

| Question   | Answer   |
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| Do you have any conflict between the inventory control (shortage and distribution etc..) and the regulatory functions? If yes, what is the best solution?  | I am less concerned about a role for an NMRA in tracking and responding to medicine shortages, as that is not the same as procurement and distribution. However, the SFDA's role in pharmaco-economic analysis and pricing is more challenging. Keeping registration and selection separate is more common, with pricing linked to reimbursement. Andy Gray (South Africa) |
| Do you have any conflict between the inventory control (shortage and distribution etc..) and the regulatory functions? If yes, what is the best solution?  | no there is no conflict because we are monitoring the products not the practice and till the releasing the product from storage that's belong to our authority according to the law. clear ?   |
| Question to Judith: Local production should be a solution to many of the challenges mentioned? What is the strides taken by PAHO Member states?  |  |
| Price transparency may also mean consumers understand how prices are set and are aware of price discrimination. In health care markets consumers often have difficulty finding useful price data. In particular, few consumers have a clear idea of what hospital stays or hospital-based procedures will cost, or understand how hospital charges are determined. |  |
| many views domestic manufacturing of medicines solves the access and affordability issues, however do you think LMICs and their economies of scale supports this argument if yes how?  |  |
| Can the evidence from other markets be used to analyze the effects of greater price transparency in health care markets, or provide guidance about what measures might best be considered?   |  |
| sounds like there's an echo or something, perhaps an administrator has a microphone open ?   |  |

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| <p>There is a need to know what areas of the system are less than optimal transparency and vulnerable to corruption. There is a need to monitor how pharmacies, hospitals, and health care providers are reimbursed for pharmaceutical products.</p>  |  |
| <p>Question in regards to the WHO-EML decision to reject the applications for effective and endorsed cancer medicines by different guidelines due to high prices, with concerns that may affect states budgets! is that the right decision from your perspective or listing those medicines and letting the states negotiate for fair prices and influencing manufacturers to lower their prices with some innovative solutions ?</p> | <p>This is a very good point, thanks for asking! I believe overall we have dismal evidence to support that universal listing is associated with better prices at global level. However, I see that WHO-EML is a best advocacy tool that may enhance penetration of new cancer drugs, at least by utilization and prescription perspectives, that to me is a proxy of re-budgeting and cancer care prioritization, when framed under UHC and financial risk protection, oriented to equity. However, what do other stakeholder feel and know?</p> |
| <p>'@Ellen: how we can make low volume high priced newer patented immunotherapy and targeted therapy medicines in LMICs?</p>  | <p>first step is that the companies should apply for registration. In many low-income countries the products are not offered, so they cannot become available. See also the Wellcome report on monoclonal antibodies</p>   |
| <p>'@Ellen: how we can make low volume high priced newer patented immunotherapy and targeted therapy medicines in LMICs?</p>  | <p>Also, some domestic companies are now developing immunotherapy agents with the promise to be more affordable and locally relevant. I am seeing many Asian companies expanding into the global market, coming with the goal of sustainability. Is this a good start?</p>   |
| <p>'@Ellen: how we can make low volume high priced newer patented immunotherapy and targeted therapy medicines in LMICs?</p>  | <p>at the Medicines Patent Pool we are trying to address this issue. Let me know if you would like to connect.</p>   |
| <p>'@Ellen: how we can make low volume high priced newer patented immunotherapy and targeted therapy medicines in LMICs?</p>  | <p>Giulia, this is such an amazing interest from MPP!</p>  |

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| <p>One problem with making prices more transparent is that the cost can vary depending on who is paying: the patient, the doctor, the insurance company, or the employer. Another issue is just not having enough price info and people not really caring about using the info that's out there. Thus, what are the recommended price transparency tools by WHO?</p>   |   |
| <p>what is the emaning by de-linkage model?</p>  | <p>Here you will find some basic information about Delinkage:<br/> <a href="https://delinkage.org">https://delinkage.org</a></p>  |
| <p>I agree we need more transparency on how prices are set, more generally, in terms of "payers" being more explicit and clearer on criteria and processes, and industry explaining better what goes into their pricing decision. But being transparent on net prices, given all the global interlinkages across countries, might have some perverse effects. Perhaps time for some global agreement? Very difficult, I know, but I think it could be a great start.</p> |   |
| <p>La transparence est un point clé , comment la concrétiser</p>   |   |
| <p>Vous avez parlé des projets pilote pour lutter contre le monopole , comment les mettre en place</p>   | <p>Les pays pourraient se réunir et convenir de financer le développement de produits de santé nécessaires, en particulier ceux qui n'intéressent pas l'industrie, comme les antibiotiques.</p> |
| <p>Last local production forum there was a session on investment and building the right investments for better access, my question is to Thomas.. This is very much applicable to high income countries and to some extent to low middle income countries but still it is more challenging what are your insights to increase investments and private capital for better access to medicines in LMICs?</p>   |   |

