

### **List of Approved Biosimilars (DCA 349 – 1<sup>st</sup> Oct 2020)**

| No. | Active Substance              | Product Name                                                            | Registration No. | Product Registration Holder               | Manufacturer                            | Reference Product         |
|-----|-------------------------------|-------------------------------------------------------------------------|------------------|-------------------------------------------|-----------------------------------------|---------------------------|
| 1.  | Adalimumab                    | AMGEVITA 40 mg/0.8 ml solution for injection in pre-filled syringe      | MAL19056101AZ    | ZUELLIG PHARMA SDN BHD                    | AMGEN MANUFACTURING, LTD, UNITED STATES | Humira (Abbvie)           |
| 2.  | Adalimumab                    | AMGEVITA 20 mg/0.4 ml solution for injection in pre-filled syringe      | MAL19056100AZ    | ZUELLIG PHARMA SDN BHD                    | AMGEN MANUFACTURING, LTD, UNITED STATES | Humira (Abbvie)           |
| 3.  | Adalimumab                    | AMGEVITA 40 mg/0.8 ml solution for injection in pre-filled autoinjector | MAL19056105AZ    | ZUELLIG PHARMA SDN BHD                    | AMGEN MANUFACTURING, LTD, UNITED STATES | Humira (Abbvie)           |
| 4.  | Bevacizumab                   | MVASI Concentrate for Solution for Infusion 25 mg/ml                    | MAL19086005ACZ   | ZUELLIG PHARMA SDN BHD                    | AMGEN MANUFACTURING, LTD, UNITED STATES | Avastin (Roche)           |
| 5.  | Erythropoietin (Epoetin Alfa) | Binocrit 2,000 IU/1 ml solution for injection in a pre-filled syringe   | MAL20112122ACZ   | NOVARTIS CORPORATION (MALAYSIA) SDN. BHD. | SANDOZ GMBH, AUSTRIA                    | Eprex (Johnson & Johnson) |
| 6.  | Erythropoietin (Epoetin Alfa) | Binocrit 4,000 IU/0.4 ml solution for injection in a pre-filled syringe | MAL20112123ACZ   | NOVARTIS CORPORATION (MALAYSIA) SDN. BHD. | SANDOZ GMBH, AUSTRIA                    | Eprex (Johnson & Johnson) |
| 7.  | Erythropoietin (Epoetin Alfa) | Binocrit 10 000 IU/1 ml solution for injection in a pre-filled syringe  | MAL20112124ACZ   | NOVARTIS CORPORATION (MALAYSIA) SDN. BHD. | SANDOZ GMBH, AUSTRIA                    | Eprex (Johnson & Johnson) |
| 8.  | Erythropoietin (Epoetin Alfa) | Binocrit 40, 000 IU/1 ml solution for injection in a pre-filled syringe | MAL20112125ACZ   | NOVARTIS CORPORATION (MALAYSIA) SDN. BHD. | SANDOZ GMBH, AUSTRIA                    | Eprex (Johnson & Johnson) |

