet         | Oral use                       |
| Malta                      | 1A Pharma GmbH                        |                  | Reprapog   | atovaquone/proguanil    | 62.5 mg/25mg    | Film-coated tablet         | Oral use                       |
| Malta                      | 1A Pharma GmbH                        |                  | Reprapog   | atovaquone/proguanil    | 250 mg/100mg    | Film-coated tablet         | Oral use                       |
| Norway                     | Mylan AB                              |                  | Eletriptan Mylan   | eletriptan              | 40 mg           | Film-coated tablet         | Oral use                       |
| Norway                     | Mylan AB                              |                  | Eletriptan Mylan   | eletriptan              | 20 mg           | Film-coated tablet         | Oral use                       |
| Norway                     | Orifarm Generics A/S                  |                  | Atovaquone/Proguanil Orifarm   | atovaquone/proguanil    | 250 mg/100mg    | Film-coated tablet         | Oral use                       |
| Poland                     |                                       | Sandoz B.V.      | Erlotinib Sandoz   | erlotinib               | 25 mg           | Film-coated tablet         | Oral use                       |
| Poland                     |                                       | Sandoz B.V.      | Erlotinib Sandoz   | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |
| Poland                     |                                       | Sandoz B.V.      | Erlotinib Sandoz   | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| Poland                     |                                       | Vipharm S.A.     | Erlotinib Vipharm  | erlotinib               | 25 mg           | Film-coated tablet         | Oral use                       |
| Poland                     |                                       | Vipharm S.A.     | Erlotinib Vipharm  | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |

| <b>Member State EU/EEA</b> | <b>Marketing Authorisation Holder</b> | <b>Applicant</b>                           | <b>Invented name</b> | <b>Active Substance</b> | <b>Strength</b> | <b>Pharmaceutical Form</b> | <b>Route of Administration</b> |
|----------------------------|---------------------------------------|--|----------------------|-------------------------|-----------------|----------------------------|--------------------------------|
| Poland                     |                                       | Vipharm S.A.                               | Erlotinib Vipharm    | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| Poland                     | Sandoz GmbH                           |  | Saquinavir Sandoz    | saquinavir              | 500 mg          | Film-coated tablet         | Oral use                       |
| Portugal                   |                                       | Brown & Burk UK, Ltd.                      | Amoxicilina Brown    | amoxicillin             | 250 mg          | Film-coated tablet         | Oral use                       |
| Portugal                   |                                       | Brown & Burk UK, Ltd.                      | Amoxicilina Brown    | amoxicillin             | 500 mg          | Film-coated tablet         | Oral use                       |
| Portugal                   |                                       | Brown & Burk UK, Ltd.                      | Amoxicilina Brown    | amoxicillin             | 750 mg          | Film-coated tablet         | Oral use                       |
| Portugal                   |                                       | Brown & Burk UK, Ltd.                      | Amoxicilina Brown    | amoxicillin             | 1000 mg         | Film-coated tablet         | Oral use                       |
| Portugal                   |                                       | Teva Pharma - Produtos Farmacêuticos, Lda. | Erlotinib Zidrium    | erlotinib               | 25 mg           | Film-coated tablet         | Oral use                       |
| Portugal                   |                                       | Teva Pharma - Produtos Farmacêuticos, Lda. | Erlotinib Zidrium    | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |
| Portugal                   |                                       | Teva Pharma - Produtos Farmacêuticos, Lda. | Erlotinib Zidrium    | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |

| Member State EU/EEA | Marketing Authorisation Holder             | Applicant                          | Invented name                                    | Active Substance | Strength | Pharmaceutical Form | Route of Administration |
|---------------------|--|------------------------------------|--|------------------|----------|---------------------|-------------------------|
| Portugal            |  | Sandoz B.V.                        | Erlotinib Sandoz                                 | erlotinib        | 25 mg    | Film-coated tablet  | Oral use                |
