



Definition of Starting Materials

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Quality assessor training 26-27th October 2009 (EMA)





9.20-10.00: Presentation

Definition on starting materials

10.00-11.00: Workshop on the definition of starting materials

11.00-11.20: *Coffee break*

11.20-12.00: Outcome of the workshop & *discussion*





Starting material definition

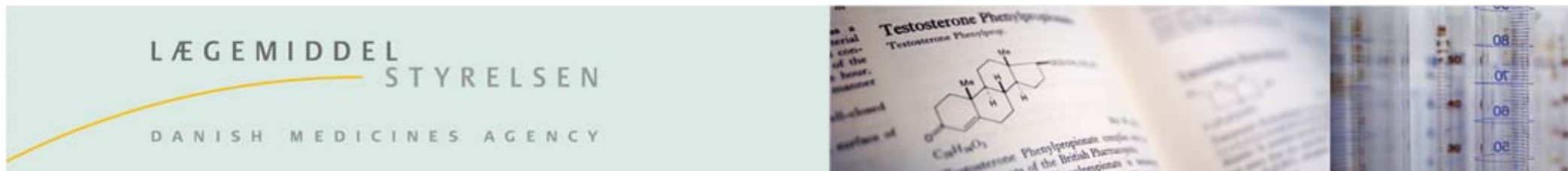
Guideline on chemistry of new active substances (into operation Feb 2004)

- Quality

“Generally, the description of the process and the synthesis schematic should include all the steps of the process, proceeding from the starting material(s) to the isolated intermediates and ultimately to the active substance. Use of starting materials **marks the beginning of the detailed description** of the process.

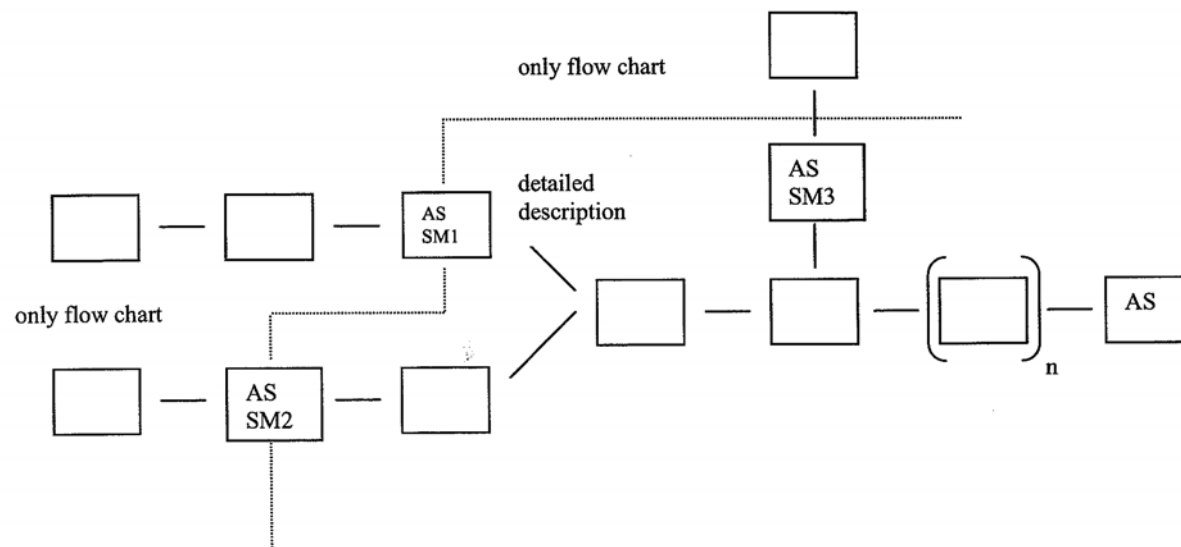
The applicant should propose and justify which substance should be considered as the Starting material (SM), e.g. incorporated as a significant structural fragment into the structure of the active substance. The name and address of the starting material supplier(s) should be provided. Information, in the form of a flow chart, indicating the synthetic process prior to the introduction of the starting material, may be useful to evaluate the suitability of its specification(s).

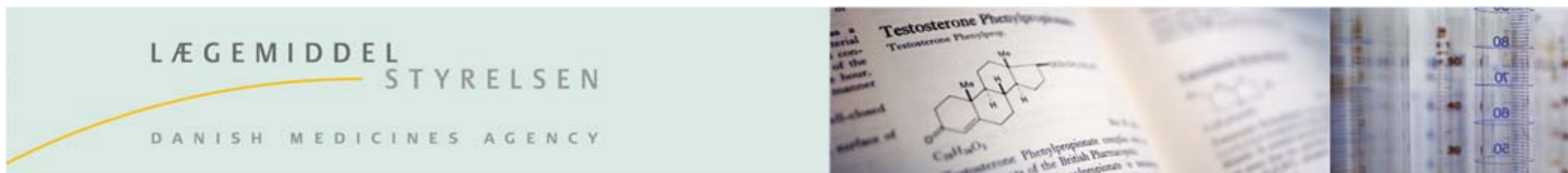




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Schematic description (illustrative only):





Guideline text and a long range of examples
were discussed

