Application for Reclassification of Poison

1. Medicine Details

1.1 Name of Poison (Active ingredient of product)

1.2 Name of Product

1.3 Dosage Form of Product

1.4 Indications

1.5 Current poison group

1.6 Proposed poison group

2. Overview (Summary of essential aspect of the proposal)

3. Background (General background such as current class status, historical context and basic chemistry fact)

4. Exposition on reclassification

4.1 Risks and benefits associated with the usage of the poison

4.2 The purpose for which a substance (poison) is to be used and the extend of use of that poison - (Current pattern of use locally and overseas)

4.3 Toxicity and safety profile of the poison

4.4 Potential for misuse / abuse of the poison

4.5 Application / Implication of reclassification of poison towards other industries

4.6 Worldwide Registration Status (*POM, PM, OTC, GSL etc.)

***POM: prescription only medicine, PM: pharmacy medicine, OTC: over the counter, GSL: general sale list**

4.7 Any other matter that may be relevant to the reclassification of the poison

5. Conclusion (Summary of Justification)

6. Supporting Data

Prepared by:

Name :
Position :
Company :
Address :
Phone :
Email :

Format Permohonan Pengelasan Semula Racun

A	**FORMAT AM**
Saiz Font	12
Jenis Tulisan	Tahoma
Perenggan	1.5 *Lines Spacing*
Nombor Mukasurat	Jangan dimasukkan. Akan dilakukan oleh pihak urusetia mengikut turutan.
B	**FORMAT KHUSUS**
1.	***Medication Details*** ***1.1 Name of Poisons (Active ingredient of product)*** ***1.2 Name of Product*** ***1.3 Dosage Form of Product*** ***1.4 Indications*** ***1.5 Current poison group*** ***1.6 Proposed poison class***
2.	***Overview (Summary of essential aspect of the proposal)***
3.	***Background (General background such as current class status, historical context and basic chemistry fact)***
4.	***Exposition on reclassification*** ***4.1 Risks and benefits associated with the usage of the poisons*** ***4.2 The purpose for which a substance (poison) is to be used and the extend of use of that poison - (Current pattern of use locally and overseas)*** ***4.3 Toxicity and safety profile of the substance*** ***4.4 Potential for misuse / abuse of the substance***

	4.5 Application / Implication of reclassification of Poison towards other industries ***4.6 Worldwide Registration Status (*POM, PM, OTC, GSL etc.)*** ****POM: prescription only medicine, PM: pharmacy medicine, OTC: over the counter, GSL: general sale list*** ***4.7 Any other matter that may be relevant to the reclassification of the Poison***
5.	***Conclusion (Summary of Justification)***
6.	***Supporting Data***

* Borang boleh dimuat turut dari laman web www.pharmacy.gov.my