MEDICINES CONTROL AGENCY

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SIGNAL NOTIFICATION for

<Active substance/INN – BRANDNAME (therapeutic class) and adverse reaction (MedDRA term)>

General guidance

This form should be used by marketing authorisation holders (MAHs) to notify detected signals for which they conclude after validation and assessment that further analysis by the MCA is required.

The requirements outlined in the MCA Guideline for Signal Management must be followed when completing the form.

Signal notifications should not be used for:

- *non-validated or refuted signals,*
- *signals to be included within PSURs or variation applications,*
- *signals meeting the definition of an emerging safety issue (unless a signal notification is requested by the Agency).*

Once completed, please send the form (in Microsoft Word format) and any attachments in a single e-mail to the MCA info@mca.gm. Please use as e-mail message subject the following format: Signal from <MAH> on <active substance> and <adverse reaction>.

All the sections should be completed with the information requested or a justification should be provided. Sections should not be left blank.

1 Administrative Information

Date of this notification	DD month YYYY
Active substance(s) (invented name(s))	<Text>
Pharmaceutical form(s)/Route(s) of administration / Strength(s)	<Text>
Marketing authorisation holder(s)	<Name(s)>
QPPV	<Name(s) and contact details>
MAH contact person for the signal	<Name(s) and contact details>
Marketing authorisation number(s)	
Country of Origin in which the MAH holds a marketing authorisation for the medicine:	
Next PSUR submission date	<DD month YYYY> ☐ PSUR not required

2 Signal Description

2.1 Highlights

Clinical relevance: <Text>

Please briefly summarise how seriousness criteria were met in the cases, e.g. fatal, life-threatening, hospitalisation etc.

Relevant statistical measures: <Text>

Please provide the relevant values (in particular the lower bound of the 95% confidence interval) as well as any other relevant statistical measures if applicable.

Patient exposure: <Text>

Please provide the most recent estimate of the population cumulatively exposed to the medicine in the post-authorisation setting and in clinical trials if applicable. Methods used to calculate the exposure do not need to be included.

Previous awareness: <Text>

Please provide information on any regulatory actions or previous assessments, performed at national or international level in relation to the signal.

Sources:

☐ Literature ☐ MAH database

☐ Clinical trials ☐ Other *[please specify below]*

2.2 Background

<Text here.>

This section should include a concise summary of the relevant information on the product(s)/ active substance (including therapeutic indication(s)), and on the adverse reaction(s) (e.g. morbidity, epidemiology, case definition, etc.).

2.3 Signal validation and further assessment

Date of the query: <DD month YYYY> Monitoring periodicity: <Text here.>

<Text here.>

This section should include a summary of all evidence, e.g. from the MAH or other databases, scientific literature, clinical trials, etc

3 Conclusion

<Text here.>

This section should include a brief statement highlighting why further analysis by the MCA is warranted and proposed actions.

4 Annexes

<Text here.>

List of literature references, if applicable

List of attachments, if applicable