| Status             | Reference  | Report type           | Product                                                  | Countries                                                                                                                    | Reporting<br>period start<br>date | DLP         | Regulatory<br>due date | Submission<br>duration | Product<br>name with<br>formulation<br>in scope | Translation | Local requir<br>ements | Pre-DLP<br>draft | VAP<br>present | VAP type | Sequence                                                          | Sequence<br>order | Created on  | Modified on | Product<br>type | Frequenc              |
|--------------------|------------|-----------------------|----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|-------------|------------------------|------------------------|-------------------------------------------------|-------------|------------------------|------------------|----------------|----------|-------------------------------------------------------------------|-------------------|-------------|-------------|-----------------|-----------------------|
| Under<br>authoring | ASR-000098 | PBRER                 | AMITRIPTY<br>LINE HYDR<br>OCHLORID<br>E                  | Australia                                                                                                                    | 01-May-202<br>5                   | 30-Sep-2025 | 09-Dec-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |          | PBRER-Acic<br>lovir-tablet                                        | 16                | 04-Jul-2025 | 04-Jul-2025 |                 | Annually              |
| Under<br>authoring | ASR-000097 | PBRER                 | 2-PROPANO<br>L                                           | Australia                                                                                                                    | 28-Apr-2025                       | 24-Sep-2025 | 03-Dec-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |          | PBRER-2-P<br>ROPANOL-t<br>ablet                                   | 1                 | 04-Jul-2025 | 04-Jul-2025 |                 | Annually              |
| Draft              | ASR-000096 | Addendum<br>Statement | CABAZITAX<br>EL                                          | China, USA,<br>India                                                                                                         | 18-Nov-2023                       | 17-Nov-2024 |                        | 70                     | CreamGel<br>5mg                                 | Yes         | Yes                    | Yes              | False          |          |                                                                   |                   | 04-Jul-2025 | 01-Jan-0001 |                 |                       |
| Under<br>review    | ASR-000095 | PADER                 | CABAZITAX<br>EL                                          | China, USA,<br>India                                                                                                         | 18-Nov-2023                       | 17-Nov-2024 |                        | 70                     | CreamGel<br>5mg                                 | Yes         | Yes                    | Yes              | False          |          |                                                                   |                   | 04-Jul-2025 | 04-Jul-2025 |                 |                       |
| Draft              | ASR-000094 | PBRER                 | ACETYLSAL<br>ICYLIC ACI<br>D+BUTALBI<br>TAL+CAFFE<br>INE | China, USA,<br>India                                                                                                         | 29-Nov-2023                       | 28-Nov-2024 |                        | 60                     | CreamGel<br>5mg                                 | Yes         | Yes                    | Yes              | False          |          |                                                                   |                   | 04-Jul-2025 | 01-Jan-0001 |                 |                       |
| Under<br>review    | ASR-000093 | PBRER                 | ABACAVIR<br>SULFATE+L<br>AMIVUDINE                       | Argentina,<br>Australia                                                                                                      | 29-Jun-2025                       | 09-Aug-2025 | 07-Nov-2025            | 4                      | 250mg<br>Tablets                                | Yes         | Yes                    | Yes              | True           | Global   | Addendum S<br>tatement-AL<br>FUZOSIN H<br>YDROCHLO<br>RIDE-tablet | 4                 | 04-Jul-2025 | 04-Jul-2025 |                 | More than<br>Annually |
| In<br>submission   | ASR-000092 | PBRER                 | ABACAVIR<br>SULFATE+L<br>AMIVUDINE                       | Argentina,<br>Australia,<br>Bahamas                                                                                          | 29-Jun-2025                       | 09-Aug-2025 | 07-Nov-2025            | 4                      | 250mg<br>Tablets                                | Yes         | Yes                    | Yes              | True           | Global   | Addendum S<br>tatement-AL<br>FUZOSIN H<br>YDROCHLO<br>RIDE-tablet | 3                 | 04-Jul-2025 | 04-Jul-2025 |                 | More than<br>Annually |
| Cancelled          | ASR-000091 | PBRER                 | Abacavir                                                 | Albania,<br>Algeria                                                                                                          | 04-Jul-2025                       | 07-Aug-2025 | 16-Oct-2025            | 3                      | 250mg<br>Tablets                                | No          | Yes                    | Yes              | True           | Global   | 6M SUSAR<br>EUCTD-Aba<br>cavir-ABACA<br>VIR                       | 5                 | 04-Jul-2025 | 04-Jul-2025 |                 | Annually              |
| Draft              | ASR-000090 | PBRER                 | ALBUMIN                                                  | China, USA,<br>India                                                                                                         | 29-Nov-2023                       | 28-Nov-2024 |                        | 90                     | CreamGel<br>5mg                                 | Yes         | Yes                    | Yes              | False          |          |                                                                   |                   | 04-Jul-2025 | 01-Jan-0001 |                 |                       |
| Draft              | ASR-000089 | PBRER                 | ACETIC<br>ACID                                           | Cabo Verde,<br>Colombia,<br>Costa Rica,<br>Kyrgyzstan,<br>Oman,<br>Palestine,<br>Panama,<br>Serbia,<br>Swaziland,<br>Tunisia | 04-Jul-2025                       | 04-Jul-2025 | 12-Sep-2025            | 3                      | Tablet<br>200mg                                 | Yes         | Yes                    | Yes              | True           | Local    | PBRER-Acic<br>lovir-Injectio<br>n                                 | 10                | 04-Jul-2025 | 04-Jul-2025 |                 | Annually              |
| Draft              | ASR-000088 | PBRER                 | ACETIC<br>ACID                                           | Colombia,<br>Kyrgyzstan,<br>Oman,<br>Palestine,<br>Panama,<br>Serbia,<br>Swaziland,<br>Tunisia                               | 04-Jul-2025                       | 04-Jul-2025 | 12-Sep-2025            | 3                      | Tablet<br>200mg                                 | Yes         | Yes                    | Yes              | True           | Local    | PBRER-Acic<br>lovir-Injectio<br>n                                 | 9                 | 04-Jul-2025 | 01-Jan-0001 |                 | Annually              |
| Draft              | ASR-000087 | PBRER                 | ACETIC<br>ACID                                           | Colombia,<br>Kyrgyzstan,<br>Oman,<br>Palestine,<br>Panama,<br>Serbia,<br>Swaziland,<br>Tunisia                               | 04-Jul-2025                       | 04-Jul-2025 | 12-Sep-2025            | 3                      | Tablet<br>200mg                                 | Yes         | Yes                    | Yes              | True           | Local    | PBRER-Acic<br>lovir-Injectio<br>n                                 | 8                 | 04-Jul-2025 | 01-Jan-0001 |                 | Annually              |
