

2110

MEDICINES CONTROL AGENCY

FACSIMILE MESSAGE

TO: Mike Arthur (H51) 506 EH

FAX NO: GRO-C

PAGES TO FOLLOW: 2

MESSAGE: MCA contribution to MS(H)
submission on the HIV Litigation

FROM: R.M. Gutowski (MB13)

ADDRESS: 2011 MT

TELEPHONE NO: GRO-C

FAX NUMBER GRO-C

Medicines Control Agency
Market Towers
1 Nine Elms Lane
London SW6 5NQ

Tel No: GRO-C

OUT OF COURT SETTLEMENT

1. Since the early 1980s, with the Opren case (still continuing) the Government, in its role as the Licensing Authority for medicines, has been involved in a number of court actions. So has the Committee on Safety of Medicines (CSM). It has always denied liability and resisted any overtures to be involved in out of court settlements because of the implied admission of liability and the risk that it would encourage further litigation and public pressure for similar settlements out of court. There is already, in addition to HIV, potential major litigation involving benzodiazepines, and the IUD Copper 7.

2. Whilst there may be unique features in the case of HIV officials do not think that any out of court settlement in that issue could be effectively ring fenced so as not to create a precedent. Any such settlement would need to involve the Licensing Authority and the CSM - it could not just include the Secretary of State in respect of his NHS responsibilities. It would accordingly be a precedent for similar out of court settlement of other claims against the Licensing Authority and CSM. It would also be likely to encourage further litigation against the Authority, which would be damaging to the integrity of the licensing system. It could lead on to over-defensive licensing decisions and reluctance of academics to serve on CSM and other S4 advisory committees, on which the Licensing Authority is reliant.

3. Any sort of court settlement could only cover those involved in litigation and be of no benefit to haemophiliacs with HIV infection who were not so involved for whatever reason.

4. Officials would accordingly advise strongly against an out of court settlement in the HIV/haemophiliacs litigation.