

# Regulatory responsiveness to public health challenges

**Date:** Tuesday, December 3<sup>rd</sup>

**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 | <b>Introduction</b><br><i>Marjon Pasmooij (CBG) &amp; Wieteke Wouters (HollandBio)</i>                                  |
| 10:05 am – 10:30 am | <b>Genotoxic impurities (MDMA and sartanen case)</b><br><i>Leon van Aarts (CBG) &amp; Priscilla Schoondermark (CBG)</i> |
| 10:30 am – 10:55 am | <b>Ebola Vaccine</b><br><i>Carla Buggenhout (Janssen)</i>   |
| 10:55 am – 11:20 am | <b>HTA</b><br><i>Rick Vreman (UU)</i>   |
| 11:20 am – 11:35 am | <b>Reflection</b><br><i>Peter Mol (UMCG &amp; CBG)</i>  |
| 11:35 am – 11:50 am | <b>Discussion &amp; questions</b><br><i>Marjon Pasmooij (CBG) &amp; Wieteke Wouters (HollandBio)</i>                    |

## 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)

Time	Topic	Speaker
10:00-10:05	Introduction	Marjon Pasmooij (CBG) en Wieteke Wouters (HollandBio)
10:05-10:30	Genotoxic impurities (MDMA and sartanen case)	Leon van Aerts (CBG) en Priscilla Schoondermark (CBG)
10:30-10:55	Ebola vaccine	Carla Buggenhout (Janssen)
10:55-11:20	HTA	Rick Vreman (UU)
11:20-11:45	Reflection	Peter Mol (UMCG & CBG)
11:45-12:00	Discussion & questions	Marjon Pasmooij (CBG) en Wieteke Wouters (HollandBio)