| In<br>submission   | ASR-000086 | PBRER                 | ACETIC<br>ACID                                           | Cabo Verde,<br>Colombia,<br>Costa Rica,<br>Kyrgyzstan,                                                                       | 04-Jul-2025                       | 04-Jul-2025 | 12-Sep-2025            | 3                      | Tablet<br>200mg                                 | Yes         | Yes                    | Yes              | True           | Local    | PBRER-Acic<br>lovir-Injectio<br>n                                 | 7                 | 04-Jul-2025 | 04-Jul-2025 |                 | Annually              |
|                    |            |                       |                                                          |                                                                                                                              |                                   |             |                        |                        |                                                 |             |                        |                  |                |          |                                                                   |                   |             |             |                 |                       |

| Status             | Reference  | Report type           | Product                                   | Countries                                                                                         | Reporting<br>period start<br>date | DLP         | Regulatory<br>due date | Submission<br>duration | Product<br>name with<br>formulation<br>in scope | Translation | Local requir<br>ements | Pre-DLP<br>draft | VAP<br>present | VAP type | Sequence                                                                        | Sequence<br>order | Created on  | Modified on | Product<br>type | Frequenc              |
|--------------------|------------|-----------------------|-------------------------------------------|---------------------------------------------------------------------------------------------------|-----------------------------------|-------------|------------------------|------------------------|-------------------------------------------------|-------------|------------------------|------------------|----------------|----------|---------------------------------------------------------------------------------|-------------------|-------------|-------------|-----------------|-----------------------|
|                    |            |                       |                                           | Oman,<br>Palestine,<br>Panama,<br>Serbia,<br>Swaziland,<br>Tunisia                                |                                   |             |                        |                        |                                                 |             |                        |                  |                |          |                                                                                 |                   |             |             |                 |                       |
| Cancelled          | ASR-000085 | PBRER                 | ACETAZOLA<br>MIDE                         | Dominican<br>Republic,<br>Guatemala,<br>Israel,<br>Lebanon,<br>Mauritania,<br>Nigeria,<br>Ukraine | 04-Jul-2025                       | 04-Jul-2025 | 12-Sep-2025            | 3                      | Tablet<br>200mg                                 | Yes         | Yes                    | Yes              | True           | Global   | PADER-Angi<br>omax-tablet                                                       | 6                 | 04-Jul-2025 | 04-Jul-2025 |                 | Annually              |
| Under review       | ASR-000084 | PBRER                 | Aciclovir                                 | Albania                                                                                           | 18-Jul-2025                       | 27-Jul-2025 | 05-Oct-2025            | 25                     | gel                                             | Yes         | Yes                    | Yes              | False          |          | PBRER-Acic<br>lovir-gel                                                         | 2                 | 04-Jul-2025 | 04-Jul-2025 |                 | Annually              |
| Under<br>review    | ASR-000083 | PADER                 | 5-FLUOROU<br>RACIL 5-FL<br>UOROURA<br>CIL | Aruba,<br>Australia                                                                               | 17-Jul-2025                       | 05-Aug-2025 | 03-Nov-2025            | 90                     | Tab 50 mg                                       | No          | Yes                    | Yes              | False          |          | 6M SUSAR<br>EUCTR-5-F<br>LUOROURA<br>CIL 5-FLUO<br>ROURACIL-<br>Tab 50 mg       | 2                 | 04-Jul-2025 | 04-Jul-2025 |                 | More than<br>Annually |
| Under<br>authoring | ASR-000082 | 6M SUSAR<br>EUCTR     | 5-FLUOROU<br>RACIL 5-FL<br>UOROURA<br>CIL | Argentina,<br>Armenia,<br>Aruba                                                                   | 01-Jul-2025                       | 01-Aug-2025 | 31-Aug-2025            | 90                     | Tab 50 mg                                       | Yes         | Yes                    | Yes              | False          |          | 6M SUSAR<br>EUCTR-5-F<br>LUOROURA<br>CIL 5-FLUO<br>ROURACIL-<br>Tab 50 mg       | 1                 | 04-Jul-2025 | 04-Jul-2025 |                 | More than<br>Annually |
| Publishing         | ASR-000081 | PBRER                 | 2-PROPANO<br>L                            | Armenia,<br>Aruba,<br>Australia                                                                   | 01-Jul-2025                       | 23-Jul-2025 | 01-Oct-2025            | 90                     | Tab 50 mg                                       | No          | Yes                    | Yes              | False          |          | PSUR-2,4-D<br>ICHLOROB<br>ENZYL ALC<br>OHOL+AMY<br>LMETACRE<br>SOL-Tab 50<br>mg | 11                | 04-Jul-2025 | 04-Jul-2025 |                 | Annually              |
| In<br>submission   | ASR-000080 | Addendum<br>Statement | 2-PROPANO<br>L                            | Aruba,<br>Australia                                                                               | 23-Jul-2025                       | 09-Aug-2025 | 10-Oct-2025            | 90                     | Tab 50 mg                                       | Yes         | Yes                    | Yes              | False          |          | PSUR-2,4-D<br>ICHLOROB<br>ENZYL ALC<br>OHOL+AMY<br>LMETACRE<br>SOL-Tab 50<br>mg | 10                | 04-Jul-2025 | 04-Jul-2025 |                 | More than<br>Annually |
| Publishing         | ASR-000079 | 6M SUSAR<br>EUCTD     | Abacavir                                  | Aruba,<br>Australia                                                                               | 07-Jul-2025                       | 18-Jul-2025 | 17-Aug-2025            | 83                     | ABACAVIR                                        | Yes         | Yes                    | Yes              | True           | Global   | 6M SUSAR<br>EUCTD-Aba<br>cavir-ABACA<br>VIR                                     | 4                 | 04-Jul-2025 | 04-Jul-2025 |                 | Annually              |
| Under<br>authoring | ASR-000078 | PBRER                 | 2-PROPANO<br>L                            | Armenia,<br>Aruba,<br>Australia                                                                   | 01-Jul-2025                       | 23-Jul-2025 | 01-Oct-2025            | 90                     | Tab 50 mg                                       | No          | Yes                    | Yes              | False          |          | PSUR-2,4-D<br>ICHLOROB<br>ENZYL ALC<br>OHOL+AMY<br>LMETACRE<br>SOL-Tab 50<br>mg | 9                 | 04-Jul-2025 | 04-Jul-2025 |                 | Annually              |
| Under<br>authoring | ASR-000077 | PBRER                 | 2-PROPANO<br>L                            | Armenia,<br>Aruba,<br>Australia                                                                   | 01-Jul-2025                       | 23-Jul-2025 | 01-Oct-2025            | 90                     | Tab 50 mg                                       | No          | Yes                    | Yes              | False          |          | PSUR-2,4-D<br>ICHLOROB<br>ENZYL ALC<br>OHOL+AMY<br>LMETACRE<br>SOL-Tab 50<br>mg | 8                 | 04-Jul-2025 | 04-Jul-2025 |                 | Annually              |
