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| **Transmissible Spongiform Encephalopathies (TSE) Questionnaire** |

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| **Introduction** | | | | | | | | |
| Consumer Healthcare Products Australia (CHP Australia) and Complementary Medicines Australia (CMA) have jointly developed this questionnaire in consultation with member companies.  This questionnaire is designed to facilitate the collection of information to enable self assessment of materials of ruminant origin against the Transmissible Spongiform Encephalopathies (TSE) - TGA approach to minimising the risk of exposure requirements.  The assessment of ruminant origin material must be undertaken in accordance with the principles and requirements detailed in the European Pharmacopoeia general monograph 1483 - Products with risk of transmitting agents of animal spongiform encephalopathies, including general text 5.2.8 - Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products.  This questionnaire should be updated when any information changes or every three years. | | | | | | | | |
|  | | | | | | | | |
| **1** | | **Company and Contact Details** | | | | | | |
| 1.1 | | Company Name: | | |  | | | |
|  | | Address: | | |  | | | |
|  | | Phone: | | |  | | | |
|  | | Facsimile: | | |  | | | |
|  | | E-mail: | | |  | | | |
|  | | Website: | | |  | | | |
|  | |  | | |  | | | |
| **2** | | **Raw Material Details** | | | | | | |
| 2.1 | | Raw Material Name: | | |  | | | |
|  | | Code: | | |  | | | |
|  | |  | | |  | | | |
| **3** | | **Declaration** | | | | | | |
| 3.1 | | I declare that the information supplied in this questionnaire is to the best of my knowledge correct. I undertake to inform customers in the event of any change to the information supplied. | | | | | | |
|  | | Signature: | | |  | | | |
|  | | Name: | | |  | | | |
|  | | Title: | | |  | | | |
|  | | Date: | | |  | | | |
|  | | This questionnaire contains the following (please indicate): | | | | | | |
|  | | Part A | | | | |  | |
|  | | Description of the quality system | | | | |  | |
|  | | Description and flowchart of the manufacturing process | | | | |  | |
|  | | Part B | | | | |  | |
|  | | EDQM certificates | | | | |  | |
|  | | Part C | | | | |  | |
|  | | Country of origin certificates | | | | |  | |
|  | | Manufacturer statements | | | | |  | |
|  | | Veterinary health certificates | | | | |  | |
| Part A | | | | | | | | |
| 1 | | Is an appropriate quality system in place to monitor starting materials of ruminant origin including any changes to the TSE status of these starting materials? | | | | | | |
|  | Yes | | | | | No | | Unknown |
|  | | Please provide a brief description of the quality system including traceability of ruminant starting materials during manufacture | | | | | | |
|  | |  | | | | | | |
|  | |  | | | | | | |
| 2 | | Does the raw material contain any starting materials of ruminant origin? | | | | | | |
|  | Yes | | | | | No | | Unknown |
|  | | If yes or unknown, please provide a description and flowchart of the manufacturing process of these starting materials. | | | | | | |
|  | |  | | | | | | |
|  | |  | | | | | | |
| 3 | | Is the raw material manufactured using any starting materials of ruminant origin? | | | | | | |
|  | Yes | | | | | No | | Unknown |
|  | | If yes or unknown, please provide a description and flowchart of the manufacturing process of these starting materials. | | | | | | |
|  | |  | | | | | | |
|  | |  | | | | | | |
| 4 | | Is the raw material exposed to any starting materials of ruminant origin during manufacture or in the primary packaging, including culture media, processing aids and enzymes? | | | | | | |
|  | Yes | | | | | No | | Unknown |
|  | | If yes or unknown, please provide a description and flowchart of the manufacturing process of these starting materials. | | | | | | |
|  | |  | | | | | | |
|  | |  | | | | | | |
|  | | If the answer was no to all of questions 2-4, please stop here and return the completed questionnaire and any attachments.  If the answer was yes or unknown to any of questions 2-4, please continue with Part B. | | | | | | |
|  | |  | | | | | | |
| Part B | | | | | | | | |
| 5 | | Is the starting material used to produce any of the following raw materials - gelatin, collagen, tallow derivatives, animal charcoal, bovine milk and milk derivatives, wool derivatives, amino acids or peptones? | | | | | | |