| Portugal            |  | Sandoz B.V.                        | Erlotinib Sandoz                                 | erlotinib        | 100 mg   | Film-coated tablet  | Oral use                |
| Portugal            |  | Sandoz B.V.                        | Erlotinib Sandoz                                 | erlotinib        | 150 mg   | Film-coated tablet  | Oral use                |
| Portugal            |  | Hetero Europe, S.L.                | Celecoxib Hetero                                 | Celecoxib        | 100 mg   | Capsule, hard       | Oral use                |
| Portugal            |  | Hetero Europe, S.L.                | Celecoxib Hetero                                 | Celecoxib        | 200 mg   | Capsule, hard       | Oral use                |
| Portugal            |  | Lupin (Europe) Ltd                 | Pregabalina Merck                                | Pregabalin       | 25 mg    | Capsule, hard       | Oral use                |
| Portugal            | Hetero Europe, S.L.                        |                                    | Eprosartan Hetero                                | eprosartan       | 600 mg   | Film-coated tablet  | Oral use                |
| Portugal            | Farmoz - Sociedade Técnico Medicinal, S.A. |                                    | Saquinavir Farmoz                                | saquinavir       | 500 mg   | Film-coated tablet  | Oral use                |
| Portugal            | Lupin (Europe) Ltd                         |                                    | Pregabalina Lupin                                | pregabalin       | 25 mg    | Capsule, hard       | Oral use                |
| Romania             |  | PharmaSwiss Česká republika s.r.o. | Erlotinib PharmaSwiss 25 mg film-coated tablets  | erlotinib        | 25 mg    | Film-coated tablet  | Oral use                |
| Romania             |  | PharmaSwiss Česká republika s.r.o. | Erlotinib PharmaSwiss 100 mg film-coated tablets | erlotinib        | 100 mg   | Film-coated tablet  | Oral use                |
| Romania             |  | PharmaSwiss Česká republika s.r.o. | Erlotinib PharmaSwiss 150 mg film-coated tablets | erlotinib        | 150 mg   | Film-coated tablet  | Oral use                |

| <b>Member State EU/EEA</b> | <b>Marketing Authorisation Holder</b> | <b>Applicant</b>                   | <b>Invented name</b>                              | <b>Active Substance</b> | <b>Strength</b> | <b>Pharmaceutical Form</b> | <b>Route of Administration</b> |
|----------------------------|---------------------------------------|------------------------------------|---|-------------------------|-----------------|----------------------------|--------------------------------|
| Romania                    |                                       | Teva B.V.                          | Erlotinib Teva Pharma 25 mg, film coated tablets  | erlotinib               | 25 mg           | Film-coated tablet         | Oral use                       |
| Romania                    |                                       | Teva B.V.                          | Erlotinib Teva Pharma 100 mg, film coated tablets | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |
| Romania                    |                                       | Teva B.V.                          | Erlotinib Teva Pharma 150 mg, film coated tablets | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| Romania                    |                                       | Sandoz B.V.                        | Erlotinib Sandoz 25 mg, film coated tablets       | erlotinib               | 25 mg           | Film-coated tablet         | Oral use                       |
| Romania                    |                                       | Sandoz B.V.                        | Erlotinib Sandoz 100 mg, film coated tablets      | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |
| Romania                    |                                       | Sandoz B.V.                        | Erlotinib Sandoz 150 mg, film coated tablets      | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| Slovakia                   |                                       | Sandoz B.V.                        | Erlotinib Sandoz 100 mg, 150 mg                   | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |
| Slovakia                   |                                       | Sandoz B.V.                        | Erlotinib Sandoz 100 mg, 150 mg                   | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| Slovakia                   |                                       | Vipharm S.A.                       | Erlotinib Vipharm 25 mg, 100 mg, 150 mg           | erlotinib               | 25 mg           | Film-coated tablet         | Oral use                       |
| Slovakia                   |                                       | Vipharm S.A.                       | Erlotinib Vipharm 25 mg, 100 mg, 150 mg           | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |
| Slovakia                   |                                       | Vipharm S.A.                       | Erlotinib Vipharm 25 mg, 100 mg, 150 mg           | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| Slovakia                   |                                       | PharmaSwiss Česká republika s.r.o. | ERLOTIB 25 mg, 100 mg, 150 mg                     | erlotinib               | 25 mg           | Film-coated tablet         | Oral use                       |

| Member State EU/EEA | Marketing Authorisation Holder | Applicant                                | Invented name   | Active Substance | Strength | Pharmaceutical Form   | Route of Administration |
|---------------------|--------------------------------|--|---|------------------|----------|-----------------------|-------------------------|
| Slovakia            |                                | PharmaSwiss<br>Česká republika<br>s.r.o. | ERLOTIB 25 mg, 100 mg,<br>150 mg  | erlotinib        | 100 mg   | Film-coated<br>tablet | Oral use                |
| Slovakia            |                                | PharmaSwiss<br>Česká republika<br>s.r.o. | ERLOTIB 25 mg, 100 mg,<br>150 mg  | erlotinib        | 150 mg   | Film-coated<br>tablet | Oral use                |
| Slovenia            |                                | Sandoz B.V.                              | Erlotinib Sandoz 25 mg<br>filmsko obložene tablete  | erlotinib        | 25 mg    | Film-coated<br>tablet | Oral use                |
| Slovenia            |                                | Sandoz B.V.                              | Erlotinib Sandoz 100 mg<br>filmsko obložene tablete   | erlotinib        | 100 mg   | Film-coated<br>tablet | Oral use                |
| Slovenia            |                                | Sandoz B.V.                              | Erlotinib Sandoz 150 mg<br>filmsko obložene tablete   | erlotinib        | 150 mg   | Film-coated<br>tablet | Oral use                |
| Spain               |                                | Sandoz B.V.                              | Erlotinib Sandoz 25 mg,<br>100 mg and 150 mg<br>comprimidos recubiertos<br>con película EFG | erlotinib        | 25 mg    | Film-coated<br>tablet | Oral use                |
| Spain               |                                | Sandoz B.V.                              | Erlotinib Sandoz 25 mg,<br>100 mg and 150 mg<br>comprimidos recubiertos<br>con película EFG | erlotinib        | 100 mg   | Film-coated<br>tablet | Oral use                |
| Spain               |                                | Sandoz B.V.                              | Erlotinib Sandoz 25 mg,<br>100 mg and 150 mg<br>comprimidos recubiertos<br>con película EFG | erlotinib        | 150 mg   | Film-coated<br>tablet | Oral use                |
| Spain               |                                | Brill Pharma, S.L.                       | Celecoxib Brill Pharma 100<br>mg and 200 mg cápsulas<br>duras                               | celecoxib        | 100 mg   | Capsule, hard         | Oral use                |

| Member State EU/EEA | Marketing Authorisation Holder             | Applicant             | Invented name  | Active Substance     | Strength     | Pharmaceutical Form | Route of Administration |
|---------------------|--|-----------------------|--|----------------------|--------------|---------------------|-------------------------|
| Spain               |  | Brill Pharma, S.L.    | Celecoxib Brill Pharma 100 mg and 200 mg cápsulas duras  | celecoxib            | 200 mg       | Capsule, hard       | Oral use                |
| Spain               |  | Accord Healthcare Ltd | Saquinavir Accord 500 mg comprimidos recubiertos con película EFG                                  | saquinavir           | 500 mg       | Film-coated tablet  | Oral use                |
| Spain               | Teva Pharma, S.L.U.                        |                       | Atovacuona/Hidrocloruro de Proguanil Teva 250 mg/100 mg comprimidos recubiertos con película EFG   | atovaquone/proguanil | 250 mg/100mg | Film-coated tablet  | Oral use                |
| Spain               | Sandoz Farmaceutica, S.A.                  |                       | Atovacuona/Hidrocloruro de Proguanil Sandoz 250 mg/100 mg comprimidos recubiertos con película EFG | atovaquone/proguanil | 250 mg/100mg | Film-coated tablet  | Oral use                |
| Spain               | Pensa Pharma, S.A.U.                       |                       | Eprosartan Pensa 600 mg comprimidos recubiertos con película EFG                                   | eprosartan           | 600 mg       | Film-coated tablet  | Oral use                |
| Spain               | Industria Química Y Farmacéutica VIR, S.A. |                       | Celecoxib VIR 200 mg cápsulas duras EFG  | celecoxib            | 200 mg       | Capsule, hard       | Oral use                |
| Sweden              |  | Sandoz B.V.           | Erlotinib Sandoz   | erlotinib            | 25 mg        | Film-coated tablet  | Oral use                |
| Sweden              |  | Sandoz B.V.           | Erlotinib Sandoz   | erlotinib            | 100 mg       | Film-coated tablet  | Oral use                |