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| 9.  | Erythropoietin (Epoetin zeta) | EPO STADA 2000IU/0.6ml Solution for Injection in a Pre-filled Syringe        | MAL15105038ACZ   | INNO BIO VENTURES SDN BHD                 | STADA ARZNEIMITTEL AG, GERMANY                     | Eprex (Johnson & Johnson) |
| 10. | Erythropoietin (Epoetin zeta) | EPO STADA 4000IU/0.4ml Solution for Injection in a Pre-filled Syringe        | MAL15105040ACZ   | INNO BIO VENTURES SDN BHD                 | STADA ARZNEIMITTEL AG, GERMANY                     | Eprex (Johnson & Johnson) |
| 11. | Erythropoietin (Epoetin zeta) | EPO STADA 10000IU/1.0ml Solution for Injection In a Pre-filled Syringe       | MAL15105039ACZ   | INNO BIO VENTURES SDN BHD                 | STADA ARZNEIMITTEL AG, GERMANY                     | Eprex (Johnson & Johnson) |
| 12. | Erythropoietin (Epoetin Alfa) | Erysaa Prefilled Syringe 2000IU/0.5mL                                        | MAL19016091ACRZ  | DUOPHARMA (M) SDN. BHD.                   | PANGEN BIOTECH INC, SOUTH KOREA                    | Eprex (Johnson & Johnson) |
| 13. | Erythropoietin (Epoetin Alfa) | Erysaa Prefilled Syringe 4000IU/0.4mL                                        | MAL19016090ACRZ  | DUOPHARMA (M) SDN. BHD.                   | PANGEN BIOTECH INC, SOUTH KOREA                    | Eprex (Johnson & Johnson) |
| 14. | Erythropoietin (Epoetin Alfa) | Erysaa Prefilled Syringe 2000IU/0.5mL                                        | MAL20016134ASZ   | DUOPHARMA (M) SDN. BHD.                   | DUOPHARMA (M) SDN. BHD.                            | Eprex (Johnson & Johnson) |
| 15. | Filgrastim                    | Zarzio 30 MU/0.5 ml solution for injection or infusion                       | MAL12035084ACZ   | NOVARTIS CORPORATION (MALAYSIA) SDN. BHD. | IDT BIOLOGIKA GMBH, GERMANY                        | Neupogen (Roche)          |
| 16. | Filgrastim                    | Zarzio 48 MU/0.5 ml solution for injection or infusion in pre-filled syringe | MAL12035085ACZ   | NOVARTIS CORPORATION (MALAYSIA) SDN. BHD. | IDT BIOLOGIKA GMBH, GERMANY                        | Neupogen (Roche)          |
| 17. | Filgrastim                    | Nivestim 120 mcg/0.2 ml solution for injection/infusion                      | MAL13085064ARZ   | HOSPIRA MALAYSIA SDN BHD                  | HOSPIRA ZAGREB D.O.O HOSPIRA ZAGREB D.O.O, CROATIA | Neupogen (Roche)          |

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| 18. | Filgrastim       | Nivestim 480mcg/0.5ml solution for injection/infusion                  | MAL13085065ARZ   | HOSPIRA MALAYSIA SDN BHD    | HOSPIRA ZAGREB D.O.O HOSPIRA ZAGREB D.O.O, CROATIA | Neupogen (Roche)          |
| 19. | Filgrastim       | Nivestim 300mcg/0.5ml solution for Injection/Infusion                  | MAL13085067ARZ   | HOSPIRA MALAYSIA SDN BHD    | HOSPIRA ZAGREB D.O.O HOSPIRA ZAGREB D.O.O, CROATIA | Neupogen (Roche)          |
| 20. | Human Insulin    | INSUGEN-N (NPH) Insulin Injection, Isophane 100IU/mL                   | MAL14015109AZ    | BIOCON SDN BHD              | BIOCON LIMITED, INDIA                              | Actrapid (Novo Nordisk)   |
| 21. | Human Insulin    | INSUGEN-R (Regular) Insulin Injection, Soluble 100IU/mL                | MAL14015110AZ    | BIOCON SDN BHD              | BIOCON LIMITED, INDIA                              | Insulatard (Novo Nordisk) |
| 22. | Human Insulin    | INSUGEN-30/70 (Biphasic) Insulin Injection, Biphasic Isophane 100IU/mL | MAL14015111AZ    | BIOCON SDN BHD              | BIOCON LIMITED, INDIA                              | Mixtard (Novo Nordisk)    |
| 23. | Human Insulin    | INSUGEN-N (NPH) Insulin Injection, Isophane 100IU/mL                   | MAL16065009ASZ   | BIOCON SDN BHD              | BIOCON SDN BHD, JOHOR, MALAYSIA                    | Actrapid (Novo Nordisk)   |
| 24. | Human Insulin    | INSUGEN-R (Regular) Insulin Injection, Soluble 100IU/mL                | MAL16045058ASZ   | BIOCON SDN BHD              | BIOCON SDN BHD, JOHOR, MALAYSIA                    | Insulatard (Novo Nordisk) |
| 25. | Human Insulin    | INSUGEN-30/70 (Biphasic) Insulin Injection, Biphasic Isophane 100IU/mL | MAL16065010ASZ   | BIOCON SDN BHD              | BIOCON SDN BHD, JOHOR, MALAYSIA                    | Mixtard (Novo Nordisk)    |