|  | Yes | | | | | No | | Unknown |
|  |  | | | | |  | |  |
| 6 | | Is the raw material compliant with the relevant sections of the current Ph. Eur. general text 5.2.8 Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products? | | | | | | |
|  | Yes | | | | | No | | Unknown |
|  | | If yes, please attach copies of EDQM certificates if available, or a letter of assurance from the manufacturer. | | | | | | |
|  | |  | | | | | | |
|  | | If the answer was yes to all of questions 5-6, please stop here and return the completed questionnaire and any attachments. | | | | | | |
|  | | If the answer was no or unknown to any of questions 5-6, please continue with Part C. | | | | | | |
|  | |  | | | | | | |
| Part C | | | | | | | | |
| 7 | | Are the animals used in the manufacture of the starting material sourced from countries with a negligible or controlled BSE risk status or from CWD free countries? (Please refer to the current list maintained at the Office International des Epizooties (OIE) website [www.oie.int/en](http://www.oie.int/en)) | | | | | | |
|  | Yes | | | | | No | | Unknown |
|  | | If yes, which countries? | | | | | | |
|  | |  | | | | | | |
|  | | Are country of origin certificates available? | | | | | | |
|  | Yes | | | | | No | | Unknown |
|  | | If yes, please attach copies. | | | | | | |
|  |  | | | | | | | |
| 8 | | Do you know the species of animal that the starting material is derived from? | | | | | | |
|  | Yes | | | | | No | | Unknown |
|  | | If yes, which species? | | | | | | |
|  | |  | | | | | | |
|  | | If yes, please provide written confirmation of these details from the starting material supplier. | | | | | | |
|  | |  | | | | | | |
| 9 | | Do you know the type of tissue that the starting material is derived from? | | | | | | |
|  | Yes | | | | | No | | Unknown |
|  | | If yes, which tissue? | | | | | | |
|  | |  | | | | | | |
|  | | Is this a Category 1B or 1C tissue derived from cervids or a category 1C tissue derived from non-cervids? (Please refer to the current Ph. Eur. general text 5.2.8 Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products) | | | | | | |
|  | Yes | | | | | No | | Unknown |
|  | If yes, please provide written confirmation of these details from the starting material supplier. | | | | | | | |
|  |  | | | | |  | |  |
| 10 | | Are the animals used in the manufacture of the starting material veterinary inspected and found healthy? | | | | | | |
|  | Yes | | | | | No | | Unknown |
|  | | If yes, please attach copies of veterinary health certificates if available, or a letter of assurance from the manufacturer. | | | | | | |
|  | |  | | | | | | |
| 11 | | Please provide the names and addresses of the manufacturing sites from which you obtained the starting materials. | | | | | | |
|  | | Company Name: | | |  | | | |
|  | | Address: | | |  | | | |
|  | | Company Name: | | |  | | | |
|  | | Address: | | |  | | | |
|  | | Company Name: | | |  | | | |
|  | | Address: | | |  | | | |
|  | | Company Name: | | |  | | | |
|  | | Address: | | |  | | | |
|  | |  | | | | | | |
|  | | Please return the completed questionnaire and any attachments. | | | | | | |
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| References | | | | | | | | |
| Office International des Epizooties (OIE) [www.oie.int/en](http://www.oie.int/en) Transmissible Spongiform Encephalopathies (TSE) - TGA approach to minimising the risk of exposure [www.tga.gov.au/industry/tse-approach.htm#.U4\_1laRZpaQ](http://www.tga.gov.au/industry/tse-approach.htm#.U4_1laRZpaQ)  |  | | --- | | European Medicines Agency (EMA) Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 Rev. 3, July 2011) |   <http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003700.pdf> | | | | | | | | |
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| **Document Revision History** | | | | | | | | |
| **Date** | | | **Version** | **Changes** | | | | |
| 16/01/12 | | | 1 | First issue. | | | | |
| 4/08/14 | | | 2 | Amended to reflect updated TGA requirements issued on the 2/04/14.  Introduction updated to reflect name change of CHC to CMA. | | | | |
| 15/07/2019 | | | 3 | Introduction updated to reflect name change of ASMI to CHP Australia. | | | | |