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Dear Ms Ferrão

Re: Investigating patient safety incidents (unexpected death or serious untoward harm)

I am writing with respect to the above consultation document and would like to thank you for the opportunity to comment on the draft Memorandum of Understanding (MOU).

The Society welcomes the MOU as a commitment to joint working between the organisations involved and hopes that this will improve efficiency and co-ordination in the handling of patient safety incidents, however we would like to make the following comments:

- The Society is both a statutory registration and professional body for pharmacists (and will, in the future operate in a similar capacity for pharmacy technicians). We would like to remind the organisations involved that the Society is unique amongst healthcare regulators and has its own long established inspectorate under s9 of the Poisons Act 1972. Our inspectorate has both inspection and enforcement powers/duties mainly under the Medicines Act 1968 and the Pharmacy and Poisons Acts in relation to registered retail pharmacy premises. The Society's inspectorate consists of experienced pharmacists and other investigators and has recently been acknowledged and praised in the Shipman Report for their role in inspection and enforcement in relation to registered retail pharmacies.

The Society inspectors currently investigate many reports of alleged untoward incidents that occur in registered retail pharmacy premises. Reports of these incidents come from a variety of sources including members of the public, healthcare professionals and patients. Incidents reported to us range from less serious harm through to serious harm and fatalities, which usually occur as a result of a medication error made by a pharmacist.

Whilst we note that the MOU is mainly intended to focus on NHS Trusts, it is acknowledged that the protocol could be applied in other circumstances, which we assume could include patient safety incidents that occur within registered retail pharmacies, particularly as most registered retail pharmacies provide medicines to patients on behalf of the NHS.

The Society inspectors have in the past worked well with the authorities in assisting with investigations into incidents involving fatalities and serious harm and would like to reiterate our commitment to joint working with the authorities, where appropriate.

- Whilst the Society welcomes the formulation of an Incident Co-ordination Group, there may on occasion be difficulties and delays involved in calling together senior level representatives of organisations. We would like to be assured that the need to formulate the Incident Co-ordination Group does not compromise the speed with which serious incidents need to be investigated and handled. Delays in investigations can have a serious effect on witness's recollections of events.
- The Society would also like to be assured that early decisions would be taken to refer individual healthcare professionals to regulatory bodies where appropriate. Many professional bodies have powers to suspend practitioners from practising. Whilst NHS Trusts and other employers may be able to suspend healthcare professionals from work where there are issues relating to competency and fitness to practise etc, there is no guarantee that such healthcare professionals will not practise elsewhere e.g. in private practice and continue to be a danger to public safety. This may have some implication with respect to Paragraph 20 and 28 of the draft MOU as the relevant regulatory body will need some material before they can suspend anyone on an interim basis. Thus the need to ensure that activities are not undertaken which may compromise subsequent investigations needs to be balanced with the overriding duties to protect other members of the public.

I hope that these comments are of use to you.

Yours sincerely

J T Giltrow (Mrs)
Chief Inspector