## Response document for consultation on the MHRA Guideline for licensing of biosimilar products

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| --- |
| About You Name: |
| Position: |
| Organisation: |
| Email: |
| Familiarity with similar biological medicinal products (biosimilars): None  Awareness Understanding Knowledge Expertise |
| Please indicate if you are responding to this consultation as an individual or on behalf of an organisation Individual  Organisation  |
| About your Organisation Type: ** Generics** – *a pharmaceuticals manufacturer of any size with most of its sales from generic drug products*   **Large Pharma** – *a pharmaceuticals firm with annual sales of more than $2bn, and which develops and manufactures patented drug products as its primary activity*   **Small/ Medium Pharma** – *a pharmaceuticals firm with less than $2bn in sales, and which develops and manufactures patented drug products as its primary activity*   **Supplier** – *a supplier of services, materials or equipment to the pharmaceutical industry (includes testing companies, consultancies, raw materials suppliers)*  **Government** –  *OMCL* *Regulator* *Other*   **Public Health** – *hospitals and medical clinics*   **Academia** – *universities and colleges*   **Other (Please state)** – |
| Focus: *Please indicate your organisations focus on small and large molecules using the scale below. 3 indicates an equal focus on small and large molecules.* **Small** 1 2 3 4 5 **Large** |
| Location (country): Head office:­­­­­­­­­­­­­­­­­­­­ Your site: |
| Organisation Size: 1-5  6-50  51-250  250-1000 1001-9999 10,000+  |
| General comments  | Stakeholder number  (To be completed by MHRA) | General comment (if any) | Outcome (if applicable)  (To be completed by MHRA) | | --- | --- | --- | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |
| 2. Specific comments on text  | Title and section number of the relevant text | Comment and rationale; proposed changes  *(If changes to the wording are suggested, they should be highlighted using 'track changes')* | Outcome  (To be completed by MHRA) | | --- | --- | --- | |  | Comment:  Proposed change (if any): |  | |  | Comment:  Proposed change (if any): |  | |  | Comment:  Proposed change (if any): |  | |  | Comment:  Proposed change (if any): |  |   Please add more rows if needed |
| 3. Would you be happy for the MHRA to contact you in order to discuss your responses in further detail? Yes  No  |
| 4. The MHRA may publish consultation responses. Do you want your response to remain confidential? Yes  Partially\*  No   \*If partially, please indicate which parts you wish to remain confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete. |

Responses can be continued onto a separate page if required. This form should be returned by email ([biosimilars@mhra.gov.uk](mailto:biosimilars@mhra.gov.uk)) to arrive by **15 November 2020.** Contributions received after that date cannot be included in the exercise.