| Under<br>review    | ASR-000076 | PBRER                 | 2-PROPANO<br>L                            | Armenia,<br>Aruba,<br>Australia                                                                   | 01-Jul-2025                       | 23-Jul-2025 | 01-Oct-2025            | 90                     | Tab 50 mg                                       | No          | Yes                    | Yes              | False          |          | PSUR-2,4-D<br>ICHLOROB<br>ENZYL ALC<br>OHOL+AMY<br>LMETACRE                     | 7                 | 04-Jul-2025 | 04-Jul-2025 |                 | Annually              |

| Status             | Reference  | Report type           | Product            | Countries                       | Reporting<br>period start<br>date | DLP         | Regulatory<br>due date | Submission<br>duration | Product<br>name with<br>formulation<br>in scope | Translation | Local requir<br>ements | Pre-DLP<br>draft | VAP<br>present | VAP type            | Sequence                                                                        | Sequence<br>order | Created on  | Modified on | Product<br>type | Frequenc              |
|--------------------|------------|-----------------------|--------------------|---------------------------------|-----------------------------------|-------------|------------------------|------------------------|-------------------------------------------------|-------------|------------------------|------------------|----------------|---------------------|---------------------------------------------------------------------------------|-------------------|-------------|-------------|-----------------|-----------------------|
|                    |            |                       |                    |                                 |                                   |             |                        |                        |                                                 |             |                        |                  |                |                     | SOL-Tab 50<br>mg                                                                |                   |             |             |                 |                       |
| Under<br>review    | ASR-000075 | Addendum<br>Statement | 2-PROPANO<br>L     | Armenia,<br>Aruba,<br>Australia | 09-Jul-2025                       | 30-Jul-2025 | 28-Sep-2025            | 90                     | Tab 50 mg                                       | No          | Yes                    | Yes              | False          |                     | PSUR-2,4-D<br>ICHLOROB<br>ENZYL ALC<br>OHOL+AMY<br>LMETACRE<br>SOL-Tab 50<br>mg | 6                 | 04-Jul-2025 | 04-Jul-2025 |                 | More than<br>Annually |
| Under<br>review    | ASR-000074 | PBRER                 | 2-PROPANO<br>L     | Armenia,<br>Aruba,<br>Australia | 01-Jul-2025                       | 23-Jul-2025 | 01-Oct-2025            | 90                     | Tab 50 mg                                       | No          | Yes                    | Yes              | False          |                     | PSUR-2,4-D<br>ICHLOROB<br>ENZYL ALC<br>OHOL+AMY<br>LMETACRE<br>SOL-Tab 50<br>mg | 5                 | 04-Jul-2025 | 04-Jul-2025 |                 | Annually              |
| Draft              | ASR-000073 | Addendum<br>Statement | 2-PROPANO<br>L     | Armenia,<br>Aruba,<br>Australia | 09-Jul-2025                       | 30-Jul-2025 | 28-Sep-2025            | 90                     | Tab 50 mg                                       | No          | Yes                    | Yes              | False          |                     | PSUR-2,4-D<br>ICHLOROB<br>ENZYL ALC<br>OHOL+AMY<br>LMETACRE<br>SOL-Tab 50<br>mg | 4                 | 04-Jul-2025 | 01-Jan-0001 |                 | More than<br>Annually |
| Under<br>authoring | ASR-000072 | PBRER                 | 2-PROPANO<br>L     | Armenia,<br>Aruba,<br>Australia | 01-Jul-2025                       | 23-Jul-2025 | 01-Oct-2025            | 90                     | Tab 50 mg                                       | No          | Yes                    | Yes              | False          |                     | PSUR-2,4-D<br>ICHLOROB<br>ENZYL ALC<br>OHOL+AMY<br>LMETACRE<br>SOL-Tab 50<br>mg | 3                 | 04-Jul-2025 | 04-Jul-2025 |                 | Annually              |
| Draft              | ASR-000071 | PBRER                 | 5-FLUOROU<br>RACIL | Armenia,<br>Aruba               | 16-Jul-2025                       | 23-Jul-2025 | 01-Oct-2025            | 90                     | Tab 50 mg                                       | Yes         | Yes                    | No               | True           | Local               | PSUR-2,4-D<br>ICHLOROB<br>ENZYL ALC<br>OHOL+AMY<br>LMETACRE<br>SOL-Tab 50<br>mg | 2                 | 04-Jul-2025 | 01-Jan-0001 |                 | Annually              |
| Under<br>review    | ASR-000070 | PBRER                 |                    | Armenia,<br>Aruba,              | 16-Jul-2025                       | 05-Aug-2025 | 03-Nov-2025            | 90                     | Tab 50 mg                                       | No          | No                     | Yes              | True           | Local               | PSUR-2,4-D<br>ICHLOROB<br>ENZYL ALC<br>OHOL+AMY<br>LMETACRE<br>SOL-Tab 50<br>mg | 1                 | 04-Jul-2025 | 04-Jul-2025 |                 | More than<br>Annually |
| Under<br>authoring | ASR-000069 | PBRER                 | Aciclovir          | Australia                       | 02-Jul-2025                       | 23-Jul-2025 | 01-Oct-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |                     | PBRER-Acic<br>lovir-tablet                                                      | 15                | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Draft              | ASR-000068 | PBRER                 | Aciclovir          | Albania                         | 09-Jun-2025                       | 24-Jul-2025 | 02-Oct-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |                     | PBRER-Acic<br>lovir-tablet                                                      | 14                | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Under<br>authoring | ASR-000067 | PBRER                 | Aciclovir          | Australia                       | 02-Jul-2025                       | 23-Jul-2025 | 01-Oct-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |                     | PBRER-Acic<br>lovir-tablet                                                      | 13                | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Under authoring    | ASR-000066 | PBRER                 | Aciclovir          | Albania                         | 09-Jul-2025                       | 29-Jul-2025 | 07-Oct-2025            | 21                     | gel                                             | Yes         | Yes                    | Yes              | True           | Global              | PBRER-Acic<br>lovir-gel                                                         | 1                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Under authoring    | ASR-000065 | Addendum<br>Statement | Aciclovir          | Australia                       | 01-Jul-2025                       | 25-Sep-2025 | 24-Nov-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |                     | PBRER-Acic<br>lovir-tablet                                                      | 12                | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Under authoring    | ASR-000064 | Addendum<br>Statement | Aciclovir          | Armenia                         | 28-Jul-2025                       | 08-Aug-2025 | 07-Oct-2025            | 723                    | Injection                                       | No          | No                     | No               | False          |                     | Addendum S<br>tatement-Aci<br>clovir-Injecti<br>on                              | 1                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Under<br>authoring | ASR-000063 | Addendum<br>Statement | Aciclovir          | Argentina                       | 07-Jul-2025                       | 31-Jul-2025 | 29-Sep-2025            | 71                     | CABAZITAX<br>EL                                 | Yes         | Yes                    | Yes              | True           | Global and<br>Local | Addendum S<br>tatement-Aci<br>clovir-CABA                                       | 3                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |