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| <p>Excuse me, I am from Cambodia. There are 3 participants from Cambodia. But one of us did not get the email so she still can't join the meeting. Her email is kou.raxmey@yahoo.com. Thanks in advance.</p>  |   |
| <p>Ok, what is the tool to monitor the products? thanks</p>   | <p>we implementing an electronic system named as track and trace which help to track each medicine from the manufacturer until releasing from the storage to the las beneficiary</p>  |
| <p>what kind of tool do you use for the monitoring?</p>   |   |
| <p>In today's world, where there's a ton of information and really tough competition in the markets, being transparent is super important for businesses to do well. It helps build trust, relationships, and boosts productivity. Plus, it's a big driver for sparking innovation. The healthcare industry is growing crazy fast worldwide. It spends trillions of dollars every year. With all that money flying around, there's a big risk of corruption, so transparency is crucial. Health procurement is especially at risk for being influenced, misused, and being inefficient, especially because it's so specialized.</p> |   |
| <p>It has been discussed that there is a disconnect between high prices of innovative therapies and their overall value, what is the role of HTA or managed entry agreements to inform pricing decision-making, what is WHO's position on this matter?</p>  | <p>I strongly believe we need HTA to be guided by standardized value metrics, to ensure consistency. Still, we need an overall 'model' to ensure decisions are locally contextual. At this point, we have value metrics but we don't use much at global level, but there are very good examples from countries, including the National Cancer Grid India, that has piloted and implemented the inclusion of value metrics in decision-making and as part of a structured framework to serve HTA purposes.</p> |

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| <p>Local production will not pick up the tab for most countries. Innovation is too overbearing. But because of outlandish prices and lack of transparency, and the fact that governments are very substantial buyers, there is room for more insistent and strategic negotiations from governments individually and as consortiums.</p>  | <p>Hi Claudia! I agree with your point. Also to add innovation is certainly important but innovation has not always translated to high-benefit medicines, especially in oncology. Negotiation based on value is essential.</p>  |
| <p>Local production will not pick up the tab for most countries. Innovation is too overbearing. But because of outlandish prices and lack of transparency, and the fact that governments are very substantial buyers, there is room for more insistent and strategic negotiations from governments individually and as consortiums.</p>  | <p>Can't emphasize Kristina's statement more! Innovation is a term that applies to technology achievements, but in an outcome-based oncology planning, to pursue impact, we need to consider both how and what new medicines deliver. Innovation alone is important, when declinated toward efficiency-improvement, contextualisation and better outcomes. Otherwise, it's just another path to pursue something that eventually is unchanged - that means, no impact. What is innovation, at the end, but for better outcomes?</p> |
| <p>Costs of pharmaceutical R&amp;D are very high, estimated to be in the range of \$1 T. Costs to develop medicines exceed \$1 M and it takes ca. 10 years to develop a new drug in some cases. According to my understanding pharmaceutical industry compensate R&amp;D costs. How to encourage more enhanced transparency about costs and pricing/pricing models, especially for innovative medicines and (emerging) technologies? Could HTA agencies play a significant role and contribute to enhanced transparency?</p> |   |
| <p>There is a need to look at regional pooled procurement mechanisms - we need political and administrative will to make this work! We cannot keep on hearing that it is difficult with financial systems. ACT now! There are exmaples of how this can work</p>  |   |

