

## **Australian HIV Observational Database (AHOD) data request**

Requested by: Industry

Reason for request: The purpose of the data is to support a submission to the Pharmaceutical Benefits Advisory Committee (PBAC) and the Medical Services Advisory Committee (MSAC) requesting the extension of the PBS restriction of a currently listed antiretroviral to include earlier treatment stages of HIV-1 , and funding of a corresponding genetic test.

Inclusion criteria: People receiving anti retroviral therapy (ART) at or after 1 January 2006

Report definitions:

Treatment cycle: ART of more than 14 days duration. Periods off treatment of less than 14 days are considered to be continued treatment using Intention to treat principles.

Background:

This report is based on all patients in AHOD having received ART between 1 January 2006 and 31 March 2011. At the time of this report 3,378 patients had been recruited to AHOD ever and 2076 patients were under active follow up.

Patient characteristics at the later date of first treatment and 1 January 2006 are described (Table 1).

The distribution of patient treatment cycle numbers as defined above, at the later date of first treatment and 1 January 2006 is described (Table 2).

The distribution of all treatment cycles observed between 1 January 2006 and 31 March 2011 by duration of cycle and treatment number is described (Table 3). This possibly includes multiple cycles per patient. Periods off treatment following a given cycle number are also summarized.

The 20 most frequently used regimens between 1 January 2006 and 31 March 2011 are also listed by treatment cycle number.

Results in this report are based on and subject to the limitations of AHOD data. AHOD data reflects the experience of patients receiving routine care. Although current recruitment is of HIV positive patients who are treatment naive or recently treated, AHOD remains a highly treatment experienced cohort. Standard quality assurance procedures are implemented across all participating AHOD sites.

Table 1: Patient characteristics at later of first treatment or 1 January 2006

|                            | <b>N=2,275</b> | <b>(%)</b> |
|----------------------------|----------------|------------|
| <b>Age</b>                 |                |            |
| 10-19                      | 1              | (0)        |
| 20-29                      | 87             | (4)        |
| 30-39                      | 518            | (23)       |
| 40-49                      | 884            | (39)       |
| 50-59                      | 549            | (24)       |
| 60-69                      | 198            | (9)        |
| 70-79                      | 36             | (2)        |
| 80-89                      | 2              | (0)        |
| <b>Gender</b>              |                |            |
| Female                     | 131            | (6)        |
| Male                       | 2144           | (94)       |
| <b>CD4</b>                 |                |            |
| <350                       | 670            | (29)       |
| 350-499                    | 473            | (21)       |
| ≥500                       | 855            | (38)       |
| ≥501                       | 277            | (12)       |
| <b>Viral Load</b>          |                |            |
| 0-200                      | 1170           | (51)       |
| 201-400                    | 165            | (7)        |
| 401-1000                   | 46             | (2)        |
| 1001-10000                 | 134            | (6)        |
| >10000                     | 346            | (15)       |
| Missing                    | 414            | (18)       |
| <b>Year First Positive</b> |                |            |
| 1980-1984                  | 109            | (5)        |
| 1985-1989                  | 443            | (19)       |
| 1990-1994                  | 519            | (23)       |
| 1995-1999                  | 502            | (22)       |
| 2000-2004                  | 312            | (14)       |
| 2005-2010                  | 284            | (12)       |
| Missing                    | 106            | (5)        |
| <b>Year of First cART</b>  |                |            |
| <1996                      | 107            | (5)        |
| 1996-1999                  | 1128           | (50)       |
| 2000-2003                  | 305            | (13)       |
| ≥2004                      | 691            | (30)       |
| Missing                    | 44             | (2)        |

Table 2 Patient treatment cycle<sup>1</sup> number at later of first treatment or 1 January 2006

|                     | <b>N=2,275</b> | <b>(%)</b> |
|---------------------|----------------|------------|
| <b>Cycle number</b> |                |            |
| 1                   | 763            | (34)       |
| 2                   | 204            | (9)        |
| 3                   | 219            | (10)       |
| 4                   | 199            | (9)        |
| 5                   | 153            | (7)        |
| 6                   | 126            | (6)        |
| 7                   | 118            | (5)        |
| 8                   | 104            | (5)        |
| 9                   | 96             | (4)        |
| 10                  | 57             | (3)        |
| 11                  | 55             | (2)        |
| 12                  | 41             | (2)        |
| 13                  | 40             | (2)        |
| 14                  | 21             | (1)        |
| 15                  | 17             | (1)        |
| 16+                 | 62             | (3)        |

1. Treatment cycle is time spent on one regimen of ART for all regimens greater than 14 days duration. Time off treatment of less than 14 days is considered to be continued treatment.

