MINISTRY OF HEALTH
SINGAPORE

SPEECH BY MINISTER FOR HEALTH MR KHAW BOON WAN
AT 14TH INTERNATIONAL CONFERENCE OF
DRUG REGULATORY AUTHORITIES
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"Safer, Better And Cheaper Drugs For All"

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Distinguished Guests and Participants

1. Singapore is honoured to host the WHO's 14th International Conference of Drug Regulatory Authorities (ICDRA). On behalf of the Singapore Government, I extend a warm welcome to all participants, especially to our overseas guests.

2. The ICDRA is the only global forum for national drug regulators to meet and discuss. Our common objective is to improve the safety, efficacy and quality of medicines around the world. In simpler terms, how to ensure that patients get safer, better and cheaper drugs?

3. All over the world, disease demographics continue to change, and in drastic ways. Infectious diseases remain a major problem, even as life-style risk factors and chronic diseases have grown to become major health challenges. As a result, healthcare systems everywhere are under tremendous stress. Rapidly aging populations and shrinking birth rates are compounding the healthcare crisis.

4. This is a classic economics problem, where demand is outstripping supply and society has to decide how best to allocate limited resources against almost unlimited demand. It is also a classic political problem as equity is involved and

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the market cannot be the sole platform to do the distribution. The issue becomes politicized as healthcare is often also a life-and-death issue.

Tele-Innovations

5. The ideal outcome is for the health sector to behave more like, say, the telecommunications sector. For example, in telephony services, there is a wide range of competing brands of mobile phones and services are improving even as prices are dropping. As a result, even the poorest villagers in third world countries often have access to basic mobile telephony, not the iPhone but some cheaper alternatives, good enough for mobile communication.

6. Unfortunately, healthcare is more complex than mobile telephony. As a result, the health sector is far from the ideal state of getting cheaper and better. But we should strive towards such an ideal outcome. There are examples of innovations which make healthcare cheaper and better. Tele-radiology is one example. In Singapore, we do not have enough radiologists to put them in polyclinics. Through tele-radiology, X-rays taken at the polyclinic are now transmitted real-time to the hospitals, with good enough quality for the radiologists to read and report on them, while the patients are still in the polyclinic. This saves the patients another trip to the polyclinic, which they previously had to do, when the radiologists' reports were received from the hospital. In fact, our simple X-rays are now read by radiologists in India, thus freeing up our radiologists to focus on more complicated scans.

7. Likewise, we do not have enough ophthalmologists to put them in polyclinics. In the past, polyclinic patients with suspected eye problems have to be referred to the hospital ophthalmology clinics. Some of these referrals turn out to be unnecessary. We now have a tele-ophthalmology service in some polyclinics, to screen such patients while they are still in the polyclinics. Pictures of the patient's retina are taken in the polyclinic and transmitted electronically to the

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hospital. There, an ophthalmologist or a specially trained technician can make a diagnosis in real time. This saves time and money for the patient who does not have an eye complication to make a trip to the hospital. Tele-ophthalmology avoids unnecessary hospital referrals, saves the patients money and allows more accurate widespread screening of eye diseases in Singapore.

8. With this positive experience, we are now doing a pilot in one hospital's Emergency Department without a resident neurologist, to allow them to consult the neurologists in the National Neuroscience Institute via the Internet. This is to help establish the cause of a stroke patient arriving at the hospital Emergency Department, so that the correct treatment can be rendered immediately. We call this service "tele-stroke". We think this will raise the level of care for stroke patients in all hospitals.

9. We need many more such "better and cheaper" innovations in health care.

10. In this context, drug regulators can play their part too. You can help to make drugs safer, better and cheaper for your patients. Allow me to share some perspectives.

Safer Drugs

11. First, how do you ensure that patients get safer drugs? There are several aspects to this subject of drug safety. One is the well known problem of counterfeit and illegal health products. While we are doing our best to ensure public access to safe medicines, there are dishonest and unscrupulous syndicates aiming to profiteer from counterfeit and illegal health products. They can be quite innovative in the way they produce counterfeits and penetrate the distribution channels. All kinds of health products are targets of counterfeiting.

12. Two years ago, our Pharmacovigilance Unit received reports of 76 men admitted to hospitals for hypoglycemia of unknown cause. 24 of them went into coma and

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among them, 10 died. Swift investigations uncovered that many of the patients had consumed an illegal herbal product called “Power 1 Walnut”. These illegal products bought from backstreets were marketed for sexual enhancement. Immediate public advisories, raids, prosecutions and swift alerts to regional drug regulators successfully minimized the fallout and impact on the people.

13. Last month, INTERPOL and WHO conducted an operation (Operation Pangea III) involving more than 40 countries, to protect public health and safety against illegal Internet sales of health products. Singapore took part in this operation, with intensified checks on suspicious websites. Twenty-six Internet platforms were screened and several individuals are now being investigated in connection with illegal sale of medicines.

14. Our experience of the “Power 1 Walnut case” and the WHO/INTERPOL Operation show how close collaborations amongst drug regulators, healthcare professionals and law enforcement authorities, are key efforts to protect public health. With criminal activities globalised, regulatory and enforcement agencies must work with their foreign counterparts to more effectively deal with trans-national pharmaceutical crime. We need many helping hands to fight this enemy. Individual consumers too must play their part by not buying medicines from dubious sources, especially the Internet.

