Data Sheets

Where a participant chooses to use a data sheet rather than an SPC to satisfy the obligations of Clause 4.5, at least the following information shall be included. Such information must be consistent with the SPC.[1] Any changes to the SPC must, within 30 calendar days of approval by the relevant regulatory authority, be reflected in the Data Sheet, in the on line NOAH Compendium of Data Sheets, in the next printed edition of the NOAH Compendium and in any printed copies of the datasheet issued to the prescriber subsequent to the change in the SPC. In certain circumstances it may not be appropriate for the changes in the SPC to be reflected in the datasheet e.g. when the product or change has been approved but not yet placed on the market by the MA holder.

Headings	*Particulars*
Name of Product	Name of the medicinal product and, if the medicinal product has an approved name, the approved name.
Presentation	Description of appearance and pharmaceutical form of the medicinal product together with the following information that is to say – (a) where the medicinal product contains active ingredients all of which can be definitively identified – (i) a list of such ingredients, each described by its approved name or monograph name or, where it has no approved name or monograph name, any other descriptive appellation, and (ii) the quantity of each such ingredient contained in each unit or dose of the medicinal product or, where there is no such unit or dose, the percentage of each such ingredient contained in the medicinal product; (b) where the medicinal product contains any active ingredient that cannot be definitively identified – (i) the information as required under (a) above in respect of each identifiable active ingredient (if any), and (ii) a description of the material to which the activity of any other ingredient is ascribed and, where appropriate, a statement of the activity or potency of the medicinal product; (c) where there are no active ingredients in the medicinal product, a statement indicating the material of which that medicinal product consists.
Uses	Principal action (if any) of the medicinal product and the purposes for which it is recommended to be used.
Dosage and Administration	Dosage (if any) for the medicinal product together with methods and routes of administration according to species and categories within species and, where appropriate, recommendations as to diluents.
Contra-Indications, Warnings, etc.	Contra-indications, warnings, precautions, and action to be taken in the event of overdosage (including, where required in the interests of safety, antidote, emergency procedure or other appropriate action) relating to the medicinal product and main side effects and adverse reactions likely to be associated with the product and, where necessary, measures for the protection of –

	(a) operators, (b) consumers of the whole or any part of a carcase or any produce of an animal to which the medicinal product has been administered, including withdrawal periods, if any, and *(continued overleaf)* (c) livestock, wildlife and others, unless there are no such particulars to be given and there is a statement to that effect.
Pharmaceutical Precautions	Special requirements for the storage of medicinal products and, where appropriate, pharmaceutical precautions including recommendations as to excipients, diluents and other additives and as to suitable containers, unless there are – (a) no such requirements, or (b) no such precautions, and a statement to that effect is made.
Legal Category	References to statutory provisions relating to sale or supply of the medicinal product.
Package Quantities	Quantity or amount of the medicinal product in each size of package or container for retail sale, or for supply in circumstances corresponding to retail sale.
Further Information	Such further information (if any) as may be necessary to assist the practitioner in the proper understanding, recognition, administration and use of the medicinal product, such information not covering more than one-tenth of the total surface area of the data sheet.
Marketing Authorisation Numbers, Names and Addresses	Marketing Authorisation number of the medicinal product and the name and address of the authorisation holder. Where the MA holder is different from the distributor this information should be provided on the data sheet.
Date of Preparation or Last Review	Date of preparation of the data sheet or, where since such preparation there has been a review or revision of the data sheet, the date of the last such review or revision.