Table 3 Treatment cycle numbers by duration for all treatment cycles from 1 January 2006 until 31 March 2011<sup>1</sup>

| Duration<br>(weeks)  | Cycle number |            |            |            |            |            |            |            |            |            |            |            |            |           |           |            | Total       |
|----------------------|--------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|-----------|-----------|------------|-------------|
|                      | 1            | 2          | 3          | 4          | 5          | 6          | 7          | 8          | 9          | 10         | 11         | 12         | 13         | 14        | 15        | 16+        |             |
| 2.01-                | 22           | 18         | 9          | 8          | 10         | 8          | 15         | 6          | 7          | 9          | 4          | 6          | 4          | 1         | 1         | 16         | 144         |
| 4.01-                | 23           | 17         | 12         | 18         | 13         | 6          | 9          | 10         | 5          | 8          | 7          | 6          | 4          | 2         | 2         | 19         | 161         |
| 6.01-                | 16           | 13         | 18         | 20         | 12         | 12         | 6          | 11         | 8          | 3          | 6          | 4          | 6          | 7         | 1         | 8          | 151         |
| 8.01-                | 11           | 17         | 13         | 10         | 11         | 6          | 8          | 5          | 4          | 5          | 6          | 5          | 4          | 3         | 3         | 5          | 116         |
| 10.01-               | 33           | 32         | 31         | 20         | 22         | 18         | 20         | 23         | 16         | 7          | 10         | 13         | 6          | 11        | 5         | 13         | 280         |
| 15.01-               | 38           | 30         | 25         | 22         | 16         | 10         | 21         | 14         | 9          | 14         | 7          | 4          | 8          | 8         | 7         | 17         | 250         |
| 20.01-               | 25           | 22         | 22         | 28         | 15         | 21         | 16         | 19         | 10         | 13         | 5          | 9          | 5          | 3         | 9         | 19         | 241         |
| 25.01-               | 25           | 22         | 17         | 24         | 14         | 16         | 8          | 16         | 11         | 6          | 10         | 5          | 5          | 2         | 5         | 20         | 206         |
| 30.01-               | 76           | 28         | 40         | 23         | 19         | 19         | 13         | 17         | 17         | 13         | 9          | 9          | 3          | 8         | 4         | 24         | 322         |
| 40.01-               | 37           | 28         | 31         | 25         | 18         | 17         | 17         | 8          | 18         | 12         | 6          | 14         | 6          | 3         | 7         | 12         | 259         |
| 50.01-               | 44           | 48         | 34         | 11         | 18         | 14         | 17         | 14         | 13         | 15         | 5          | 6          | 6          | 2         | 4         | 11         | 262         |
| 60.01-               | 29           | 41         | 24         | 23         | 14         | 11         | 5          | 6          | 13         | 8          | 8          | 6          | 6          | 4         | 3         | 20         | 221         |
| 70.01-               | 36           | 15         | 22         | 17         | 22         | 14         | 12         | 7          | 7          | 7          | 10         | 3          | 9          | 4         | 5         | 12         | 202         |