| S | Status             | Reference  | Report type           | Product                                                  | Countries                                                                                                             | Reporting<br>period start<br>date | DLP         | Regulatory<br>due date | Submission<br>duration | Product<br>name with<br>formulation<br>in scope | Translation | Local requir<br>ements | Pre-DLP<br>draft | VAP<br>present | VAP type            | Sequence                                                                          | Sequence<br>order | Created on  | Modified on | Product<br>type | Frequenc              |
|---|--------------------|------------|-----------------------|----------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------|-------------|------------------------|------------------------|-------------------------------------------------|-------------|------------------------|------------------|----------------|---------------------|-----------------------------------------------------------------------------------|-------------------|-------------|-------------|-----------------|-----------------------|
|   |                    |            |                       |                                                          |                                                                                                                       |                                   |             |                        |                        |                                                 |             |                        |                  |                |                     | ZITAXEL                                                                           |                   |             |             |                 |                       |
|   | Jnder<br>uthoring  | ASR-000062 | Simplified<br>PADER   | 5-FLUOROU<br>RACIL 5-FL<br>UOROURA<br>CIL                | USA                                                                                                                   | 14-Jul-2025                       | 31-Jul-2025 | 29-Sep-2025            | 82                     | ETANERCE<br>PT                                  | Yes         | No                     | No               | True           | Global and<br>Local | Simplified PA<br>DER-5-FLU<br>OROURACI<br>L 5-FLUOR<br>OURACIL-E<br>TANERCEP<br>T | 4                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
|   | Jnder<br>authoring | ASR-000061 | 6M SUSAR<br>EUCTD     | Abacavir                                                 | Australia                                                                                                             | 07-Jul-2025                       | 18-Jul-2025 | 17-Aug-2025            | 83                     | ABACAVIR                                        | Yes         | Yes                    | Yes              | True           | Global              | 6M SUSAR<br>EUCTD-Aba<br>cavir-ABACA<br>VIR                                       | 3                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
|   | Jnder<br>authoring | ASR-000060 | PADER                 | PEMETREX<br>ED                                           | United<br>States                                                                                                      | 07-Jul-2025                       | 30-Jul-2025 | 08-Oct-2025            | 122                    | Angiomax                                        | Yes         | Yes                    | Yes              | True           | Global              | PADER-PEM<br>ETREXED-A<br>ngiomax                                                 | 4                 | 03-Jul-2025 | 03-Jul-2025 |                 | Half-Yearly           |
|   | Under<br>outhoring | ASR-000059 | 6M SUSAR<br>EUCTR     | ABACAVIR<br>SULFATE                                      | Austria                                                                                                               | 15-Jul-2025                       | 29-Jul-2025 | 28-Aug-2025            | 92                     | ETANERCE<br>PT                                  | Yes         | Yes                    | Yes              | True           | Global              | 6M SUSAR<br>EUCTR-ABA<br>CAVIR SUL<br>FATE-ETAN<br>ERCEPT                         | 2                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
|   | Jnder<br>uthoring  | ASR-000058 | PBRER                 | 5-FLUOROU<br>RACIL                                       | Armenia,<br>Aruba,<br>Australia,<br>Burkina<br>Faso,<br>Democratic<br>Republic of<br>the Congo,<br>Congo,<br>Djibouti | 13-Jul-2025                       | 01-Aug-2025 | 30-Oct-2025            | 6                      | Tab 50 mg                                       | No          | No                     | No               | False          |                     | PBRER-5-FL<br>UOROURA<br>CIL-Tab 50<br>mg                                         | 3                 | 03-Jul-2025 | 03-Jul-2025 |                 | More than<br>Annually |
|   | Jnder<br>uthoring  | ASR-000057 | 6M SUSAR<br>EUCTD     | Abacavir                                                 | Australia                                                                                                             | 07-Jul-2025                       | 18-Jul-2025 | 17-Aug-2025            | 83                     | ABACAVIR                                        | Yes         | Yes                    | Yes              | True           | Global              | 6M SUSAR<br>EUCTD-Aba<br>cavir-ABACA<br>VIR                                       | 2                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
|   | Jnder<br>uthoring  | ASR-000056 | Simplified<br>PADER   | 5-FLUOROU<br>RACIL 5-FL<br>UOROURA<br>CIL                | USA                                                                                                                   | 14-Jul-2025                       | 31-Jul-2025 | 29-Sep-2025            | 82                     | ETANERCE<br>PT                                  | Yes         | No                     | No               | True           | Global and<br>Local | Simplified PA<br>DER-5-FLU<br>OROURACI<br>L 5-FLUOR<br>OURACIL-E<br>TANERCEP<br>T | 3                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
|   | Jnder<br>authoring | ASR-000055 | PADER                 | PEMETREX<br>ED                                           | United<br>States                                                                                                      | 07-Jul-2025                       | 30-Jul-2025 | 08-Oct-2025            | 122                    | Angiomax                                        | Yes         | Yes                    | Yes              | True           | Global              | PADER-PEM<br>ETREXED-A<br>ngiomax                                                 | 3                 | 03-Jul-2025 | 03-Jul-2025 |                 | Half-Yearly           |
| S | Scheduled          | ASR-000054 | PBRER                 | Aciclovir                                                | Albania                                                                                                               | 09-Jun-2025                       | 24-Jul-2025 | 02-Oct-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |                     | PBRER-Acic<br>lovir-tablet                                                        | 11                | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
|   | Under<br>outhoring | ASR-000053 | Addendum<br>Statement | Aciclovir                                                | Argentina                                                                                                             | 07-Jul-2025                       | 31-Jul-2025 | 29-Sep-2025            | 71                     | CABAZITAX<br>EL                                 | Yes         | Yes                    | Yes              | True           | Global and<br>Local | Addendum S<br>tatement-Aci<br>clovir-CABA<br>ZITAXEL                              | 2                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
