Response to proposal for a novel cancer drug pricing model

Toon van der Gronde, Hubertus G. Leufkens and Toine Pieters

In their recent News & Views article (Sustainability and affordability of cancer drugs: a novel pricing model. *Nat. Rev. Clin. Oncol.* **15**, 405–406 (2018))[1], Uyl-De Groot and Löwenberg outline a new universal algorithm for setting the price of new drugs in oncology. Their ambitious proposal is intended to standardize a complicated and fragmented pricing process. The international drug market is dynamic and diverse[2]. Having a universal pricing mechanism could indeed be helpful in addressing the imbalances in drug pricing and improve access to medicines for many patients, including those with non-oncological diseases. However, we would like to point out some thoughts on the proposed algorithm.

First, the scope of the algorithm seems to be limited to the USA and European Union (EU). Outrage about high drug prices and the associated limitations in access to potentially life-saving drugs are certainly not limited to these regions. Importantly, most of the economic and population growth in the next few decades, and subsequently the burden of disease, will be in developing areas of Asia and Africa. Therefore, to have a truly universal framework, these regions would have to be included. Furthermore, the correction factors for countries with varying levels of economic development should be based on a more sophisticated tool than the one proposed, based on gross domestic product per capita equivalent costs per disability-adjusted life year averted[3].

Second, all parameters of the algorithm carry inherent risks of unwanted stakeholder behaviour, by both industry and payers. Acknowledging research and development (R&D) costs seems reasonable, but this does not necessarily encourage improvements in clinical benefit. Even if the price of R&D could be calculated objectively (the analysis cited by the authors[4] is already highly debated[5–7]) and if governments succeed in transnationally coordinating the reimbursement of R&D costs, this could stimulate spending on R&D with very little incentive to bring meaningful improvements in the quality of life of patients.

Third, years left on patent is a parameter that provides ample opportunity for interest-based manoeuvring. Patents are frequently extended or renewed based on additional research efforts (such as extension of a patent after the completion of research in paediatric populations[8,9]) or changes in formulation, thus making estimates of remaining patent life unreliable. Furthermore, the 3-year evaluation period would incentivize producers to delay the launch of any new drug indications until after the recalculation, so that the target population is smaller and, therefore, the accepted drug price will be higher. Similarly, such measures would encourage companies to introduce new indications as quickly as possible following recalculation, in order to maximize financial benefit at the expense of both patients and health-care providers.

In conclusion, the development of a universal framework to guide something as complex as the drug pricing process is an admirable undertaking that merits ample debate. Any model that is adopted will drive stakeholder behaviour towards optimally satisfying their own interests. The key challenge is, therefore, to align the interests of stakeholders with those of the general public. Even the best available model, value-based pricing, can lead to unacceptable outcomes and limitations in access. This scenario is seen in the recent debate around hepatitis C products, which have superb clinical benefits but are unaffordable for the population[2]. The proposed algorithm is a laudable initiative, but requires careful assessment to ensure the provision of a framework that helps streamline the pricing process and also ensures equal access to new drugs for patients around the world.

There is a reply to this letter by Uyl-de Groot, C. A. & Löwenberg, B. *Nat. Rev. Clin. Oncol.* https://doi.org/10.1038/s41571-018-0063-6 (2018).

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Competing interests
T.v.d.G. works in a full-time position for AstraZeneca. AstraZeneca had no influence on any aspect of this manuscript. H.G.L. reports that he is the past chairman of Dutch Medicines Evaluation Board and past member of the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP), and scientific director of the Utrecht WHO Collaborating Centre for Pharmaceutical Policy and Regulation. This centre accepts no direct funding or donations from the pharmaceutical industry or other private parties. T.P. declares no competing interests.

REPLY

Reply to 'Response to proposal for a novel cancer drug pricing model'

Carin A. Uyl-de Groot and Bob Löwenberg

We agree with the statement (in response to our original publication[1]) that the development of an improved framework for drug pricing requires streamlining of the process to ensure equal access of patients with new drugs (Response to proposal for a novel cancer drug pricing model. *Nat. Rev. Clin. Oncol.* https://doi.org/10.1038/s41571-018-0062-7)[2]. This requirement has been precisely the motivation for our entirely different approach in proposing a novel pricing system. Some potential practical impediments are also

highlighted. Excuses to avoid implementing changes to the current practice of drug pricing will always exist. These excuses have helped to maintain the current impasse of unsustainable and insufficiently accessible cancer drug delivery to patients in need of treatment. There is no such thing as a perfect model for drug pricing and any system that is adopted can be further improved based on accumulating experiences. The emphasis of our proposal is to identify the key variables in the decision process and to move and take action, we hope with the full support of all stakeholders, actively supporting the necessity of change.

While we agree that aligning the interests of stakeholders, including the industry, with those of society is of the utmost importance, we emphasize that the current balance is unreasonable: exceptional profits have resulted in insufficient access to essential drugs and pose a threat to the sustainability of national health-care systems. On many occasions these issues have been raised by various stakeholders, including patient groups, policy makers, professional, scientific, and medical societies.

As a very recent example, the European Parliament has adopted a resolution on options for improving access to medicines in the European Union (EU)[3]. The text of this resolution states that more transparency is urgently required in determining the costs of research and development, including the proportion of publicly funded trials and the costs of marketing. The language of the resolution is unambiguous regarding the equal rights of citizens of the EU, and the resolution stipulates that access to essential medicines should be improved substantially. Our model is in line with this resolution. Patients have a fundamental right to health and to receive the best available medical treatment, therefore we have to address this challenging issue together. We hope that our model will be instrumental in creating an acceptable balance between social and economic entrepreneurship.

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Competing interests
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