15. But drug safety issues do not merely arise from criminal activities. Legitimate medical advancements may also create safety concerns. Cell and tissue therapy, gene therapy and nanotechnology are generating new medical applications ranging from drug screening, detection, and diagnosis to new forms of treatment. However, inappropriate use and inadequate regulation and surveillance of new technologies can put patients at risk. We need better scientific evidence of medical benefits versus risk to patients.

16. Yet another aspect of drug safety concern specific subgroups of population. Certain drugs may impact such subgroups differently than the normal population.

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We need good research into areas such as pharmacogenetics to help build up information on treatment efficacy and safety in subgroups of population. The ultimate aim is to formulate regulatory and clinical approaches which can enhance the safe use of medications in certain subgroups of our population.

Better Drugs

17. Second, how do we ensure that patients get better drugs? This comes under the purview of the pharmaceutical companies. Commercial interest will drive them to invest in R&D and drug discovery. Our job is to respect their intellectual property rights so that they get a fair return on their R&D investments. But I think we have an added duty to facilitate their work, so that new drugs can be brought to market quickly and efficiently, once their safety and efficacy have been proven. This will save cost for the manufacturers, which we hope they will pass on to consumers.

18. For example, our Health Sciences Authority adopts a review process that allows "rolling submission" of scientific data by the pharmaceutical company from on-going clinical trials. This approach enables market access to the drug soon after clinical trials are completed. While this approach is not applicable in all cases, it is a viable option in situations when there is strong public health justification. We applied this approach in a recent case involving a vaccine against a viral infection prevalent in the region and which causes severe diarrhea in children and infants. HSA worked in partnership with the company to ensure that sufficient data was available to establish safety and efficacy at the registration stage, and cut down the overall review time.

19. At the same time, drug regulators must keep up with research and innovation in medical technology. As an example, the traditional regulatory frameworks for chemical drugs are no longer adequate for new technologies. Regulators will need to be creative when formulating risk-based regulatory frameworks for these

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emerging product categories in view of different scientific and technical issues for which the concerns may not be fully understood yet.

20. It is with this in mind that HSA has set up the HSA Academy to engage various regulators, scientists and other stakeholders globally to develop regulatory science, with the objective of improving the drug development framework. We hope that the benefits of such innovation and advances would ultimately translate to patient benefits, both locally and elsewhere.

Cheaper Drugs

21. Third, how to ensure that patients have access to cheaper drugs? This is the trickiest area. In healthcare, progress in medical technology has almost always resulted in rising healthcare costs. New drugs, therapies and screening tests are not always more cost-effective than existing ones. Their benefits in terms of improvements in health outcomes can be modest, in relation to the heavy accompanying price tag. For example, while some of the newer generation oncology drugs have provided improvements to health outcomes of some cancer patients, many of these are considered marginal in terms of mortality reduction or quality of life. It is still the older drugs that form the backbone to most chemotherapy regimens.

22. Our focus should be on increasing value for patients by achieving a greater health outcome per dollar spent. That is why we actively encourage the use of generic medicines, once the patent has expired.

23. As a heart patient, I have seen how my anti-cholesterol drug prices have come down rapidly over the years. It has saved millions of heart patients millions of dollars worldwide. It is not just in heart disease medicine. Big Pharma have been lamenting at the impending patent expiry of their top blockbusters. Psychiatrists told me that many expensive psychiatric drugs will run out of patent period soon. While the pharmaceutical companies are unhappy, I am very happy for our patients.

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24. Our job as drug regulators is to facilitate the entry of generics and their use. But we need to ensure the quality and safety of these generic products. As the capacity of drug regulators in different countries can vary due to resource constraints, it can only be beneficial for our patients if drug regulators work closely together to share information. For example, drug regulators can identify reference agencies that you trust and can rely on for various aspects of regulatory decision making. This will lessen the need to duplicate assessments or other types of regulatory activity. Through such information and work sharing, your people will be able to access safe and high quality medicines faster.

25. This is one key approach that Singapore has adopted so that although HSA is able to carry out first-in-world evaluation of products to international standards, many medicines are assessed based on decisions taken by our reference agencies and supported by information exchanged through confidentiality agreements and memoranda of understanding. In this way, regulators could leverage on one another in the pre-market evaluation of pharmaceutical products.

Conclusion

26. We all have a part to help make healthcare better and cheaper. This is the only way to ensure that medical advances truly benefit all, including the poor. If medical advances become increasingly being priced out of reach of the low income group, we will all have failed in our primary mission.

27. In the case of drug regulators, your primary mission is to help bring safer, better and cheaper drugs to your people. This requires you to innovate to meet the challenges of a fast paced biomedical sector and of a highly globalised industry. This requires you to cooperate and collaborate with government, academia, and health care organizations.

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28. In closing, let me congratulate WHO on having successfully nurtured this important drug regulatory gathering over the last thirty years. You have in the process done much to improve the global safety and quality of medicines. I wish you even greater success in the future. May you have a productive conference, and a memorable stay in Singapore.

Thank you.

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