CBG MEB

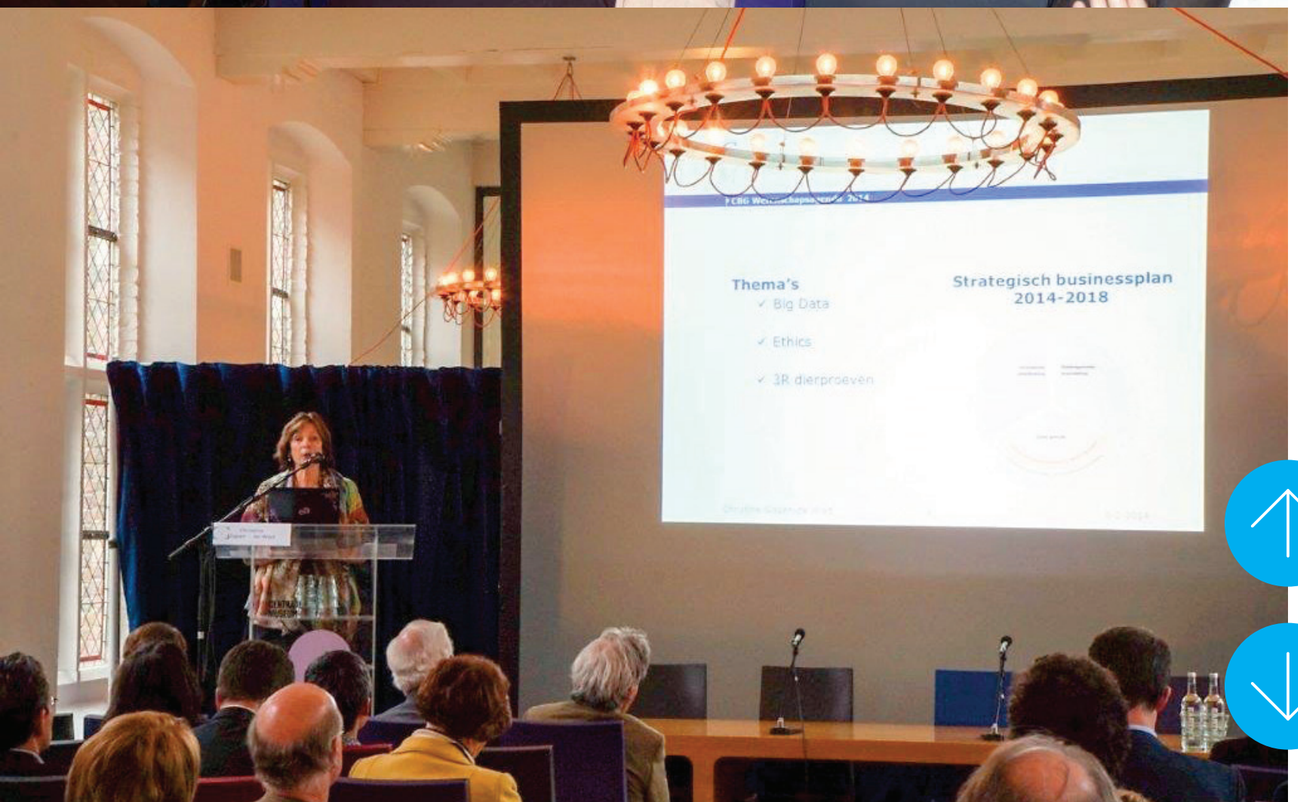
Invitation MEB Regulatory Science Day

Generic Drugs in Society

The Regulator's Dilemma

FRIDAY FEBRUARY 3, 2017 / 12.00 – 18.00 HOURS

LEEUWENBERGH / SERVAASBOLWERK 1A /3512 NK UTRECHT



Program

Chair Dr. Christine Gispen-de Wied, MEB

12.00 - 13.00 h	**Registration & light lunch**
13.00 - 13.05 h	**Welcome** Drs. Stan van Belkum, Deputy - Director MEB
13.05 - 13.20 h	**Introduction to the topic** Dr. Marc Maliepaard, Senior clinical assessor MEB
13.20 - 13.40 h	**Faith of clinicians in generic drugs** Dr. Gabe Sonke, Oncologist AVL/MEB Board Member
13.40 - 14.00 h	**The patient's experience** Patient representative from MEB network
14.00 - 14.30 h	**The validity of the generic principle in drug regulation** Abby Yu, MSc., Maastricht University/MEB
14.30 - 15.15 h	**Break & Regulatory Science Pitch Podia** • **Predicting safety for the individual patient** Pieter Glerum, MSc., Maastricht University/MEB • **Risk minimization efforts** Remy Francisca, MSc., Erasmus University Rotterdam/MEB • **Medicine shortages** Doerine Postma, MSc., Utrecht University / KNMP
15.15 - 15.35 h	**Interchangeability poses a safety risk on the patient?** Dr. Thijs Giezen, Hospital Pharmacist SAHZ/Young MEB
15.35 - 15.55 h	**Improving communication to prescriber and consumer** Prof. Dr. Petra Denig, UMCG
15.55 - 16.45 h	**Plenary discussion** Prof. Dr. Bert Leufkens, UU/Chair MEB Board
16.45 - 18.00 h	**Drinks & Networking**

About

Generic drugs have a long standing tradition in our health care system. They are in place to reduce cost and allow innovation in drug development. Generic drugs can access the market when bioequivalence of the active substance to the innovator drug has been proven, following certain pharmacokinetic principles. Ongoing complaints about efficacy and safety of generic drugs appear in the media, starting with antiepileptic drugs more than a decade ago. In particular switching from innovator to generic or from generic to generic is considered problematic both by consumer and prescriber. It has challenged the regulator how to preserve the validity of the bioequivalence principle, and, as important, how to communicate trustworthy to society. It appears that regulatory authorities take different approaches. The question that is put forward in this symposium is how regulatory science can contribute to current knowledge and is able to pave the way to new insights that strengthen regulatory decisions, understandable in today's society.

The MEB Science Day is organized to promote and share our endeavors in regulatory science with our collaborating (academic) partners and to enhance knowledge and network building: 'The knowledge of the world is only to be acquired in the world and not in the library' (after Lord Chesterfield 1694-1773).

Registration

Deadline for registration is January 20, 2017, please use the link below:
http://www.formdesk.com/collegeterbeoordelingvangenees/CBG_Wetenschapsdag2017

After registration, you will receive a confirmation through e-mail.
Please bring this confirmation as entry document.

For more information:
Barbara Veluw-Greebe
Telephone: 088 - 224 86 71
E-mail: _Dienstpostbus_MO_II@cbg-meb.nl

'Declare the past, diagnose the present, foretell the future' *(Hippocrates 460-370 BC)*

Feel invited to participate in an exciting crosstalk with experts in the field.