| Member State EU/EEA | Marketing Authorisation Holder | Applicant                          | Invented name                | Active Substance         | Strength         | Pharmaceutical Form | Route of Administration |
|---------------------|--------------------------------|------------------------------------|------------------------------|--------------------------|------------------|---------------------|-------------------------|
| Sweden              |                                | Sandoz B.V.                        | Erlotinib Sandoz             | erlotinib                | 150 mg           | Film-coated tablet  | Oral use                |
| Sweden              | Sandoz A/S                     |                                    | Horisto                      | atovaquone/<br>proguanil | 62.5 mg/<br>25mg | Film-coated tablet  | Oral use                |
| Sweden              | Sandoz A/S                     |                                    | Horisto                      | atovaquone/<br>proguanil | 250 mg/<br>100mg | Film-coated tablet  | Oral use                |
| Sweden              | Mylan AB                       |                                    | Eletriptan Mylan             | eletriptan               | 20 mg            | Film-coated tablet  | Oral use                |
| Sweden              | Mylan AB                       |                                    | Eletriptan Mylan             | eletriptan               | 40 mg            | Film-coated tablet  | Oral use                |
| Sweden              | Orifarm Generics A/S           |                                    | Atovaquone/Proguanil Orifarm | atovaquone/<br>proguanil | 250 mg/<br>100mg | Film-coated tablet  | Oral use                |
| Sweden              | Medical Valley Invest AB       |                                    | Celecoxib Medical Valley     | celecoxib                | 100 mg           | Capsule, hard       | Oral use                |
| Sweden              | Medical Valley Invest AB       |                                    | Celecoxib Medical Valley     | celecoxib                | 200 mg           | Capsule, hard       | Oral use                |
| The Netherlands     |                                | PharmaSwiss Česká republika s.r.o. | ERLOTIB                      | erlotinib                | 25 mg            | Film-coated tablet  | Oral use                |
| The Netherlands     |                                | PharmaSwiss Česká republika s.r.o. | ERLOTIB                      | erlotinib                | 100 mg           | Film-coated tablet  | Oral use                |
| The Netherlands     |                                | PharmaSwiss Česká republika s.r.o. | ERLOTIB                      | erlotinib                | 150 mg           | Film-coated tablet  | Oral use                |
| The Netherlands     |                                | Sandoz B.V.                        | Erlotinib Sandoz             | erlotinib                | 25 mg            | Film-coated tablet  | Oral use                |

| <b>Member State EU/EEA</b> | <b>Marketing Authorisation Holder</b> | <b>Applicant</b>      | <b>Invented name</b>           | <b>Active Substance</b> | <b>Strength</b> | <b>Pharmaceutical Form</b> | <b>Route of Administration</b> |
|----------------------------|---------------------------------------|-----------------------|--------------------------------|-------------------------|-----------------|----------------------------|--------------------------------|
| The Netherlands            |                                       | Sandoz B.V.           | Erlotinib Sandoz               | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |
| The Netherlands            |                                       | Sandoz B.V.           | Erlotinib Sandoz               | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| The Netherlands            |                                       | Sandoz B.V.           | Erlotinib Sandoz               | erlotinib               | 25 mg           | Film-coated tablet         | Oral use                       |
| The Netherlands            |                                       | Sandoz B.V.           | Erlotinib Sandoz               | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |
| The Netherlands            |                                       | Sandoz B.V.           | Erlotinib Sandoz               | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| The Netherlands            |                                       | Accord Healthcare Ltd | Saquinavir Accord              | saquinavir              | 500 mg          | Film-coated tablet         | Oral use                       |
| The Netherlands            |                                       | Teva B.V.             | Erlotinib PCH                  | erlotinib               | 25 mg           | Film-coated tablet         | Oral use                       |
| The Netherlands            |                                       | Teva B.V.             | Erlotinib PCH                  | erlotinib               | 100 mg          | Film-coated tablet         | Oral use                       |
