Drug evaluation involves many actors

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The drug evaluation process engages many different groups in society: the pharmaceutical company developing the drug, the national drug agency, international authorities such as the European Medicines Agency and the US Food and Drug Administration, committees for establishing national drug treatment guidelines, drug selection committees, the prescribing physician, and finally, the patient are those directly involved. Indirect actions and opinions are put forward by pharmacists, nurses, media, lawyers, politicians and patients' relatives and friends. Judgments and opinions will coincide for several of these actors but there might also be total contradiction in the final conclusion from some of them. Who is right … and who is wrong? All can be judged to be right from their perspectives. A physician may be negative about a certain drug in the drug formulary committee but then prescribe the same drug some hours later for a patient not responding to another therapy!

All actors emphasise the beneficial effect to the patient and at the same time want to protect the patient from damage due to drug-related adverse effects. The first actor to evaluate the drug is the drug authorities. Their task is most difficult because of the limited knowledge and experience that will exist for a new drug. They must take a safety perspective in favour of the patient. Their position is also dual. If a drug is approved for marketing and becomes a great success, the drug company is honoured. However, the authority that approved the drug will be seriously blamed if the drug is a failure with deleterious adverse effects.

The most extensive knowledge about the drug is held by the pharmaceutical company. Even this knowledge is limited, however, since relatively few treated patients make up their knowledge base. The success of the drug is of high importance for further development of other medicines and the survival of the company. Clinical studies with comparisons to competing drugs or previous treatments are used in marketing to emphasise the positives of the drug and gain a position in the market.

Physicians try to be as well informed as possible and read the scientific literature specific to the area of their prime interest, presented in national medical journals, guidelines and recommendations from national focus groups, the drug formulary committee, supported or independent meetings and workshops. There is a continuous flow of drug information they have to catch. Nevertheless, their most important informants according to them are colleagues in the same clinic or the same specialty, and the patients.

The patient is the final decision maker on the success of a new drug. The medication must suit the patient to be accepted and its advantages must be recognised. Patients often want a pronounced positive effect within hours or days. Side effects are feared beforehand and after taking the first doses. Intolerable side effects to the patient, but not necessarily recognised by the prescribing physician, will cause a patient to stop taking the drug or to amend doses. Information from media, friends and family might give an exaggerated view on the disadvantages of the drug. Other misconceptions play a great role, for example, green tablets give more side effects than white tablets, injections are more efficient than tablets, suppositories are seldom used in the UK but more in southern Europe, or an attractive name. Fear of drugs being chemical poisons is widespread, although the majority of drugs are generated from plants and other biological sources. Nevertheless, if the patient does not take the medicine it will never be sold. Irrespective of the obvious benefits, low patient acceptance will not create the economic success that is necessary for the development of new drugs. Thus patients are the most important determinants for the overall outcome of a new drug.

There are many facts and professional opinions, mixed with misconceptions and irrationality, that are combined together in the final overall conclusion of the value of a drug. This brief survey highlights some opinions from those who are directly involved but further understanding and knowledge is necessary to improve the situation and also patients need to be included in evaluations. Cases from the actors giving opinions on a drug are highly interesting and illuminate the process in more depth, for example, a paper published in the *European Journal of Hospital Pharmacy*. Your contribution is highly welcome.

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