Genetically modified medicine; research questions related to new possibilities for treatment and prevention

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Until now, there has been an interesting discrepancy in Europe between the public distrust of biotechnology used for the genetic modification of plants and crops which are used for food of human beings and animals, as opposed to the use for the production of genetically modified medicine. Genetically modified medicine may take the form of genetic modification, but also of GM pharmaceuticals such as insulin. This discrepancy may elicit surprise, since the use of GM crops for food is used for the nourishment of human bodies, and GM pharmaceuticals are also inserted into human bodies in the form of pills or vaccines. Both types of GM products could therefore raise similar concerns with respect to health, safety and (future) wellbeing of human beings.

Since the 1970s, recombinant DNA (rDNA) technology arose and became known as the technology to perform genetic modification (Mora & Torres, 2010). The debate about the desirability of GMOs was first initiated by scientists who expressed concerns and identified possible risks with regard to GMOs. But some GMOs attracted also a lot of public debate: such as agricultural GMOs used to produce food for human beings or animals.

In Europe, the public opinion with regard to GMOs in the agricultural sector remain mainly sceptical and/or ambivalent (Legge et al. 2010; Gaskell et al., 2010; Devos et al., 2007). While many different issues are raised - such as concerns about the usefulness of GMOs, socioeconomic impacts, (loss of) freedom of choice, unnaturalness of genetic modification, inequalities between industrialized and poor countries, fallibility of experts, and sustainability of agriculture- the most important topic of public concern remains the safety of GMO food, and the consequences it may have for individual and public health. (Schuttelaer et al 2006; Legge et al 2010; Devos et al., 2007; Stol & Nelis, 2010). Most prominent among the risks mentioned for human beings are that GM food could disrupt or silence some existing genes, or modify their expression, or it could alter patterns of metabolites. It supposedly could lead to the development of new allergies, harmful toxins that the body cannot handle, or antibiotic resistance. (Legge et al 2010) Based on such considerations, consumers indicated in 2010 that safety was their main reason to object to GM food, even though the European Union (EU) declared the GM products safe for human use (Stol & Nelis, 2010).

It is interesting that genetic modification in the agricultural sector receives so much public attention, while the application of genetic modification in medicine is hardly objected to at all. In fact, the public has even expressed positive expectations with regard to the development of GM medicine. (Stol & Nelis, 2010) This is especially surprising because specific health-related concerns are raised with respect to GM food -including concerns about future resistance against antibiotics- which are not raised with respect to medicine. How can this discrepancy be explained?

It may be hypothesized, of course, that the public may be more appreciative of GM medicine as opposed to GM food because its risk-benefit balance differs when treatment of a diseased body is

concerned, while food is in principle consumed by healthy bodies. But GM medicine does not only solve a health problem. There are also new GM vaccines being produced(for example against influenza), which are supposed to protect the public against outbreaks of infectious disease. This raises the question whether present public acceptance of GM medicine will persist in the future, and also whether it vaccines will be accepted as well, which are in principle used on healthy bodies to prevent disease-outbreaks at a population level.

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Empirical questions

- How can this discrepancy between the hot debate about GM food, and the lack of debate about GM medicine be explained?
- Are members of the public aware of the GM nature of some medicines?
- What kind of expectations do members of the public have with regard to GM medicine and to GM food?
- What hard and soft impacts play a role in the public's considerations about (the future of) GM food and GM medicine?
- What are the different values and norms that play a role in the public's considerations about GM medicine as opposed to GM food?
- What is the role of 'trust' in people's expectations?
- What do people consider risks and benefits related to GM food and medicine? (And how do they perform the risk-benefit analysis?)
- How does the public assessment of GM medicine for treatment purposes compare to the public assessment of GM vaccines used for prevention of infectious diseases?

Ethical questions

- How should risks be communicated to patients/members of the public to whom GM medicine/vaccines are proposed? (How much information is sufficient/ justified to make an informed choice possible)
- How can we strike a balance between protection of autonomy (informed choice) and protection of the health of the public? (Is 'nudging' allowed when GM medicine/vaccines are proposed?)
- What is the responsibility of individual members of the public, of professionals, of health care institutes (such as hospitals), insurance companies regarding GM medicine/vaccines?
- What is the responsibility of researchers and pharmaceutical companies with regard to the public acceptance of GM medicine/vaccines?
- Should there be a division of roles with regard to care for safety, health, public trust and autonomy?

Policy questions

- Are there reasons to expect more controversy in the future regarding GM medicine or GM vaccines for prevention?
- What consequences can this have for the future public acceptance of medicine/vaccines, and for the protection of the health of the public? (Can it lead, for example, to lesser acceptance of vaccines, inefficient herd immunity, outbreaks of infectious diseases)

- How can policy-makers prepare for this future?
- Should the public have a role in decision making about future policy regarding disease management with GM medicine/vaccines? (If yes, what role?)

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