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Biosimilar drugs prescription and professional liability

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The pharmacological prescription represents an important area of interest in professional liability's context due to the always-growing demand to Physician to restrain the expenses while guaranteeing their patients' health, as recommended by the World Health Organisation . Biosimilar drugs, as bioequivalent drugs, are an opportunity for national health services to save economical resources, allowing a wider access to cures to patients . Therefore institutional stakeholders internationally encourage biosimilars' prescription even if some differences can be observed in different Countries .

A prosperous debate upon this matter has been raised, counterpoising Authors who are extremely confident about using biosimilar drugs to other Authors who promote a cautious approach , especially when the indication has been obtained through "extrapolation".

There are two clear examples of the problems linked to the idiosyncratic adverse reactions of biological drugs: TGN1412 and Eprex . Both these experiences should suggest caution in prescribing biological drugs whenever their indications have not been obtained by ad-hoc clinical studies, nonetheless regulatory authorities' guidelines allow the indication gathered through extrapolation. What would be the responsibility of the prescriber Physician in case of adverse reaction, when prescribing drugs according to the regulations? How to implement cost/effectiveness analysis together with the standard of care in an innovative model of professional liability?

Affirming that economical aspects do not concern health workers, rather, those would represent an obstacle for good clinical practice, are no longer sustainable positions; however, it is mandatory to guarantee that a money-saving shaped policy can be ethically acceptable. This is not an easy quest, but it can't be postponed any longer.

The reference in governmental recommendations to the "best Knowledge and Belief" for those physicians who want to prescribe a more expensive drug becomes an excessive burden for the prescribing Physicians themselves.

Nonetheless, everyone who has a role of responsibility (physicians and institutional stakeholders as well) needs to explain and justify his own behaviour to society and to any other interested party (accountability). Moreover it must be remembered that in clinical practice it is not allowed to avoid the sharing with patients about treatments (information and consent) or to move away from evidence based medicine.

Key-words. Biosimilar, drugs, professional, liability

SUBJECT: Clinical Legal and Forensic Medicine **TOPICS:** Medical malpractice