|   | Under<br>authoring | ASR-000052 | Addendum<br>Statement | Aciclovir                                                | Argentina                                                                                                             | 07-Jul-2025                       | 31-Jul-2025 | 29-Sep-2025            | 71                     | CABAZITAX<br>EL                                 | Yes         | Yes                    | Yes              | True           | Global and<br>Local | Addendum S<br>tatement-Aci<br>clovir-CABA<br>ZITAXEL                              | 1                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| S | Scheduled          | ASR-000051 | PBRER                 | Aciclovir                                                | Australia                                                                                                             | 01-Jul-2025                       | 31-Aug-2025 | 09-Nov-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |                     | PBRER-Acic<br>lovir-tablet                                                        | 10                | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| S | Scheduled          | ASR-000050 | PBRER                 | 2,4-DICHLO<br>ROBENZYL<br>ALCOHOL+<br>AMYLMETA<br>CRESOL | Armenia,<br>Aruba,<br>Angola                                                                                          | 02-Jul-2025                       | 17-Jul-2025 | 25-Sep-2025            | 5                      | 250mg<br>Tablets                                | Yes         | Yes                    | Yes              | True           | Global              | PBRER-Acic<br>lovir-250mg<br>Tablets                                              | 2                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| 4 |                    |            |                       |                                                          |                                                                                                                       |                                   |             |                        |                        |                                                 |             |                        |                  |                |                     |                                                                                   |                   |             |             |                 | ,                     |

| Status             | Doforence  | Papart turns      | Broduct                                                  | Countries                                                                                                             | Donartina                   | DI B        | Dogulatem              | Subminsis              | Droduct                                         | Translation | l cool resuit          | Bro DI B         | VAR            | VAD tures | Saguenee                                  | Soguenes          | Crosted or  | Modified    | Droduct         | Eromone               |
|--------------------|------------|-------------------|----------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|-----------------------------|-------------|------------------------|------------------------|-------------------------------------------------|-------------|------------------------|------------------|----------------|-----------|-------------------------------------------|-------------------|-------------|-------------|-----------------|-----------------------|
| Status             | Reference  | Report type       | Product                                                  | Countries                                                                                                             | Reporting period start date | DLP         | Regulatory<br>due date | Submission<br>duration | Product<br>name with<br>formulation<br>in scope | Translation | Local requir<br>ements | Pre-DLP<br>draft | VAP<br>present | VAP type  | Sequence                                  | Sequence<br>order | Created on  | Modified on | Product<br>type | Frequenc              |
| Under<br>authoring | ASR-000049 | PBRER             | Aciclovir                                                | Albania                                                                                                               | 09-Jun-2025                 | 24-Jul-2025 | 02-Oct-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |           | PBRER-Acic<br>lovir-tablet                | 9                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Under authoring    | ASR-000048 | PBRER             | Aciclovir                                                | Albania                                                                                                               | 09-Jun-2025                 | 24-Jul-2025 | 02-Oct-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |           | PBRER-Acic<br>lovir-tablet                | 8                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Scheduled          | ASR-000047 | PBRER             | ACETYLCY<br>STEINE                                       | Australia                                                                                                             | 01-May-202<br>5             | 30-Sep-2025 | 09-Dec-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |           | PADER-Angi<br>omax-tablet                 | 5                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Under authoring    | ASR-000046 | PBRER             | ACETYLCY<br>STEINE                                       | Australia                                                                                                             | 01-May-202<br>5             | 30-Sep-2025 | 09-Dec-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |           | PADER-Angi<br>omax-tablet                 | 4                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Under<br>authoring | ASR-000045 | 6M SUSAR<br>EUCTD | 2,4-DICHLO<br>ROBENZYL<br>ALCOHOL+<br>AMYLMETA<br>CRESOL | Argentina,<br>Armenia,<br>Aruba,<br>Canada,<br>Angola                                                                 | 16-Jul-2025                 | 22-Jul-2025 | 21-Aug-2025            | 90                     | Tab 50 mg                                       | No          | No                     | Yes              | True           | Local     | PBRER-5-FL<br>UOROURA<br>CIL-Tab 50<br>mg | 2                 | 03-Jul-2025 | 03-Jul-2025 |                 | More than<br>Annually |
| Scheduled          | ASR-000044 | PBRER             | 5-FLUOROU<br>RACIL                                       | Armenia,<br>Aruba,<br>Australia,<br>Burkina<br>Faso,<br>Democratic<br>Republic of<br>the Congo,<br>Congo,<br>Djibouti | 13-Jul-2025                 | 01-Aug-2025 | 30-Oct-2025            | 6                      | Tab 50 mg                                       | No          | No                     | No               | False          |           | PBRER-5-FL<br>UOROURA<br>CIL-Tab 50<br>mg | 1                 | 03-Jul-2025 | 03-Jul-2025 |                 | More than<br>Annually |
| Under<br>authoring | ASR-000043 | PBRER             | ACETYLCY<br>STEINE                                       | Australia                                                                                                             | 01-May-202<br>5             | 30-Sep-2025 | 09-Dec-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |           | PADER-Angi<br>omax-tablet                 | 3                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Scheduled          | ASR-000042 | PBRER             | ACETIC<br>ACID                                           | Aruba, Denmark, Djibouti, Greece, Liberia, Moldova, Pakistan, Senegal, Syrian Arab Republic, Cote D'ivoire            | 02-Jul-2025                 | 02-Jul-2025 | 10-Sep-2025            | 4                      | Tablet<br>200mg                                 | Yes         | Yes                    | Yes              | True           | Global    | PBRER-Acic<br>lovir-Injectio<br>n         | 6                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Draft              | ASR-000041 | PBRER             | ACETIC<br>ACID                                           | Aruba, Denmark, Djibouti, Greece, Liberia, Moldova, Pakistan, Senegal, Syrian Arab Republic, Cote D'ivoire            | 02-Jul-2025                 | 02-Jul-2025 | 10-Sep-2025            | 4                      | Tablet<br>200mg                                 | Yes         | Yes                    | Yes              | True           | Global    | PBRER-Acic<br>lovir-Injectio<br>n         | 5                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Scheduled          | ASR-000040 | PADER             | 5-FLUOROU<br>RACIL                                       | Argentina,<br>Armenia,<br>Burkina<br>Faso,<br>Algeria,<br>Angola                                                      | 14-Jul-2025                 | 14-Jul-2025 | 13-Aug-2025            | 90                     | Tab 50 mg                                       | No          | Yes                    | Yes              | True           | Local     | PADER-2-P<br>ROPANOL-T<br>ab 50 mg        |                   | 03-Jul-2025 | 03-Jul-2025 |                 | Quarterly             |
