**Annual Compliance Assessment Report** for General Sale Wholesale Distributors

The requirement to complete the Annual Compliance Assessment Report has been introduced to support the risk-based approach to inspections of general sale wholesale distributors (see the ‘Guide to the Quality System for General Sale Wholesale Distributors’, on [www.hpra.ie](http://www.hpra.ie)). The report will allow the HPRA to monitor compliance outside of the inspection process.

1. Please complete one Annual Compliance Assessment Report for each wholesale distribution authorisation (WDA) held.
2. Please complete all relevant sections of this form. Incomplete submissions will be returned.
3. Electronic submission is preferable. Otherwise, please complete in block capitals legibly using black ink.
4. The assessment report, describing any changes made in the previous year and/or the future changes planned for the following two years, should be returned during January and no later than **31 January** of that year. For example, a report detailing changes made during 2023 should be submitted between 1and 31 January 2024 and should include any planned changes for 2024 and 2025.
5. Failure to submit this assessment report within the above timeframe will result in an increase to the inspection frequency of your facility.
6. The information provided will be reviewed by our inspection team and may result in a non-routine inspection of your facility.

Section 1 General Details

|  |  |
| --- | --- |
| Wholesale distribution authorisation (WDA) number | *Include details of your WDA number and site of operation.*      |

|  |  |
| --- | --- |
| Assessment report for year | *Insert year.*      |

Section 2 Changes

Please list any significant changes in processes, facilities, equipment, personnel or workload since the last HPRA inspection.

|  |  |  |
| --- | --- | --- |
| **Type of change** | **Yes/No** | **Provide details of change** |
| New medicinal product range introduced, e.g. medicinal product requiring different storage conditions | [ ]  Yes [ ]  No |       |
| Premises: significant modification to the wholesaling facilities, e.g. extension of premises  | [ ]  Yes [ ]  No |       |
| Equipment: new or modified equipment used for storage, control of records, picking/packing and environmental monitoring | [ ]  Yes [ ]  No |       |
| Personnel: Any changes to key personnel involved in GDP activities | [ ]  Yes [ ]  No |       |
| Workload: any significant increase or decrease in the amount of GDP work undertaken | [ ]  Yes [ ]  No |       |

Where a change has been made, has a variation to your authorisation been submitted to the HPRA?

[ ]  Yes

[ ]  No

**If yes**, insert date(s) of submission and the HPRA assigned case reference number(s):

|  |
| --- |
|       |

**If no**, insert date when the variation will be submitted:

|  |
| --- |
|       |

Section 3 Future activities

Please list any known significant changes in processes, facilities, equipment, personnel or workload proposed for implementation within the next 24 months.

|  |
| --- |
|       |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| section 4 DECLARATIONI hereby declare that, to the best of my knowledge and belief, all the particulars given in this application are correct, truthful and complete.

|  |  |
| --- | --- |
| Signature:       | Date:       |
|  |  |
| Print name:        | Title/position:       |

(BLOCK CAPITALS) (see notes below)

|  |  |
| --- | --- |
| Signature:       | Date:       |
|  |  |
| Print name:        | Title/position:       |

(BLOCK CAPITALS) (see notes below)*Notes:* The signatures provided above **must include** the Responsible Person (RP) for the operation as named on the WDA.The signatories must take all reasonable precautions and exercise all due diligence, to ensure that any information they provide to the HPRA is not false or misleading in any material particular, in accordance with relevant Regulations which make it an offence to provide false or misleading information. |

Please return the completed form to:

Annual Compliance Assessment Report

Healthcare Products Distribution Section

Health Products Regulatory Authority

Kevin O’Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Tel: + 353 1 676 4971

Fax: + 353 1 676 7836

Email: compliance@hpra.ie