Title: From evidence-based to hope-based medicine? Ethical aspects on conditional market authorization of and early access to new cancer drugs

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From evidence-based to hope-based medicine[1]? Ethical aspects on conditional market authorization of and early access to new cancer drugs.

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Abstract: There is a strong patient demand for early access to potentially beneficial cancer drugs. In line with this authorization agencies like the European Medicines Agency are providing drugs with conditional market authorisation based on positive interim analyses. This implies that drugs are used with insecure evidence of efficacy and adverse side-effects. Several authors have pointed to ethical problems with such a system but up to date no indepth ethical analysis of this system is found which is the aim of this article. Drawing of the four generally accepted principles of medical ethics: beneficence, nonmaleficence, respect for autonomy and justice the ethical pros and cons of conditional market authorisation are analysed. From the perspective of beneficence and non-maleficence it is found that the main problem is not risk of adverse side-effects to patients, but rather risk of less beneficial outcomes than what can be expected which could change incentives for patients' choice of treatment. This is also related to the extent to which patients might make an autonomous choice, especially taking into account problematic psychological attitudes and biases in medical decision-making. However, the main problem is related to justice and an equitable distribution of scarce health-care resources given the opportunity cost of drugs treatment. When using resources on cancer treatments which later might be found to be less efficacious than was first expected, other patients (in and outside the cancer field) are deprived of potentially more beneficial treatments even though their needs might be equally or more severe. At the same time, demanding more evidence has an ethical cost to patients in terms of depriving them of potential benefits in terms of reduced mortality and morbidity. In order to handle these ethical conflicts further research and analyses are required and it is suggested that pricing strategies and information requirements are alternatives to be further explored.
Keywords: Conditional Market Authorisation, Evidence, Ethics, Beneficence, Non-maleficence, Justice, Autonomy

[1] The title in inspired by a press release from the German insurance trust GKV Spitzenverband with the title Stepwise market approval of new pharmaceuticals; Principle of hope should not displace principle of safety 1. Stepwise market approval of new pharmaceuticals: Principle of hope should not displace principle of safety [press release]. GKV Spitzenverband web page: GKV Spitzenverband2016.