| Draft              | ASR-000039 | PBRER             | PEMBROLIZ<br>UMAB                                        | China, USA,<br>India                                                                                                  | 29-Nov-2023                 | 28-Nov-2024 |                        | 60                     | CreamGel<br>5mg                                 | Yes         | Yes                    | Yes              | False          |           |                                           |                   | 03-Jul-2025 | 01-Jan-0001 |                 |                       |
| In<br>submission   | ASR-000038 | PBRER             | ACETIC<br>ACID                                           | Aruba, Denmark, Djibouti, Greece, Liberia, Moldova, Pakistan, Senegal, Syrian Arab                                    | 02-Jul-2025                 | 02-Jul-2025 | 10-Sep-2025            | 4                      | Tablet<br>200mg                                 | Yes         | Yes                    | Yes              | True           | Global    | PBRER-Acic<br>lovir-Injectio<br>n         | 4                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |

|   | Status             | Reference  | Report type       | Product                    | Countries                                                                                                  | Reporting<br>period start<br>date | DLP         | Regulatory<br>due date | Submission<br>duration | Product<br>name with<br>formulation<br>in scope | Translation | Local requir<br>ements | Pre-DLP<br>draft | VAP<br>present | VAP type            | Sequence                                                  | Sequence<br>order | Created on  | Modified on | Product<br>type | Frequenc              |
|---|--------------------|------------|-------------------|----------------------------|------------------------------------------------------------------------------------------------------------|-----------------------------------|-------------|------------------------|------------------------|-------------------------------------------------|-------------|------------------------|------------------|----------------|---------------------|-----------------------------------------------------------|-------------------|-------------|-------------|-----------------|-----------------------|
|   |                    |            |                   |                            | Republic,<br>Cote D'ivoire                                                                                 |                                   |             |                        |                        |                                                 |             |                        |                  |                |                     |                                                           |                   |             |             |                 |                       |
|   | Under<br>authoring | ASR-000037 | PADER             | 2-PROPANO<br>L             | Armenia,<br>Aruba,<br>Burkina<br>Faso                                                                      | 01-Aug-2025                       | 08-Aug-2025 | 20-Nov-2025            | 90                     | Tab 50 mg                                       | No          | Yes                    | No               | True           | Global              | PADER-2-P<br>ROPANOL-T<br>ab 50 mg                        | 4                 | 03-Jul-2025 | 03-Jul-2025 |                 | More than<br>Annually |
|   | Draft              | ASR-000036 | PADER             | 2-PROPANO<br>L             | Armenia,<br>Aruba                                                                                          | 30-Jul-2025                       | 08-Aug-2025 | 06-Nov-2025            | 90                     | Tab 50 mg                                       | No          | No                     | Yes              | True           | Global              | PADER-2-P<br>ROPANOL-T<br>ab 50 mg                        | 3                 | 03-Jul-2025 | 01-Jan-0001 |                 | More than<br>Annually |
|   | In<br>submission   | ASR-000035 | PBRER             | ACETIC<br>ACID             | Aruba, Denmark, Djibouti, Greece, Liberia, Moldova, Pakistan, Senegal, Syrian Arab Republic, Cote D'ivoire | 02-Jul-2025                       | 02-Jul-2025 | 10-Sep-2025            | 4                      | Tablet<br>200mg                                 | Yes         | Yes                    | Yes              | True           | Global              | PBRER-Acic<br>lovir-Injectio<br>n                         | 3                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
|   | Cancelled          | ASR-000034 | PADER             | 2-PROPANO<br>L             | Armenia,<br>Aruba                                                                                          | 30-Jul-2025                       | 08-Aug-2025 | 06-Nov-2025            | 90                     | Tab 50 mg                                       | No          | No                     | Yes              | True           | Global              | PADER-2-P<br>ROPANOL-T<br>ab 50 mg                        | 2                 | 03-Jul-2025 | 03-Jul-2025 |                 | More than<br>Annually |
|   | Cancelled          | ASR-000033 | PBRER             | ACETIC<br>ACID             | Cyprus,<br>Gambia,<br>Kuwait,<br>Cario                                                                     | 03-Jul-2025                       | 03-Jul-2025 | 01-Oct-2025            | 3                      | Tablet<br>200mg                                 | No          | Yes                    | Yes              | True           | Global              | PBRER-Acic<br>lovir-Injectio<br>n                         | 2                 | 03-Jul-2025 | 03-Jul-2025 |                 | More than<br>Annually |
|   | Publishing         | ASR-000032 | PBRER             | Aciclovir                  | Albania                                                                                                    | 09-Jun-2025                       | 24-Jul-2025 | 02-Oct-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |                     | PBRER-Acic<br>lovir-tablet                                | 7                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
|   | Draft              | ASR-000031 | PADER             | 2-PROPANO<br>L             | Armenia,<br>Aruba                                                                                          | 30-Jul-2025                       | 08-Aug-2025 | 06-Nov-2025            | 90                     | Tab 50 mg                                       | No          | No                     | Yes              | True           | Global              | PADER-2-P<br>ROPANOL-T<br>ab 50 mg                        | 1                 | 03-Jul-2025 | 01-Jan-0001 |                 | More than<br>Annually |
|   | Under<br>authoring | ASR-000030 | PBRER             | Aciclovir                  | Argentina                                                                                                  | 14-Jul-2025                       | 31-Jul-2025 | 29-Oct-2025            | 82                     | Injection                                       | Yes         | Yes                    | Yes              | True           | Global and<br>Local | PBRER-Acic<br>lovir-Injectio<br>n                         | 1                 | 03-Jul-2025 | 03-Jul-2025 |                 | More than<br>Annually |
|   | Under authoring    | ASR-000029 | PBRER             | Aciclovir                  | Australia                                                                                                  | 01-May-202<br>5                   | 31-Aug-2025 | 09-Nov-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |                     | PBRER-Acic<br>lovir-tablet                                | 6                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
|   | Under authoring    | ASR-000028 | PBRER             | Aciclovir                  | Australia                                                                                                  | 01-Jul-2025                       | 21-Aug-2025 | 30-Oct-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |                     | PBRER-Acic<br>lovir-tablet                                | 5                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
