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## Best Practice & Research Clinical Gastroenterology



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### Expensive cancer drugs and just health care



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#### A B S T R A C T

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Extremely expensive drugs which cost more than 100.000 \$ per year for the treatment of one patient are increasingly common. The benefit of these drugs may either be not accessible to many patients or the overall costs could lead to a heavy burden on the health care system and public resources. This article describes the overall background of this trend and addresses the problem of expensive drugs from a perspective of just health care and just health outcomes. Therefore, basic aspects of just health care are outlined such as goods and principles relevant from a perspective of justice. This framework is applied to the allocation of expensive drugs on three levels. These reflections will demonstrate that there is no simple solution to this problem, and that the decisions cannot be taken by experts, but should be the result of an open, transparent, and fair public dialogue on health priorities.

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#### Introduction

Medical interventions may be expensive for different reasons. Some surgical procedures are complicated and time-consuming and therefore costly. Diagnostic interventions may require expensive technological devices such as a CT or MRI scanner. The focus of this article is on particularly expensive pharmaceutical drugs. This refers to a relatively new phenomenon, which may reflect a general trend in the development of new pharmaceutical drugs and the provisions for health care, which is also playing a prominent role in gastroenterology [1,2]. If this supposed trend indeed becomes

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a reality, it would raise difficult ethical questions regarding just distribution or allocation of health care resources [3].

According to the 2011 health statistics of the Organisation of Economic Cooperation and Development (OECD), pharmaceuticals accounted for around one sixth of health care spending in OECD-countries. From 2000 to 2009, average spending on pharmaceuticals has increased by 50%. During this time spending on pharmaceuticals (an increase of 3.5) has not risen any faster than average health care spending in general (an increase of 4%), which reverses the general trend in the past. Since 2009 spending on pharmaceuticals even dropped by –0.5% due to the financial crises and measures of price control. In 2011 the average spending for pharmaceutical drugs was 483 \$ per capita [4].

The pharmaceutical drugs this article refers to by far exceed this figure for the annual per capita consumption of pharmaceuticals in general. In 2010, eculizumab, a monoclonal antibody used to treat the rare disease paroxysmal nocturnal haemoglobinuria (PNH) cost nearly 1000 times as much for the treatment of one patient per year: 409,000 \$. Matthew Herper, a staff writer for Forbes magazine, lists this drug at the top of the list of the ten most expensive pharmaceuticals available, which were priced at 200,000 \$ on average [5]. Most of these drugs target rare diseases or ‘orphan diseases’, officially defined in the EU as diseases from which less than five persons in 10,000 suffer [6].

Providing access to drugs for orphan diseases has been considered an important ethical problem, and was addressed by the European Union in 2000 (see <http://www.eurordis.org/eu-rare-disease-policy>, accessed 23.11.2013). It might seem as though only a small number of people are afflicted with such diseases, so financing this provision and consequently allocating the appropriate pharmaceuticals fairly would not be the most complicated aspect of this problem, even if these drugs are hyper-expensive. However, the number of ‘orphan diseases’ is on the rise. David Hunter estimates that there are 6000–7000 diseases that meet the criteria, and each week about five new ones are added in the medical literature [6].

Another important development in this context is the discovery of genetic subtypes of cancer, which practically splits cancers of one organ into many different rare diseases. Consequently, newly discovered pharmaceuticals only work in a small subgroup of cancer patients, and as a consequence of this, a higher price is charged for them, albeit not as high as for the pharmaceuticals for ‘orphan diseases’ mentioned above. A well-known example is bevacizumab, which is a monoclonal antibody also used for the treatment of colorectal cancer. The treatment of one patient costs around 50,000 \$ annually, which is still a hundred times more than the average per capita cost for pharmaceuticals in OECD countries [7].

### **Interconnected trends: expensive drugs, ‘personalized medicine’ and rising health care costs**

Expensive drugs for rare diseases and for cancer, such as eculizumab and bevacizumab, seem to be becoming more common. In a recent article about expensive drugs, Peter Werth refers to 39 new drugs that were approved by the FDA in 2012, all of which were either new drugs for rare diseases or drugs that showed marginal improvements over existing cancer drugs. Since this number of approvals is the highest in more than a decade, there is hope that a trend of increasingly difficult pharmaceutical innovation may be reversed [7].

This development might be part of a more general trend toward so-called ‘personalized medicine’. Seeing as though medical doctors have been asked to be aware of the individual character and living circumstances of their patients since as early as Hippocrates, some commentators have remarked that ‘personalized medicine’ is in fact what medicine was always supposed to be [8]. The allegedly new idea is that medical treatment should be adapted to the biological features of a single patient. However, at least for now, some critical commentators of this terminology have rightly remarked that we should rather refer to it as ‘stratified medicine’. Patients are actually divided into groups – or their therapy is ‘stratified’ – and not treated on the basis of a genuine assessment of what distinguishes them as individuals. One important aspect in this new medical development is the possibility of a personal genome scan, which is supposed to reveal genetic risks and disease dispositions for an early treatment or life style intervention. The second important aspect is pharmacogenetics or the adaptation of treatment options according to the genetically determined response of one patient or a group of patients to a specific pharmaceutical drug [8,9].

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