Model letter 4
Approving a marketing authorization

Application number .....

The Managing Director
[Name of company]
[Address]
[Date]:

Attention: Regulatory Affairs Manager

Dear Sir/Madam

I refer to the application dated *[date of application]* for *[marketing authorization or periodic review or variation]* of:

Proprietary name (trade name) .....
Approved generic name(s) .....
Strength(s) per dosage unit .....
Dosage form .....
Name of authorization holder* .....

*[*Must be a person or company in the country in which marketing is being authorized. This letter should normally be addressed to the marketing authorization holder.]*

Evaluation of the application has been completed. Approval under *[name of legislation]* is granted, subject to the conditions in this letter and its attachments. This letter and its attachments constitute the marketing authorization. The details of this marketing authorization are as follows.

Marketing authorization number .....
Date from which marketing is authorized .....
Expiry date of this marketing authorization .....
(after this date you must apply for renewal of the authorization)

The conditions which apply to this approval are as follows...

A *General conditions applying to all authorized products:*

- The product(s) must conform with all the details provided in your application and as modified in subsequent correspondence.
- No changes may be made to the product without prior approval, except for changes of the type listed in *[name of regulatory authority]*'s policy on "Changes to pharmaceutical aspects which may be made without prior approval". The conditions in that policy apply.
- The approved sites of manufacture are those in Attachment 1.
- The approved shelf-life is that in Attachment 2.
- The only Product Information (PI) that may be supplied with or for this product must be the PI that is approved. Attachment 3 is a copy of the approved PI.
- The Product information may not be altered without prior approval, except for safety updates that further restrict use of the product. Any such safety-related changes must be notified to *[name of regulatory authority]* within five days of making the change.

- The product information must include the marketing authorization number and the date from which marketing is authorized. This information must appear in the top right hand corner of the first page of the Product information, in letters of at least 1.5 mm tall.
- All advertising and promotion of the product(s) must be consistent with the approved product information.

B *Additional specific conditions applying to this product:*

- [...for example, "Distribution is restricted to hospitals specializing in oncology".....]
- [.....]
- [.....]

If you have any doubt as to the meaning of this letter and its attachments, you should contact the undersigned prior to commencing marketing.

Yours faithfully

[Name]
[Signature]

authorized person under [name of legislation]

Marketing authorization
Attachment 1

Product:

Proprietary name (trade name) .....
Approved generic name(s) .....
Strength(s) per dosage unit .....
Dosage form .....
Name of authorization holder .....
Marketing authorization number .....
Date from which marketing is authorized .....
Expiry date of this marketing authorization .....

The approved manufacturers are as follows.

Production stage	Name of site	Street address of site	Manufacturing step
[Active pharmaceutical ingredient I]			Production
[Active pharmaceutical ingredient II]			Production
Finished product			[For example granulation]
			[For example sterilization]
			[For example packaging]
			[For example quality control]

Marketing authorization
Attachment 2

Product:

Proprietary name (trade name) .....
Approved generic name(s) .....
Strength(s) per dosage unit .....
Dosage form .....
Name of authorization holder .....
Marketing authorization number .....
Date from which marketing is authorized .....
Expiry date of this marketing authorization .....

Approved shelf-life:

The approved shelf-life of this product when packaged and labelled as detailed in the application and modified in subsequent correspondence is as follows.

Pack	Shelf-life	Storage conditions
[For example, PVC/Al blisters, 25 and 50 tablets per blister]	18 months	Store below 30-C Protect from moisture
[For example, HDPE bottles]	3 years	Store below 30-C Protect from moisture

Restrictions on sale or distribution:

[Normally at least one of these, and possibly different restrictions for different strengths]

- Scheduled narcotic;
- Restricted prescription-only distribution (specify - for example, hospitals only);
- Prescription only;
- Pharmacy only;
- Over the counter (OTC).