|   | Scheduled          | ASR-000027 | PBRER             | 2-PROPANO<br>L             | Argentina,<br>Angola                                                                                       | 01-Jul-2025                       | 24-Jul-2025 | 02-Oct-2025            | 90                     | Tab 50 mg                                       | Yes         | Yes                    | Yes              | False          |                     | PBRER-2-P<br>ROPANOL-T<br>ab 50 mg                        |                   | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
|   | Draft              | ASR-000026 | PBRER             | 2-PROPANO<br>L             | Albania,<br>Algeria,<br>Angola                                                                             | 17-Jul-2025                       | 01-Aug-2025 | 10-Oct-2025            | 90                     | Tab 50 mg                                       | No          | No                     | No               | True           | Global              | PBRER-2-P<br>ROPANOL-T<br>ab 50 mg                        |                   | 03-Jul-2025 | 01-Jan-0001 |                 | Annually              |
|   | Duplicate          | ASR-000025 | PBRER             | CABAZITAX<br>EL            | China, USA,<br>India                                                                                       | 18-Nov-2023                       | 17-Nov-2024 |                        | 70                     | CreamGel<br>5mg                                 | Yes         | Yes                    | Yes              | False          |                     |                                                           |                   | 03-Jul-2025 | 03-Jul-2025 |                 |                       |
|   | Publishing         | ASR-000024 | PBRER             | AMLODIPIN<br>E<br>BESYLATE | Australia                                                                                                  | 01-Jul-2025                       | 22-Aug-2025 | 31-Oct-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |                     | PBRER-AML<br>ODIPINE BE<br>SYLATE-tabl<br>et              | 3                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
|   | Under<br>authoring | ASR-000023 | 6M SUSAR<br>EUCTR | ABACAVIR<br>SULFATE        | Austria                                                                                                    | 15-Jul-2025                       | 29-Jul-2025 | 28-Aug-2025            | 92                     | ETANERCE<br>PT                                  | Yes         | Yes                    | Yes              | True           | Global              | 6M SUSAR<br>EUCTR-ABA<br>CAVIR SUL<br>FATE-ETAN<br>ERCEPT | 1                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
|   | Publishing         | ASR-000022 | PBRER             | AMLODIPIN                  | Australia                                                                                                  | 01-Jul-2025                       | 22-Aug-2025 | 31-Oct-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |                     | PBRER-AML                                                 | 2                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| 4 |                    |            |                   |                            |                                                                                                            |                                   |             |                        |                        |                                                 |             |                        |                  |                |                     |                                                           |                   |             |             |                 |                       |

| Status             | Reference  | Report type           | Product                                      | Countries        | Reporting<br>period start<br>date | DLP         | Regulatory<br>due date | Submission<br>duration | Product<br>name with<br>formulation<br>in scope | Translation | Local requir<br>ements | Pre-DLP<br>draft | VAP<br>present | VAP type            | Sequence                                                                                | Sequence<br>order | Created on  | Modified on | Product<br>type | Frequenc              |
|--------------------|------------|-----------------------|----------------------------------------------|------------------|-----------------------------------|-------------|------------------------|------------------------|-------------------------------------------------|-------------|------------------------|------------------|----------------|---------------------|-----------------------------------------------------------------------------------------|-------------------|-------------|-------------|-----------------|-----------------------|
|                    |            |                       | E<br>BESYLATE                                |                  |                                   |             |                        |                        |                                                 |             |                        |                  |                |                     | ODIPINE BE<br>SYLATE-tabl<br>et                                                         |                   |             |             |                 |                       |
| Under authoring    | ASR-000021 | PADER                 | Angiomax                                     | United<br>States | 02-Jul-2025                       | 03-Jul-2025 | 01-Sep-2025            | 1                      | 250mg<br>Tablets                                | Yes         | Yes                    | Yes              | True           | Global              | PADER-Angi<br>omax-tablet                                                               | 2                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Under authoring    | ASR-000020 | PBRER                 | AZATHIOPR<br>INE                             | Azerbaijan       | 29-Apr-2025                       | 25-Sep-2025 | 04-Dec-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |                     | PBRER-Acic<br>lovir-tablet                                                              | 4                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Under<br>authoring | ASR-000019 | PBRER                 | AMLODIPIN<br>E<br>BESYLATE                   | Australia        | 01-Jul-2025                       | 31-Aug-2025 | 09-Nov-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |                     | PBRER-Acic<br>lovir-tablet                                                              | 3                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Under<br>authoring | ASR-000018 | Simplified<br>PADER   | 5-FLUOROU<br>RACIL 5-FL<br>UOROURA<br>CIL    | USA              | 14-Jul-2025                       | 31-Jul-2025 | 29-Sep-2025            | 82                     | ETANERCE<br>PT                                  | Yes         | No                     | No               | True           | Global and<br>Local | Simplified PA<br>DER-5-FLU<br>OROURACI<br>L 5-FLUOR<br>OURACIL-E<br>TANERCEP<br>T       | 2                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Under<br>authoring | ASR-000017 | Addendum<br>Statement | ABACAVIR+<br>DOLUTEGR<br>AVIR+LAMI<br>VUDINE | Bahamas          | 08-Jul-2025                       | 30-Jul-2025 | 28-Sep-2025            | 163                    | CABAZITAX<br>EL                                 | Yes         | Yes                    | Yes              | True           | Global              | Addendum S<br>tatement-AB<br>ACAVIR+DO<br>LUTEGRAVI<br>R+LAMIVUD<br>INE-CABAZI<br>TAXEL | 1                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Under authoring    | ASR-000016 | PADER                 | PEMETREX<br>ED                               | United<br>States | 07-Jul-2025                       | 30-Jul-2025 | 08-Oct-2025            | 122                    | Angiomax                                        | Yes         | Yes                    | Yes              | True           | Global              | PADER-PEM<br>ETREXED-A<br>ngiomax                                                       | 2                 | 03-Jul-2025 | 03-Jul-2025 |                 | Half-Yearly           |
