Regulatory responsiveness to public health challenges

Date: Tuesday, December 3rd
Time: 10:00 am – 12:00 pm (CET)
Location: Zoom Video Conferencing
Registration: Required
Organizing partners: RSNN

Program

Moderator: *Marjon Pasmooij (CBG) & Wieteke Wouters (HollandBio)*

10:00 am – 10:05 am	**Introduction** *Marjon Pasmooij (CBG) & Wieteke Wouters (HollandBio)*
10:05 am – 10:30 am	**Genotoxic impurities (NMDA and sartanen case)** *Leon van Aarts (CBG) & Priscilla Schoondermark (CBG)*
10:30 am – 10:55 am	**Ebola Vaccine** *Carla Buggenhout (Janssen)*
10:55 am – 11:20 am	**HTA** *Rick Vreman (UU)*
11:20 am – 11:35 am	**Reflection** *Peter Mol (UMCG & CBG)*
11:35 am – 11:50 am	**Discussion & questions** *Marjon Pasmooij (CBG) & Wieteke Wouters (HollandBio)*

RSNN
Regulatory Science Netwerk Nederland

FIGON DMD Virtual Series
Regulatory responsiveness to public health challenges

3 December 2020
10:00-12:00
Zoom Video Conferencing

Topic

Regulatory systems generally operate within a well-circumscribed regulatory framework and place high value on the predictability, transparency and thoroughness of regulatory procedures. Nonetheless, these systems are also confronted with public health emergencies where rapid action is required to support access to efficacious treatments. Importantly, safety and quality of these regulatory responses should not be comprised by its rapid nature.

In this webinar we want to explore several recent cases in which the regulatory system had to respond rapidly to emerging issues. The first case will discuss is the regulatory response to the nitrosamine impurities found in the sartan class of medicines. Regulators identified these impurities in the middle of 2018, responding by implementation of a set of regulatory actions to safeguard public health, as well as new requirements to prevent such events in the future. The second case will describe the regulatory response to viral emergencies, where we will use Ebola and COVID-19 as examples; in both cases there has been a strong call on regulators to be play a facilitating role to assure that safe and effective vaccines reach citizens globally as soon as possible.

In addition, lessons learned from adaptation of regulatory systems in response to rapidly emerging issues may also hold value beyond the scope of these public health emergencies. Based on the examples discussed, we also want to reflect on this broader theme.

Program

Moderator **Marjon Pasmooij (CBG) en Wieteke Wouters (HollandBio)**

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11:45-12:00	Discussion & questions	Marjon Pasmooij (CBG) en Wieteke Wouters (HollandBio)