

Appendix 1

Maximum Drug Package Size

Dosage Form	Category	Maximum Unit Package Size	
Tablets, pills, capsules, troche, sublingual tablet	Prescription drugs or instruction drugs	Under 1000 tablets	
	OTC drugs	Under 500 tablets	
Oral liquid	Instruction drugs OR OTC drugs	For one single use only and under 100ml	
Injection	Administered by physicians	no more than 100 vials or ampoules per box (excluding solvent)	
Drops or spray for eyes, nose or ears	Prescription drugs, instruction drugs, OTC drugs	Under 100ml	
Ointment	Prescription drugs or instruction drugs	Without containing antibiotics	Under 1000g
		Containing antibiotics	Under 100g
	OTC drugs	Under 100g	
Suppository	Prescription drugs, instruction drugs, OTC drugs	Under 100 tablets	
Powder, granule (excluding pharmaceutical preparation for manufacturing)	Prescription drugs, instruction drugs	Under 1000g	
	OTC drugs	Under 500g	
Liquid, tincture, elixir, spirit, liniment, syrup, suspension, emulsion (excluding API)	Prescription drugs or instruction drugs	Without containing antibiotics	Under 4000ml
		Containing antibiotics	Under 1000ml
	OTC drugs	Under 500ml	

Note:

1. In situations where the package size stated on a license exceeds the maximum limit, then, with the central health competent authority's pre-approval, manufactures can continue using the existing licences without the obligation to file a post-approval change.

2. As long as the maximum package size is observed, manufacturers may adjust package sizes to satisfy market demands without the need to apply for post approval changes. However, if the package size goes over the limit, an application of post approval change shall be filed with the submission of the purchase orders made by health care providers or academic groups.
3. As a principle, the common minimum package size is the minimum two-day dose for an adult.
4. Liquid preparation shall not be packed in pop cans / bottles.
5. Oral liquid should be packed in a single use adult dose. The unit package size should be under 100ml.
6. In principle, suspension and gel in aluminium foil or plastic pouches should be in a single use dose.
7. Licences should clearly indicate whether a cannula or an infusion set is provided with an injection product. Manufacturers shall also submit 40 sets of cannulas or infusion sets and their specifications to the health authority for examination. If the cannulas or infusion sets have been licensed, then their license numbers should be specified and no further testing is required.
8. The minimum package size of API is 0.5kg. However, for those where only a small quantity is used, the minimum package size is the quantity for manufacturing 100,000 tablets, 100,000 injections, 100,000 ointment tubes or 100,000g drugs.
9. The maximum package size of eye wash is 500ml.
10. For syrup containing codeine that is categorized as an instruction drug, the three-day dose is the maximum package size.
11. Tablets and capsules containing ephedrine or pseudoephedrine can only be in boxed aluminium foil pack. For instruction drugs, the maximum package size is 7-day doses for an adult. Regulations stated in notes 1 and 2 are not applicable.
12. The package size for drugs for the cold, pain relief and coughing liquid is between 4000ml and one single dose for an adult.