| The Netherlands            |                                       | Teva B.V.             | Erlotinib PCH                  | erlotinib               | 150 mg          | Film-coated tablet         | Oral use                       |
| The Netherlands            | Teva Nederland B.V.                   |                       | Atovaquon/Proguanil HCl Teva   | atovaquone/proguanil    | 250 mg/100mg    | Film-coated tablet         | Oral use                       |
| The Netherlands            | Teva Nederland B.V.                   |                       | Atovaquon/Proguanil HCl Teva   | atovaquone/proguanil    | 62.5 mg/25mg    | Film-coated tablet         | Oral use                       |
| The Netherlands            | Sandoz B.V.                           |                       | Atovaquon/Proguanil HCl Sandoz | atovaquone/proguanil    | 62.5 mg/25mg    | Film-coated tablet         | Oral use                       |
| The Netherlands            | Sandoz B.V.                           |                       | Atovaquon/Proguanil HCl Sandoz | atovaquone/proguanil    | 250 mg/100mg    | Film-coated tablet         | Oral use                       |



| <b>Member State EU/EEA</b> | <b>Marketing Authorisation Holder</b> | <b>Applicant</b>      | <b>Invented name</b>   | <b>Active Substance</b>  | <b>Strength</b>    | <b>Pharmaceutical Form</b> | <b>Route of Administration</b> |
|----------------------------|---------------------------------------|-----------------------|--|--------------------------|--------------------|----------------------------|--------------------------------|
| The Netherlands            | Sandoz B.V.                           |                       | Atovaquon/Proguanil HCl Sandoz   | atovaquone/<br>proguanil | 62.5 mg/<br>25mg   | Film-coated tablet         | Oral use                       |
| The Netherlands            | Sandoz B.V.                           |                       | Atovaquon/Proguanil HCl Sandoz   | atovaquone/<br>proguanil | 250 mg/<br>100mg   | Film-coated tablet         | Oral use                       |
| The Netherlands            | Sandoz B.V.                           |                       | Saquinavir Sandoz  | saquinavir               | 500 mg             | Film-coated tablet         | Oral use                       |
| The Netherlands            | Sandoz B.V.                           |                       | Saquinavir Sandoz  | saquinavir               | 500 mg             | Film-coated tablet         | Oral use                       |
| The Netherlands            | Hetero Europe, S.L.                   |                       | Celecoxib Hetero   | celecoxib                | 100 mg             | Capsule, hard              | Oral use                       |
| The Netherlands            | Hetero Europe, S.L.                   |                       | Celecoxib Hetero   | celecoxib                | 200 mg             | Capsule, hard              | Oral use                       |
| United Kingdom             |                                       | Brown & Burk UK, Ltd. | ROSUVASTATIN 5 MG FILM-COATED TABLETS                                    | rosuvastatin             | 5 mg               | Film-coated tablet         | Oral use                       |
| United Kingdom             |                                       | Brown & Burk UK, Ltd. | ROSUVASTATIN 10MG FILM-COATED TABLETS                                    | rosuvastatin             | 10 mg              | Film-coated tablet         | Oral use                       |
| United Kingdom             |                                       | Brown & Burk UK, Ltd. | ROSUVASTATIN 20 MG FILM-COATED TABLETS                                   | rosuvastatin             | 20 mg              | Film-coated tablet         | Oral use                       |
| United Kingdom             |                                       | Brown & Burk UK, Ltd. | ROSUVASTATIN 40 MG FILM-COATED TABLETS                                   | rosuvastatin             | 40 mg              | Film-coated tablet         | Oral use                       |
| United Kingdom             |                                       | Brown & Burk UK, Ltd. | TRAMADOL / PARACETAMOL BROWN & BURK 37.5 MG / 325 MG FILM-COATED TABLETS | tramadol/<br>paracetamol | 37.5 mg/<br>325 mg | Film-coated tablet         | Oral use                       |

| <b>Member State EU/EEA</b> | <b>Marketing Authorisation Holder</b> | <b>Applicant</b>      | <b>Invented name</b>   | <b>Active Substance</b>        | <b>Strength</b> | <b>Pharmaceutical Form</b> | <b>Route of Administration</b> |
|----------------------------|---------------------------------------|-----------------------|--|--------------------------------|-----------------|----------------------------|--------------------------------|
| United Kingdom             |                                       | Brown & Burk UK, Ltd. | Irbesartan/Hydrochlorothiazide Brown & Burk 150mg/12.5mg Film-coated tablets | irbesartan/hydrochlorothiazide | 150 mg/12.5 mg  | Film-coated tablet         | Oral use                       |