| 80.01-               | 28           | 14         | 11         | 11         | 13         | 8          | 11         | 6          | 8          | 6          | 2          | 1          | 5          | 0         | 0         | 8          | 132         |
| 90.01-               | 29           | 15         | 10         | 12         | 18         | 15         | 5          | 5          | 5          | 5          | 8          | 4          | 4          | 5         | 3         | 12         | 155         |
| 100.01-              | 57           | 35         | 25         | 33         | 32         | 29         | 18         | 21         | 16         | 11         | 11         | 13         | 11         | 4         | 2         | 14         | 332         |
| 120.01-              | 39           | 34         | 26         | 26         | 22         | 22         | 18         | 12         | 19         | 16         | 9          | 6          | 10         | 6         | 3         | 17         | 285         |
| 140.01-              | 40           | 30         | 33         | 33         | 17         | 17         | 16         | 13         | 13         | 10         | 9          | 5          | 3          | 4         | 3         | 10         | 256         |
| 160.01-              | 31           | 20         | 9          | 27         | 15         | 13         | 8          | 7          | 7          | 6          | 7          | 8          | 9          | 4         | 3         | 5          | 179         |
| 180.01-              | 24           | 24         | 17         | 17         | 10         | 10         | 12         | 8          | 7          | 8          | 5          | 6          | 5          | 5         | 2         | 10         | 170         |
| 200.01-              | 38           | 44         | 35         | 28         | 25         | 18         | 21         | 8          | 14         | 12         | 9          | 5          | 5          | 4         | 3         | 18         | 287         |
| 240.01-280           | 62           | 69         | 75         | 75         | 74         | 47         | 40         | 36         | 36         | 17         | 23         | 11         | 11         | 3         | 2         | 14         | 595         |
| <b>Total</b>         | <b>763</b>   | <b>616</b> | <b>539</b> | <b>511</b> | <b>430</b> | <b>351</b> | <b>316</b> | <b>272</b> | <b>263</b> | <b>211</b> | <b>176</b> | <b>149</b> | <b>135</b> | <b>93</b> | <b>77</b> | <b>304</b> | <b>5206</b> |
| Median (days)        | 503          | 471.5      | 456        | 601        | 589.5      | 582        | 499        | 380        | 492        | 421        | 519.5      | 328        | 524        | 306       | 310       | 346        | 486         |
| LQ                   | 204          | 184.5      | 183        | 180        | 197        | 186        | 135.5      | 136        | 198        | 158        | 171        | 132        | 162        | 104       | 141       | 137.5      | 169         |
| UQ                   | 992          | 1126.5     | 1133       | 1212       | 1311       | 1131       | 1135       | 1017       | 1110       | 982        | 1118       | 945        | 964        | 903       | 654       | 817.5      | 1080        |
| <b>Off treatment</b> | <b>102</b>   | <b>71</b>  | <b>65</b>  | <b>38</b>  | <b>33</b>  | <b>38</b>  | <b>28</b>  | <b>25</b>  | <b>26</b>  | <b>24</b>  | <b>17</b>  | <b>19</b>  | <b>14</b>  | <b>9</b>  | <b>10</b> | <b>28</b>  | <b>547</b>  |
| Median (days)        | 524.5        | 410        | 286        | 315.5      | 139        | 225.5      | 133.5      | 138        | 123.5      | 134.5      | 129        | 86         | 104.5      | 101       | 64        | 86.5       | 204         |
| LQ                   | 159          | 159        | 119        | 119        | 63         | 68         | 54         | 91         | 38         | 57.5       | 42         | 38         | 75         | 63        | 32        | 43         | 77          |
| UQ                   | 1055         | 954        | 726        | 860        | 324        | 525        | 366.5      | 303        | 243        | 368.5      | 306        | 207        | 168        | 243       | 154       | 117        | 590         |

