16:11:01 From Juliana rodriguez to All panelists : we can not hear you

16:34:54 From Andres Arauz : Hi, I have two questions regarding the first barrier (trials) if you have the time:

1. in your paper you mention that science has advanced and that comparability of protein analytical studies are enough without recurring to clinical trials. This is a key element to help us sustain waivers of clinical trials. Could you please refer specifically to what those scientific advances are?

2. In your paper you mention that when there is enough information on comparability in the public domain, then clinical trials can be waived. Does this open a route for approval without clinical trials when the biogeneric has been already been approved in another jurisdiction by another agency? Would this fact, in itself, even though trial data are protected by exclusivity or secrecy, be enough to be considered "public domain"?

16:36:18 From Daniel Cazar to All panelists : Biogenerics! YES!

16:38:10 From Edwin Mena to All panelists : How long take INVIMA according the new regulation 1782, the evaluation of Biossimi

16:38:40 From Edwin Mena to All panelists : dossier and main barrier or requeriments?

16:38:59 From Global Health Centre Research, Graduate Institute Geneva : Hi all, please make sure you are sending questions to all panelists and attendess in the chat

16:40:42 From Roberta Dorneles to All panelists : Good afternoon everyone,

Thank you for the great presentation.

I'd like to emphasize two points:

Firstly, what is your opinion on WHO's recommendation to regulatory agencies to seeking and granting sanitary regulation for products biosimilars available on the international market? Is this possible in Brazil, for example? How could it be done?

Secondly, On the biosimilars efficacy and safety debate, how can we dispute the bigpharma-imposed narrative that this alternative treatment can not replace products in monopoly situation?

Thank you so much

16:40:44 From Emmanuel Fajardo : Has Colombia approved any biogenerics to date using the abbreviated comparability pathway?

16:43:14 From helen bygrave to All panelists : In Colombia do you know what proportion of insulin used in the public sector is from a biosimilar producer; what kind of challenges were faced with health care workers and patients moving to biosimilar products ( acceptability etc )

16:43:33 From helen bygrave : In Colombia do you know what proportion of insulin used in the public sector is from a biosimilar producer; what kind of challenges were faced with health care workers and patients moving to biosimilar products ( acceptability etc )

16:46:36 From Judit Rius Sanjuan to All panelists : Thak you Carolina, very interesting presentation. Has an impact analysis been done of the Colombian approach versus other countries approaches? e.g. how competitive is the Colombia market compared to other countries and which are the policies/legal strategies that are best practices or seem to have worked better?

16:46:39 From James Elliott to All panelists : There have been a few biosimilar insulins launched to the market (e.g. Ademlog) but so far the prices have not been discounted so much (~15-20%). 1. In your view, why is this the case? 2. What can civil society advocate for to use biosimilars to bring down prices / increase access?

16:46:39 From Luz Franco to All panelists : I would like to ask if the abrviate route is applicable for monoclonal antibodies that has been market in Colombia for more than 15 years, they have a robust post market experience.

16:48:35 From Luisa Fernanda Rojas Chavarro : You mentioned that in abbreviated comparability approach it is necessary to do pharmacodynamic study, could you please indicate me, exactly which studies they refer to? Thank you.

16:48:39 From christa cepuch to All panelists : does Colombia have pharmacovigilance program for biologics / biosimliars specifically?

16:51:02 From christa cepuch : hi Carolina, many thanks! does Colombia have pharmacovigilance program for biologics / biosimliars specifically?

16:51:32 From Allan Vivas to All panelists : Is it relevant for Invima that this Biosimilars grant FDA or EMA?

16:52:26 From Patricia Gaillard Olokose to All panelists : Are there other latin american regulatory agencies, maybe supported by INVIMA, interested in adopting the same strategy in regulating biocompetitors?

16:56:15 From Global Health Centre Research, Graduate Institute Geneva to Sergio Pulido and all panelists : i will give you the floor next

16:59:07 From Patricia Gaillard Olokose : Are there other latin american regulatory agencies, maybe supported by INVIMA, interested in adopting the same strategy in regulating biocompetitors?

16:59:07 From ADRIANA ROBAYO to All panelists : Thanks, so interesting

17:00:53 From Global Health Centre Research, Graduate Institute Geneva to Andres Arauz and all panelists : andres, have your questions being addressed during the presentation?

17:02:18 From Andres Arauz : i don't think so

17:03:55 From Luz Franco : it is required to have active pharmacovigilance program for Biologics products, this program is in charge of MAH

17:04:15 From Allan Vivas to All panelists : Can you answer offline my question?

17:04:58 From Global Health Centre Research, Graduate Institute Geneva to Allan Vivas and all panelists : We will ask Carolina to answer questions not address live, we apologize for the lack of time

17:08:48 From Luz Franco : thanks a lot

17:08:59 From Timothy Lunceford-Stevens to All panelists : is USA only importing Biologics or is the university research network creating biologists? and then giving them to pharmacy to raise the price to Patients?

17:09:07 From Edwin Mena : could send to everyone this presentation? thank you

17:09:29 From Allan Vivas to All panelists : Thank you!

17:09:32 From Andrea Reyes to All panelists : Thanks a lot

17:09:36 From Erika Dueñas to All panelists : thanks Carolina

17:09:41 From Suerie Moon to Andres Arauz and all panelists : Thank you everyone, especially Carolina and Marcela