Proposals to lessen the shortage of essential cancer drugs, generics and biosimilars in the US and the world

Essential cancer and supportive drug shortage in the US seriously affects cancer care, and increases cost pressure on the health system. These drugs are mostly off-patent generics. Collaborative efforts of FDA, pharmacists, physicians and pharmaceutical companies slightly improve this problem. However, these measures are partial. For an issue of multiple complexities there is no single magic stick that could solve it. The underlying economic issues and lack of incentives for production need to be addressed to arrive at innovative and permanent solutions for this multifactorial problem [1, 2].

Generics constitute about 80% of drug prescriptions of all medical specialties in the US. This study [1] aimed to explore scientific and effective solutions to maintain sustainability and affordability of most cancer drugs in the US and the world.
Among short-term measures to ease a crisis were:
a) use of an alert system with priorities to control drug shortages
b) minimization of drug wastage during administration
c) purchasing drugs from grey markets to compensate shortages
d) FDA approved importing some off-patent or unapproved drugs from developing countries as a temporary alternative solution. However, this would not be considered as a sustainable solution and it could create shortages in developing countries [1].
Pricing policies in Europe for generics motivate more production and brand-name drugs are cheaper than in the US. However, shortage of essential and generic cancer drugs in Europe is caused by exporting to make profits due to price differences between Member States. The Europe Union has introduced quotas to stop exporting practices that worsen the situation due to parallel trade. Setting an average sales prices (ASP) for generics would increase the total cost of cancer care unless there was a parallel reduction in the price of brand-name drugs, as is the case in Europe.
Brain storming ideas to improve profits and incentives of producers have been discussed [1, 3]. Major pharmaceutical companies distribute their generics in and outside the US. These off-patent products need incentives, such as:
a) Prescription Drug User Fee Act new version would raise industry fees by 6%. This speeds FDA approval of new devices and biosimilars and inspection of foreign drug production.
b) Repair the system of compensation of oncologists in the US – and hopefully would be inspired by many less affluent countries – reducing their dependence on prescription incentives for expensive drugs by paying them for all services presented (consultation, diagnosis and treatment) regardless of the number and the content of their prescriptions.
c) Repair the system of remuneration for pharmacists.
d) Carry out research into the repurposed utilization of single or newer combinations of older drugs to improve the continuity of gaining profits for production of these drugs.
e) Not-for-profit oncologists coalitions could address measures for shortages that

include scientific research.
f) Reasonable profit after patent protection ends could encourage pharmaceutical companies to produce their older drug or its active ingredients for other companies producing generics in the US and the world. The system has to be profitable for all parties. Gradual price reduction of drugs after the end of patent protection and giving priority for the purchase of the brand-name drug at a lower price after their patent has expired, even if it is at a slightly higher price than generics in different groups of countries or for the generics made of the originator's active ingredients, hence giving incentives for both the originator manufacturers and the development of profitable generics industries in different countries.
g) Despite complexities and variability, regular reviewing of the pricing of drugs in affluent and less affluent countries are required.
h) Import of generics from developing countries could be more activated after bilateral agreement including surveillance and providing technology to insure quality. All would win.
i) International measures concerning smuggling of cheaper packs have to be condensed.
j) More multicentre clinical trials are important to ensure the therapeutic equivalence of generics and biosimilars and this could be the route to increase affordability of better value cancer care drugs in the world.
The author suggested 'The Fourth way' as a new malleable and pragmatic system for the international economy [1]. The whole article could be a model for application of the 'The Fourth way' in the field of this study that could affect positively all stakeholders, endorse innovation in ideas and to keep both the progress in science with its costs and increasing affordability of better value cancer care in the world within win-win scenarios [1, 3].

Conflict of interest

The author of the research paper [1] declared that there were no conflicts of interest. Abstracted by Professor Ahmed Elzawawy, President of ICEDOC, President of AORTIC and Director of SEMCO.

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