| Publishing         | ASR-000015 | PADER                 | PEMETREX<br>ED                               | United<br>States | 07-Jul-2025                       | 30-Jul-2025 | 08-Oct-2025            | 122                    | Angiomax                                        | Yes         | Yes                    | Yes              | True           | Global              | PADER-PEM<br>ETREXED-A<br>ngiomax                                                       | 1                 | 03-Jul-2025 | 03-Jul-2025 |                 | Half-Yearly           |
| Under authoring    | ASR-000014 | ACO                   | 2-PROPANO<br>L                               | Aruba            | 06-Jul-2025                       | 29-Jul-2025 | 27-Sep-2025            | 15                     | Injection                                       | No          | No                     | No               | False          |                     | ACO-2-PRO<br>PANOL-Injec<br>tion                                                        | 1                 | 03-Jul-2025 | 03-Jul-2025 |                 | More than<br>Annually |
| In<br>submission   | ASR-000013 | Simplified<br>PADER   | 5-FLUOROU<br>RACIL 5-FL<br>UOROURA<br>CIL    | USA              | 14-Jul-2025                       | 31-Jul-2025 | 29-Sep-2025            | 82                     | ETANERCE<br>PT                                  | Yes         | No                     | No               | True           | Global and<br>Local | Simplified PA<br>DER-5-FLU<br>OROURACI<br>L 5-FLUOR<br>OURACIL-E<br>TANERCEP<br>T       | 1                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Completed          | ASR-000012 | 6M SUSAR<br>EUCTR     | ABACAVIR<br>SULFATE                          | Guatemala        | 16-Jul-2025                       | 08-Aug-2025 | 07-Sep-2025            | 71                     | DICHLORO<br>BENZYL                              | Yes         | No                     | No               | False          |                     | 6M SUSAR<br>EUCTR-ABA<br>CAVIR SUL<br>FATE-DICHL<br>OROBENZY<br>L                       | 1                 | 03-Jul-2025 | 03-Jul-2025 |                 | Quarterly             |
| In<br>submission   | ASR-000011 | 6M SUSAR<br>EUCTD     | Abacavir                                     | Australia        | 07-Jul-2025                       | 18-Jul-2025 | 17-Aug-2025            | 83                     | ABACAVIR                                        | Yes         | Yes                    | Yes              | True           | Global              | 6M SUSAR<br>EUCTD-Aba<br>cavir-ABACA<br>VIR                                             | 1                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Under<br>authoring | ASR-000010 | PBRER                 | AMLODIPIN<br>E<br>BESYLATE                   | Australia        | 01-May-202<br>5                   | 23-Oct-2025 | 01-Jan-2026            | 90                     | tablet                                          | No          | No                     | No               | False          |                     | Addendum S<br>tatement-AL<br>FUZOSIN H<br>YDROCHLO<br>RIDE-tablet                       | 2                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |
| Under<br>authoring | ASR-00009  | Addendum<br>Statement | ALFUZOSIN<br>HYDROCHL<br>ORIDE               | Australia        | 01-Jul-2025                       | 18-Sep-2025 | 17-Nov-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |                     | Addendum S<br>tatement-AL<br>FUZOSIN H<br>YDROCHLO<br>RIDE-tablet                       | 1                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually              |

| Status             | Reference | Report type       | Product                                                  | Countries                                    | Reporting<br>period start<br>date | DLP         | Regulatory<br>due date | Submission<br>duration | Product<br>name with<br>formulation<br>in scope | Translation | Local requir<br>ements | Pre-DLP<br>draft | VAP<br>present | VAP type | Sequence                                                                                     | Sequence<br>order | Created on  | Modified on | Product<br>type | Frequenc |
|--------------------|-----------|-------------------|----------------------------------------------------------|----------------------------------------------|-----------------------------------|-------------|------------------------|------------------------|-------------------------------------------------|-------------|------------------------|------------------|----------------|----------|----------------------------------------------------------------------------------------------|-------------------|-------------|-------------|-----------------|----------|
| Under authoring    | ASR-00008 | PADER             | Angiomax                                                 | Armenia                                      | 02-May-202<br>5                   | 02-Oct-2025 | 01-Dec-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |          | PADER-Angi<br>omax-tablet                                                                    | 1                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually |
| Under<br>authoring | ASR-00007 | Simplified PADER  | Angiomax                                                 | Australia                                    | 01-Jul-2025                       | 19-Sep-2025 | 18-Nov-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |          | Simplified PA<br>DER-Angiom<br>ax-tablet                                                     | 2                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually |
| Under<br>authoring | ASR-00006 | Simplified PADER  | Angiomax                                                 | Australia                                    | 01-Jul-2025                       | 19-Sep-2025 | 18-Nov-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |          | Simplified PA<br>DER-Angiom<br>ax-tablet                                                     | 1                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually |
| In<br>submission   | ASR-00005 | 6M SUSAR<br>EUCTR | Aciclovir                                                | Aruba                                        | 13-May-202<br>5                   | 14-Aug-2025 | 13-Sep-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |          | PBRER-Acic<br>lovir-tablet                                                                   | 2                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually |
| Under<br>review    | ASR-00004 | 6M SUSAR<br>EUCTD | 2,4-DICHLO<br>ROBENZYL<br>ALCOHOL+<br>AMYLMETA<br>CRESOL | Argentina,<br>Armenia,<br>Aruba              | 14-Jul-2025                       | 21-Jul-2025 | 20-Aug-2025            | 90                     | Tab 50 mg                                       | No          | No                     | Yes              | False          |          | 6M SUSAR<br>EUCTD-2,4-<br>DICHLORO<br>BENZYL AL<br>COHOL+AM<br>YLMETACR<br>ESOL-Tab<br>50 mg | 1                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually |
| Under<br>authoring | ASR-00003 | PBRER             | AMLODIPIN<br>E<br>BESYLATE                               | Australia                                    | 01-May-202<br>5                   | 14-Oct-2025 | 23-Dec-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |          | PBRER-AML<br>ODIPINE BE<br>SYLATE-tabl<br>et                                                 | 1                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually |
| Under authoring    | ASR-00002 | PBRER             | Aciclovir                                                | Australia                                    | 30-Jun-2025                       | 28-Aug-2025 | 06-Nov-2025            | 90                     | tablet                                          | No          | No                     | No               | False          |          | PBRER-Acic<br>lovir-tablet                                                                   | 1                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually |
| Under<br>authoring | ASR-00001 | PBRER             | Aciclovir                                                | Albania,<br>Argentina,<br>Algeria,<br>Angola | 02-Jul-2025                       | 23-Jul-2025 | 01-Oct-2025            | 3                      | 250mg<br>Tablets                                | Yes         | Yes                    | Yes              | True           | Global   | PBRER-Acic<br>lovir-250mg<br>Tablets                                                         | 1                 | 03-Jul-2025 | 03-Jul-2025 |                 | Annually |