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| <p>Yes, Kristina, hi! Excessive expression of the 'innovation- very-high-cost' is detrimental to all. It may come to a 'shooting-your-foot' situation for industry and governments. No one being able to pay and no one being able to buy.</p>   |  |
| <p>great! many thanks. further information need to me about the electronic system then. keep in touch.</p>   |  |
| <p>IGBA ,Given the stringent regulatory environment that significantly drives down prices, especially for generic companies like ours, even when we are the first to introduce a generic product, what strategies can be implemented to address this issue? How can we navigate these strict regulatory authorities to ensure a viable pricing strategy that allows for successful product launches?</p>   | <p>Regulation is important and must be assure quality. there are possibilities to improve the efficiency, for example of scientific requirements or of maintenance requiriements. This can make it more sustainable.</p> |
| <p>Hi, Emily Dowdalls from Wemos foundation in the Netherlands here. I am curious how IGBM looks at the WHO Fair Pricing definition and if fair pricing regulation should improve the availability of medicines (reduce the shortages issue)</p>   |  |
| <p>A recent WIPO report found that intellectual property enabled all stakeholders - biotechs, universities, and pharmaceutical companies - to share information and was instrumentally to the rapid development of COVID vaccinees and therapeutics and that without IP protections and mechanisms for partnership grounded in IP, there would have been significant delays in access. Could Thomas from IFPMA speak more to the role of IP and address the comment that out of 350,000 patents granted by the US PTO, a fraction (only 100 as noted by the other speaker) may only be abused.</p> |  |

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| <p>my question is to Dr Ali / SFDA ,If our product's suggested price is determined based on several alternatives available in the market, but it turns out to be not cost-effective, will this result be the determining factor for price reduction, even though other alternatives continue to enjoy high prices in private markets and tenders?</p>   |  |
| <p>Adrian said that to assure the sustainability of off-patent health products, we have to assure that price competition is taking place. Is there any suggestion on how can we enforce those suppliers comply to what we need, I mean, sometimes, there are trade-offs, for example price with remains shelf-life of medicines, etc that on the other side, often we do not have any other options that that few suppliers (that often act as cartels)?</p>  |  |
| <p>With respect to capacity of local pharma industry in LMICs, I noticed many times their formulations are not cost effective, because there is no attention to product development. These companies, therefore, unable to manufacture even the most common dosage forms of essential medicines. There is also a need to build capacity targeting their product development approaches/product formulas so that they continue manufacture what they are able to in a cost-effective manner. Having an optimized, cost-effective formula these companies could save significantly and help themselves divert resources to manufacture new medical therapies and able to investment in advanced dosage forms.</p> | <p>Great comment. This report outlines many of the challenges, including the need for significant investment in healthcare and ensuring demand for products: <a href="https://cms.wellcome.org/sites/default/files/2023-01/Wellcome-Biovac-BCG-Scaling-up-African-vaccine-manufacturing-capacity-report-2023_0.pdf">https://cms.wellcome.org/sites/default/files/2023-01/Wellcome-Biovac-BCG-Scaling-up-African-vaccine-manufacturing-capacity-report-2023_0.pdf</a></p> |
| <p>Equity-based tier pricing and market transparency (emphasis on publicly shared knowledge on RnD costs and patents) are important pillars to move forward with fair pricing</p>   |  |

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| Transparency in pricing has been noted by many speakers, but even the OECD has noted, “Coordinated international action on fully disclosing data on net prices is not necessarily desirable or sustainable as it would require extraordinary political commitment to overcome dominant national self-interest.” Could any speakers address the fact that transparency would further exacerbate inequalities across countries with lower income country being then unable to use novel payment models designed to improve affordability. |   |
| my question is to Dr Ali / SFDA , Are the prices of generic products in countries with lower incomes than Saudi Arabia taken into account when you priced those products in KSA ?   |   |
| Please see the link to AIM's Fair Pricing Calculator: our contribution to finding a new balance: <a href="https://fairpricingcalculator.eu/">https://fairpricingcalculator.eu/</a>  |   |
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| <b>Title</b>  | <b>Link</b>   |
| Delinkage   | <a href="https://delinkage.org">https://delinkage.org</a>   |
| Scaling Up African Vaccine Manufacturing Capacity   | <a href="https://cms.wellcome.org/sites/default/files/2023-01/Wellcome-Biovac-BCG-Scaling-up-African-vaccine-manufacturing-capacity-report-2023_0.pdf">https://cms.wellcome.org/sites/default/files/2023-01/Wellcome-Biovac-BCG-Scaling-up-African-vaccine-manufacturing-capacity-report-2023_0.pdf</a> |
| AIM's Fair Pricing Calculator   | <a href="https://fairpricingcalculator.eu/">https://fairpricingcalculator.eu/</a>   |
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