



Presidenza del Consiglio dei Ministri

ITALIAN NATIONAL BIOETHICS COMMITTEE

SECRECY IN DRUG REGULATORY SYSTEM PROCEDURES

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abstract

The document tackles the ethical issues raised by the secrecy of data in new drugs authorisation procedures and in the information relative to the drug's development after its introduction on the market. The regulatory authorities are sworn to secrecy due to European regulations and therefore they make public only summative documents about the documentation and the procedures on the basis of which a new drug is introduced on the market. The pharmaceutical industry believes it has the right to uphold the secrecy to avoid spreading information that could be useful to the competition, given the large capital they have to invest to develop a new drug.

The NBC believes that ethics demands the full availability of the data – with well-defined regulations – to scientific societies or patients and consumers associations, insofar as toxicological data and clinical studies are concerned, seen as the patients participate to the trials free of charge and with risk (even if limited). The availability of these data must be possible only after the procedures of authorisation or rejection have been completed. The NBC observes that the Food and Drug Administration publishes all the data whilst this does not happen with the European body EMA and consequently with all national agencies. The NBC hopes for an abolition of the secrecy so that the patients' interest can prevail over industrial interests.