2. Treatment cycles are for patients on ART after 1 Jan 1996 in AHOD. Includes multiple cycles per patient. Regimens are truncated at 1 Jan 2006 if prior and at 31Mar2011 if after.
3. Treatment cycle is time spent on one regimen of ART for regimens of >14 days duration.
4. Median duration in days (lower quartile – upper quartile)
5. Off treatment if not receiving ART for more than 14 days after specified cycle number.

Table 4 Treatment cycle numbers by twenty most frequent treatment combinations for all treatment cycles from 1 January 2006 until 31 March 2011<sup>1</sup>

| Regimen                                      | 1          | 2          | 3          | 4          | 5          | 6          | 7          | 8          | 9          | 10         | 11         | 12         | 13         | 14        | 15        | 16+        | Total       |
|--|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|-----------|-----------|------------|-------------|
| Truvada-Efavirenz                            | 108        | 55         | 22         | 21         | 10         | 6          | 5          | 8          | 4          | 2          | 1          | 0          | 1          | 0         | 0         | 0          | 243         |
| Truvada-Nevirapine                           | 47         | 32         | 34         | 23         | 21         | 16         | 12         | 13         | 7          | 6          | 4          | 1          | 1          | 0         | 0         | 0          | 217         |
| Truvada-Atazanavir-Ritonavir                 | 23         | 23         | 14         | 21         | 13         | 17         | 11         | 10         | 15         | 6          | 6          | 8          | 3          | 2         | 1         | 6          | 179         |
| Kivexa-Nevirapine                            | 27         | 36         | 19         | 27         | 17         | 16         | 6          | 7          | 4          | 5          | 2          | 3          | 2          | 1         | 0         | 0          | 172         |
| Atripla                                      | 39         | 50         | 30         | 14         | 7          | 2          | 2          | 2          | 5          | 1          | 0          | 1          | 0          | 0         | 0         | 0          | 153         |
| Abacavir-Lamivudine-Nevirapine               | 11         | 27         | 21         | 27         | 14         | 11         | 10         | 10         | 9          | 4          | 1          | 0          | 1          | 0         | 0         | 1          | 147         |
| Combivir-Nevirapine                          | 49         | 23         | 16         | 14         | 13         | 4          | 2          | 2          | 0          | 1          | 1          | 1          | 0          | 0         | 0         | 0          | 126         |
| Kivexa-Efavirenz                             | 27         | 21         | 11         | 17         | 6          | 5          | 6          | 1          | 4          | 1          | 2          | 0          | 1          | 1         | 0         | 1          | 104         |
| Truvada-Kaletra                              | 23         | 10         | 8          | 8          | 8          | 6          | 7          | 5          | 2          | 3          | 4          | 0          | 4          | 2         | 1         | 5          | 96          |
| Emtricitabine-Efavirenz-Tenofovir            | 43         | 10         | 12         | 8          | 2          | 1          | 2          | 2          | 2          | 2          | 1          | 1          | 2          | 1         | 1         | 0          | 90          |
| Lamivudine-Nevirapine-Tenofovir              | 2          | 14         | 14         | 15         | 11         | 5          | 10         | 2          | 6          | 1          | 1          | 0          | 1          | 0         | 0         | 0          | 82          |
| Kivexa-Atazanavir-Ritonavir                  | 4          | 8          | 9          | 9          | 8          | 4          | 9          | 8          | 5          | 2          | 6          | 2          | 0          | 0         | 0         | 2          | 76          |
| Lamivudine-Efavirenz-Tenofovir               | 17         | 7          | 18         | 6          | 5          | 5          | 5          | 3          | 3          | 0          | 0          | 0          | 0          | 2         | 0         | 3          | 74          |
| Combivir-Efavirenz                           | 34         | 27         | 6          | 4          | 1          | 0          | 0          | 0          | 0          | 0          | 1          | 0          | 0          | 0         | 0         | 0          | 73          |
| Emtricitabine-Atazanavir-Ritonavir-Tenofovir | 14         | 9          | 5          | 3          | 4          | 8          | 6          | 3          | 3          | 2          | 4          | 1          | 1          | 2         | 1         | 5          | 71          |
| Trizivir                                     | 12         | 12         | 21         | 6          | 2          | 3          | 1          | 1          | 1          | 1          | 0          | 0          | 1          | 0         | 1         | 0          | 62          |
| Lamivudine-Atazanavir-Ritonavir-Tenofovir    | 1          | 4          | 6          | 7          | 6          | 5          | 6          | 5          | 4          | 6          | 2          | 1          | 0          | 0         | 4         | 4          | 61          |
| Abacavir-Lamivudine-Efavirenz                | 7          | 7          | 6          | 8          | 6          | 7          | 3          | 1          | 5          | 0          | 1          | 0          | 1          | 1         | 0         | 1          | 54          |
| Truvada-Raltegravir                          | 17         | 8          | 7          | 3          | 1          | 2          | 1          | 1          | 1          | 1          | 0          | 1          | 0          | 2         | 0         | 2          | 47          |
| Lamivudine-Kaletra-Tenofovir                 | 2          | 3          | 2          | 5          | 4          | 4          | 0          | 3          | 6          | 2          | 2          | 4          | 2          | 4         | 0         | 1          | 44          |
| All Others                                   | 256        | 230        | 258        | 265        | 271        | 224        | 212        | 185        | 177        | 165        | 137        | 125        | 114        | 75        | 68        | 273        | 3035        |
| <b>Total</b>                                 | <b>763</b> | <b>616</b> | <b>539</b> | <b>511</b> | <b>430</b> | <b>351</b> | <b>316</b> | <b>272</b> | <b>263</b> | <b>211</b> | <b>176</b> | <b>149</b> | <b>135</b> | <b>93</b> | <b>77</b> | <b>304</b> | <b>5206</b> |
| Off Treatment                                | 102        | 71         | 65         | 38         | 33         | 38         | 28         | 25         | 26         | 24         | 17         | 19         | 14         | 9         | 10        | 28         | 547         |

1. Treatment cycles are for patients on ART after 1 Jan 1996 in AHOD. Includes multiple cycles per patient. Regimens truncated at 1 Jan 2006 if prior and at 31Mar2011 if after.
2. Includes combination ARVs
3. Treatment cycle is time spent on one regimen of ART for regimens of >14 days duration.