Statement to WHO EML Secretariat on behalf of ISOPP

Mr. Secretary, and esteemed members of the WHO EML Secretariat; my name is John Wiernikowski, I'm a Pediatric Oncology Clinical Pharmacist based at McMaster University and McMaster Children's Hospital in Hamilton, Canada. I have the pleasure of representing, and making this statement on behalf of the International Society of Oncology Pharmacy Practitioners.

First, we wish to acknowledge the hard work of organizations and individuals who submitted proposals for addition to the essential medicines list this year. This is not a small undertaking.

Our remarks are with respect to the agents we list here. [slide 2]

Our members practicing in low and middle income countries have identified these medicines as ones that have a low probability of being adopted on to their national list of essential medicines. This opinion is informed by the fact that medicines of similar class added to the 2019 EML have had little to no uptake to their national lists of essential medicines to date. The reasons for this are multi-factorial but are anchored on prohibitive costs. To be sure, these immunotherapeutic agents and targeted therapies represent important breakthroughs in the armamentarium of agents to treat cancer. In the case of immunotherapies, responses are generally seen promptly with survival curves comparing existing standard treatments separating early (typically within 3-6 months); but, while responses have been durable to date, the survival curves remain largely parallel and are not flattening out so these are not curative treatments.

Many low and middle income countries have health care systems that are an amalgam of private and public funding, and in rare situations, having no public funding, with any and all health care costs being borne by individuals. With rising costs of cancer medicines, funding approaches have become increasingly diverse and standardization of treatment regimens more difficult. In Brazil for example, cancer drugs are no longer being added to the national EML, instead, they are grouped into disease specific treatment regimens. This results in no standardization of treatment approaches within the publicly funded system, and expensive therapies being accessible only to those who can afford private health insurance. Our society espouses the principle that access to equitable, high quality health care should not depend on socio-economic status.

Furthermore, in order for these agents to be used most cost-effectively, the health systems in which they are used must have the proper infrastructure to perform the requisite molecular/bio-marker testing to identify which patients are most likely to benefit from these therapies. Indeed, in high income countries with the appropriate infrastructure, this is still something we are learning to do. The capacity to perform this type of testing is still severely lacking in low and middle income countries, which will negatively impact on the cost effective use of these agents.

The additional (and perhaps most important) resource that is in short supply in low and middle income countries is the human resource. Many of these medicines proposed for addition to the EML have side effect and toxicity profiles that may require more frequent monitoring and prompt recognition in order to mitigate harm to the patient. This will require additional training and ideally more personnel if these medicines are to be adopted and used safely.

Finally, and sadly, addition of any expensive medicine to a national EML, can result in governments & health ministries licensing and purchasing by virtue of low cost, medicines that are of substandard quality or outright counterfeit. In my own domain of practice of pediatric oncology this has happened twice, and with the same drug, asparaginase. A drug used in the treatment of childhood acute lymphoblastic leukemia. Firstly in Brazil, where for cost reasons, the ministry of health switched to a lower cost asparaginase product, a product that was full of impurities, and had very low asparaginase activity. This resulted in increased rates of relapse in children who received this product. More recently, the same happened in Chile, with the product in this case being manufactured in a substandard facility. The product had low asparaginase activity and microbial contamination, resulting in children receiving this product being infected, and at least 2 children dying as a result.
Our Society would like put forth the following for your consideration [slide 3]
We strongly support the addition of Rasburicase which despite its cost, can be used very cost effectively in high risk populations.

That WHO and its partners globally work to accelerate development of high quality bio-similar/generic versions of the proposed agents, and to build the infrastructure required to most effectively use these medicines including added human resources. I'm going to make a shameless pitch for my profession here and encourage you to read our just published position paper on the role of the oncology pharmacy team in cancer care at the link provided here.

Finally, we encourage the WHO and partners to develop standardized disease specific treatment regimens for resource constrained settings, a continuing activity of SIOP and something our members would be pleased to participate in.

Thank you again, for giving us the opportunity to present here today.