| United Kingdom             |                                       | Brown & Burk UK, Ltd. | Irbesartan/Hydrochlorothiazide Brown & Burk 300mg/12.5mg Film-coated tablets | irbesartan/hydrochlorothiazide | 300 mg/12.5 mg  | Film-coated tablet         | Oral use                       |
| United Kingdom             |                                       | Brown & Burk UK, Ltd. | Irbesartan/Hydrochlorothiazide Brown & Burk 300mg/25mg Film-coated tablets   | irbesartan/hydrochlorothiazide | 300 mg / 25mg   | Film-coated tablet         | Oral use                       |
| United Kingdom             |                                       | Brown & Burk UK, Ltd. | Rasagiline Brown & Burk 1mg Tablets  | rasagiline                     | 1 mg            | Film-coated tablet         | Oral use                       |
| United Kingdom             |                                       | Lupin (Europe) Ltd    | Duloxetine Lupin 20mg GR capsules  | duloxetine                     | 20 mg           | Capsule                    | Oral use                       |
| United Kingdom             |                                       | Lupin (Europe) Ltd    | Duloxetine Lupin 30mg GR capsules  | duloxetine                     | 30 mg           | Capsule                    | Oral use                       |
| United Kingdom             |                                       | Lupin (Europe) Ltd    | Duloxetine Lupin 40mg GR capsules  | duloxetine                     | 40 mg           | Capsule                    | Oral use                       |
| United Kingdom             |                                       | Lupin (Europe) Ltd    | Duloxetine Lupin 60mg GR capsules  | duloxetine                     | 60 mg           | Capsule                    | Oral use                       |
| United Kingdom             | Teva UK Limited                       |                       | MAFAMOZ 250MG/100MG FILM-COATED TABLETS                                      | atovaquone/proguanil           | 250 mg/100mg    | Tablet                     | Oral use                       |
| United Kingdom             | Teva UK Limited                       |                       | MAFAMOZ 62.5MG/25 MG FILM-COATED TABLETS                                     | atovaquone/proguanil           | 62.5 mg/25mg    | Tablet                     | Oral use                       |

| <b>Member State EU/EEA</b> | <b>Marketing Authorisation Holder</b> | <b>Applicant</b> | <b>Invented name</b>   | <b>Active Substance</b>  | <b>Strength</b>  | <b>Pharmaceutical Form</b> | <b>Route of Administration</b> |
|----------------------------|---------------------------------------|------------------|--|--------------------------|------------------|----------------------------|--------------------------------|
| United Kingdom             | Sandoz Limited                        |                  | REPRAPOG 62.5 MG/25 MG FILM-COATED TABLETS                   | atovaquone/<br>proguanil | 62.5 mg/<br>25mg | Film-coated tablet         | Oral use                       |
| United Kingdom             | Sandoz Limited                        |                  | REPRAPOG 250 MG/100 MG FILM-COATED TABLETS                   | atovaquone/<br>proguanil | 250 mg/<br>100mg | Film-coated tablet         | Oral use                       |
| United Kingdom             | Brown & Burk UK Limited               |                  | AMOXICILLIN SUGAR FREE 3G POWDER FOR ORAL SUSPENSION SACHETS | amoxicillin              | 3443.35 mg       | Powder for oral suspension | Oral use                       |
| United Kingdom             | Hetero Europe, S.L.                   |                  | EPROSARTAN 300 MG FILM-COATED TABLETS                        | eprosartan               | 300 mg           | Film-coated tablet         | Oral use                       |
| United Kingdom             | Hetero Europe, S.L.                   |                  | EPROSARTAN 400 MG FILM-COATED TABLETS                        | eprosartan               | 400 mg           | Film-coated tablet         | Oral use                       |
| United Kingdom             | Hetero Europe, S.L.                   |                  | EPROSARTAN 600 MG FILM-COATED TABLETS                        | eprosartan               | 600 mg           | Film-coated tablet         | Oral use                       |
| United Kingdom             | Bristol Laboratories Limited          |                  | CELECOXIB CAPSULES, HARD 100MG                               | celecoxib                | 100 mg           | Capsule, hard              | Oral use                       |
| United Kingdom             | Bristol Laboratories Limited          |                  | CELECOXIB CAPSULES, HARD 200MG                               | celecoxib                | 200 mg           | Capsule, hard              | Oral use                       |
| United Kingdom             | Lupin (Europe) Ltd                    |                  | Pregabalin Lupin 25mg hard capsules                          | pregabalin               | 25 mg            | Capsule, hard              | Oral use                       |