KEI statement: 24rd meeting of the WHO Expert Committee on the Selection and Use of Essential Medicines

24 April 2023

KEI will address two issues.

First, in considering the inclusion of medically effective but costly medicines, the Committee can be explicit that a product should be included on a national list **when** and **if** the product is available at an affordable price.

The high prices for new medicines are often due to policies, and not physics, chemistry, biology, or manufacturing costs.

Policies to grant or protect a monopoly, through patents on inventions, regulatory exclusivities or protection of know-how secrecy, are often justified as instruments to induce investments in R&D. But this may not be appropriate where incomes are low and the monopoly undermines the objective of access to medicine for all.

Governments can regulate or eliminate monopolies, and some do.

Governments can and should also implement alternative mechanisms that delink R&D incentives from a government backed temporary monopoly. This year, it is more obvious than ever that it is more likely that a monopoly will effectively regulate the government than the government will effectively regulate the monopoly. We need to acknowledge the evidence that monopolies are nearly impossible to regulate in the public interest, particularly as regards the global inequality of access to new medicines.

Placement of an effective treatment on the EML can legitimize access expanding policies, and the contrary is also true. Drug companies often say that if a drug is not on the EML, governments should not regulate or eliminate the monopoly.

In the past, drug companies have cynically claimed that the low number of patented medications on the EML is evidence that patents are not a barrier to global access to essential medicines, even though the opposite is logically the case.

Second, the treatment of rare diseases is not unimportant in developing countries. It is not appropriate for the EML to focus solely on products with the greatest incidence. In 2023, developing countries are both able and inclined to provide treatments for rare diseases, when the treatments are affordable.

In high income countries, a remarkably high percentage of new drug approvals are now for rare diseases. Twenty years ago (2003), 19 percent of USA FDA novel drug approvals were classified as Orphan Products. Last year, 52 percent of novel drug approvals were Orphan Products.

Melissa Barber's comments on the application for risdiplam, a small molecule drug used to treat spinal muscular atrophy, notes that the question of whether or not medicines for rare diseases should be included on the EML is not a new one, and also highlights that inclusion of medicines into the Model List of Essential Medicines can in itself be an important step in catalyzing policy actions that may lead to more affordable pricing.

In conclusion, our two points are:

1. The Committee should be explicit that a product should be included on a national list when and if the product is available at an affordable price,

2. The Committee should recognize the growing importance of drugs to treat rare diseases.