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| 26. | Infliximab       | Remsima Powder for Concentrate for Solution for Infusion                     | MAL15015118ACRZ  | CELLTRION HEALTHCARE MALAYSIA SDN. BHD. | CELLTRION,INC., SOUTH KOREA                             | Remicade (Johnson & Johnson) |
| 27. | Insulin Glargine | BASALOG Insulin Glargine Injection (rDNA Origin) 100 IU/mL                   | MAL16065057AZ    | BIOCON SDN BHD                          | BIOCON, INDIA                                           | Lantus (Sanofi)              |
| 28. | Insulin Glargine | BASALOG ONE Insulin Glargine Injection (rDNA Origin) 100 IU/mL Prefilled Pen | MAL17107078AZ    | BIOCON SDN BHD                          | BIOCON, INDIA                                           | Lantus (Sanofi)              |
| 29. | Insulin Glargine | BASALOG Insulin Glargine Injection (rDNA Origin) 100 IU/mL                   | MAL18026007ASZ   | BIOCON SDN BHD                          | BIOCON SDN BHD, JOHOR, MALAYSIA                         | Lantus (Sanofi)              |
| 30. | Insulin Glargine | BASALOG ONE Insulin Glargine Injection (rDNA origin) 100IU/mL, Prefilled Pen | MAL18046014ASZ   | BIOCON SDN BHD                          | BIOCON SDN BHD, JOHOR, MALAYSIA                         | Lantus (Sanofi)              |
| 31. | Pegfilgrastim    | Pelgraz 6 mg solution for injection in a pre-filled syringe                  | MAL20076003AZ    | ACCORD HEALTHCARE SDN. BHD.             | INTAS PHARMACEUTICALS LIMITED BIOPHARMA DIVISION, INDIA | Neulastim (Amgen)            |
| 32. | Rituximab        | TruximaTM (rituximab) 10mg/ml Concentrate for Solution for Infusion          | MAL18086131AZ    | CELLTRION HEALTHCARE MALAYSIA SDN. BHD. | CELLTRION, INC., SOUTH KOREA                            | Mabthera (Roche)             |
| 33. | Somatropin       | SciTropin A 5mg/1.5ml (15 IU) Cartridge Solution for Injection               | MAL20102067AZ    | UNITED ITALIAN TRADING (M) SDN BHD      | SANDOZ GMBH, AUSTRIA                                    | Genotropin (Pfizer)          |

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| 34. | Somatropin       | SciTropin A 10mg/1.5ml (30 IU) Cartridge Solution for Injection               | MAL20102068AZ    | UNITED ITALIAN TRADING (M) SDN BHD      | SANDOZ GMBH, AUSTRIA         | Genotropin (Pfizer) |
| 35. | Trastuzumab      | Hertraz 440mg Powder for Concentrate                                          | MAL18106049AZ    | DUOPHARMA (M) SDN. BHD.                 | BIOCON LIMITED, INDIA        | Herceptin (Roche)   |
| 36. | Trastuzumab      | ZUHERA Trastuzumab for Injection (rDNA Origin) 150mg/vial                     | MAL18126013AZ    | BIOCON SDN BHD                          | BIOCON LIMITED, INDIA        | Herceptin (Roche)   |
| 37. | Trastuzumab      | ZUHERA Trastuzumab for Injection (rDNA Origin) 440 mg/vial                    | MAL18126014AZ    | BIOCON SDN BHD                          | BIOCON LIMITED, INDIA        | Herceptin (Roche)   |
| 38. | Trastuzumab      | Herzuma (trastuzumab) 150 mg Powder for Concentrate for Solution for Infusion | MAL19056037AZ    | CELLTRION HEALTHCARE MALAYSIA SDN. BHD. | CELLTRION, INC., SOUTH KOREA | Herceptin (Roche)   |
| 39. | Trastuzumab      | Herzuma (trastuzumab) 440 mg Powder for Concentrate for Solution for Infusion | MAL19056038AZ    | CELLTRION HEALTHCARE MALAYSIA SDN. BHD. | CELLTRION, INC., SOUTH KOREA | Herceptin (Roche)   |