## Clause-by-Clause tracking – TGO107 – New to Old

| TGO107 | Sunsetting TGO 87 | Regulatory requirement | Summary of change from current standard |
|---|---|---|---|
| **Preliminary** | | | |
| 4 | 4 | No change | Definitions - Redrafted to clarify intent |
| 6 | 5 (1) | Decrease | Exemption to 'Exempt Autologous HCT products' |
| **General requirements** | | | |
| 8(1) | 6(2) | No change | No change |
| 8(2) | *Not in standard* | Increase | **New** – Clarifies that labels must be securely attached and appropriate to maintain integrity |
| 8(3) | 6(1) | No change | Redrafted to clarify intent |
| 8(4) | 5(2) | No change | No change |
| **Labels of HCT materials** | | | |
| 9(1) | 6(3), 6(4) | No change | Redrafted to clarify intent |
| 9(2) | 6(5) | No change | Redrafted to clarify intent |
| **Labels of biologicals** | | | |
| 10(1) | 6(5 -8) | No change | Redrafted to clarify intent |
| 10(2) | *Not in standard* | No change | **New** – Clarifies requirements of the order |
| **Schedule 1** | | | |
| Item 1 | 6(3)(a) | Decrease | Alternative of machine-readable codes |
| Item 2 -5 | 6(3)(b -e) | No change | No change |
| **Schedule 2 – Part 1** | | | |
| Item 1 | 6(6)(a) | Decrease | Alternative of machine-readable codes |
| Item 2 | 6(6)(b) | No change | No change |

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| Item 3 | 6(6)(c) | No change | No change |
| Item 4 | 6(6)(p) | No change | No change |
| Item 5 | *Not in standard* | Increase | **New** – Designated patient identifier for directed allogeneic Biologicals |
| Item 6 | 6(6)(d) | No change | No change |
| Item 7 | 6(6)(e) | No change | No change |
| **Schedule 2 – Part 2** | | | |
| Item 1 | 6(6)(p) | No change | No change |
| Item 2 | *Not in standard* | Increase | **New** – Designated patient identifier for directed allogeneic Biologicals |
| Item 3 | 6(6)(d) | No change | No change |
| Item 4 | 6(6)(e) | No change | No change |
| Item 5 | 6(6)(f) | No change | No change |
| Item 6 | *Not in standard* | Increase | **New** – Approved indication - class 3 and 4 Biologicals only |
| Item 7 | *Not in standard* | Increase | **New** – intended use - class 1 and 2 Biologicals only |
| Item 8 | *Not in standard* | Increase | **New** – therapeutic use - Biologicals not included in the Register |
| Item 9 | 6(6)(g) | No change | No change |
| Item 10 | 6(6)(g) | No change | No change |
| Item 11 | 6(6)(h) | No change | No change |
| Item 12 | 6(6)(i) | No change | No change |
| Item 13 | 6(6)(k) | No change | No change |
| Item 14 | 6(6)(l) | No change | No change |

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| Item 15 | 6(6)(m) | No change | No change |
| Item 16 | 6(6)(n) | No change | No change |
| Item 17 | 6(6)(o) | No change | No change |
| Item 18 | *Not in standard* | Increase | **New** –instructions for preparation |
| Item 19 | 6(6)(r) | No change | No change |
| Item 20 | 6(6)(s) | No change | No change |
| Item 21 | 6(6)(s) | No change | No change |
| Item 22 | *Not in standard* | Increase | **New** – interactions |
| Item 23 | *Not in standard* | Increase | **New** –incompatibilities |
| Item 24 | *Not in standard* | Increase | **New** –Pregnancy, breastfeeding or impact on fertility warnings |
| Item 25 | *Not in standard* | Increase | **New** – Allergy warnings |
| Item 26 | *Not in standard* | Increase | **New** – effect on personal behaviours warnings |
| Item 27 | 6(6)(s) | No change | No change |
| Item 28 | *Not in standard* | Increase | **New** –instructions for adverse event reporting |
| Item 29 | 6(6)(t) | No change | No change |
| Item 30 | *Not in standard* | Increase | **New** – information on biochemical, biodynamic or biokinetic properties - class 3 and 4 only |
| Item 31 | *Not in standard* | Increase | **New** – information on clinical trials - class 3 and 4 Biologicals only |
| Item 32 | *Not in standard* | Increase | **New** – information on toxicology studies - class 3 and 4 Biologicals only |