Appendix 4: Requirements regarding the pharmaceuticals

1. General

The pharmaceutical is used for mixing at the hospital pharmacies/units, and the handling thereof involves working environment risks due to the nature of the pharmaceutical.

The pharmaceuticals must be delivered in vials, and it is an essential requirement that there is no, nor will be, overpressure in the vials, and that the caps of the vials remain tight after needle perforation.

In the evaluation of the Supplier's tender for pharmaceuticals under the framework contract, emphasis has been given to a number of elements of importance to the safety of the staff in connection with the use of the pharmaceutical, including that the outer surface of the packaging is free of any residue from the pharmaceutical, and that both the primary and secondary packaging are generally of a quality and design that ensure the greatest possible safety to the staff in the use of the pharmaceutical.

In the evaluation of tenders, emphasis will also be given to the physico-chemical stability of the pharmaceutical. In connection with information about the supplier's own stability tests, the stability data must be for the pharmaceutical in the packaging types used by the hospital pharmacies/units. These packaging types, which are purchased under a framework agreement previously put up for tender, are indicated in Appendix 4A.

The supplier's information on the pharmaceuticals offered in relation to these elements, see paras 2, 3 and 4 below, are considered a requirement for the pharmaceuticals covered by the framework agreement, and a change of these elements will therefore be considered a defect in the products delivered.

2. Cleanness of the packaging

The Supplier's protection of the outer surface of the packaging from any residue of the pharmaceutical is described in the Supplier's tender. Reference is therefore made to the relevant part of the tender, see also para 1 above.

3 Quality of the packaging

The Supplier's description of the quality and design of the packaging in terms of its manageability to the staff and the suitability of the packaging to offer the greatest possible safety to the staff in connection with the use of the pharmaceutical is set out in the Supplier's tender. Reference is therefore made to the relevant part of the tender, see also para 1 above.

4 Shelf life

The Supplier's information on the physico/chemical stability of the pharmaceutical in a ready-to-use solution where the shelf-life is longer than the shelf-life indicated in the summary of product characteristics is set out in the Supplier's tender. Reference is therefore made to the relevant part of the tender, see also para 1 above.