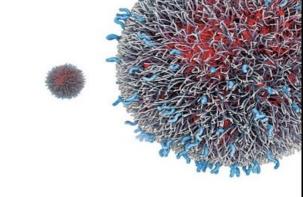
EVENT PROGRAMME

30 November 2021, from 10.00 to 11.30 CET

Free online meeting

Hosted by MEP Petar Vitanov (S&D, Bulgaria)



Nanomedicines and nanosimilars: the medical need for a centralised EMA regulatory process



Housekeeping rules



- Please don't forget to mute yourself.
- This meeting will be recorded.
- All participants have access to the chat.
- It is possible to send separate messages by clicking on the image of the person you want to talk to, and so you will be able to start a private conversation with him/her.
- We will have a Q&A session at the end of the meeting, but feel free to write your questions down in the chat. We will share with them with our speakers in due time.



Nanomedicines and nanosimilars: the medical need for a centralised EMA regulatory process

10.00 - 10.05

Welcoming remarks

• Mike Isles, European Alliance for Access to Safe Medicines

10.05 - 10.15

Setting the scene

MEP Petar Vitanov, S&D (Bulgaria)

10.15 - 10.55

Why do nanomedicines and nanosimilars require a centralised regulatory pathway

- Prof. Scott McNeil, University of Basel (Switzerland)
- · Jon De Vlieger, Working Group on non-biological complex drugs, Lygature
- FIP representative, credentials

10.55 - 11.05

DG SANTE: next steps

· Andrzej Rys, DG SANTE Director for health systems, medical products and innovation

11.05 - 11.30

Open debate and concluding remarks



- MEP Petar Vitanov, S&D (Bulgaria)
- Mike Isles, European Alliance for Access to Safe Medicines













ANNALS OF THE NEW YORK ACADEMY OF SCIENCES

Issue: Equivalence of Complex Drug Products
CONCISE ORIGINAL REPORT

How to select a nanosimilar

Alain Astier,^{1,a} Amy Barton Pai,^{2,a} Marco Bissig,^{3,a} Daan J.A. Crommelin,^{4,a} Beat Flühmann,^{5,a} Jean-Daniel Hecq,^{6,a} Josefien Knoeff,^{5,7,a} Hans-Peter Lipp,^{8,a} Alberto Morell-Baladrón,^{9,a} and Stefan Mühlebach^{5,10,a}

¹Department of Pharmacy, Henri Mondor University Hospitals, Créteil, France. ²Department of Clinical Pharmacy, University of Michigan, Ann Arbor, Michigan. ³Hospital Pharmacy, Ospedale Regionale di Lugano, Lugano, Switzerland. ⁴Deptartment of Pharmaceutical Sciences, Utrecht University, the Netherlands. ⁵Vifor Pharma Ltd., Glattbrugg, Switzerland. ⁶Hospital Pharmacy, University Hospital of Mont-Godinne, Yvoir, Belgium. ⁷Faculty of Sciences, Vrije Universiteit Amsterdam, the Netherlands. ⁸Hospital Pharmacy, Universitätsklinikum Tübingen, Germany. ⁹Hospital Pharmacy, La Princesa Hospital, Madrid, Spain. ¹⁰Department of Pharmaceutical Sciences, University of Basel, Basel, Switzerland

Address for correspondence: Beat Flühmann, Vifor Pharma Ltd., Flughofstrasse 61, 8152 Glattbrugg, Switzerland. beat.fluehmann@viforpharma.com

Nanomedicines in the class of nonbiological complex drugs (NBCDs) are becoming increasingly available. Up to 23 nanomedicines have been approved, and approximately 50 are in clinical development. Meanwhile, the first nanosimilars have entered the market through the generic approval pathway, but clinical differences have been observed. Many healthcare professionals may be unaware of this issue and must be informed of these clinically relevant variances. This article provides a tool for rational decision making for the inclusion of nanomedicines into the hospital formulary, including defined criteria for evaluation of substitutability or interchangeability. The tool was generated by conducting a roundtable with an international panel of experts and follows the same thought process that was developed and published earlier for the selection of biologicals/biosimilars. In addition to the existing criteria for biosimilars, a set of seven criteria was identified that specifically apply to nanosimilars. These include (1) particle size and size distribution, (2) particle surface characteristics, (3) fraction of uncaptured bioactive moiety, (4) stability on storage, (5) bioactive moiety uptake and (6) distribution, and (7) stability for ready-to-use preparation. Pharmacists should utilize their pharmaceutical expertise to use the appropriate criteria to evaluate the comparability of the drug to decide on interchangeability or substitutability.



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ANNALS OF THE NEW YORK ACADEMY OF SCIENCES

Issue: Equivalence of Complex Drug Products

Meanwhile, the first nanosimilars have clinical differences have been specified the market through the Meanwhile, the first nanosimilars have clinical differences have been specified to the first nanosimilars have clinical differences have been specified to the first nanosimilars have clinical differences have been specified to the market through the ma wieanwhile, the mist handsimilars have entered the market this deep to generic approval pathway, but clinical differences manual approval pathway approval pathway approval pathway approval pathway. generic approval painway, but clinical differences have been this may be unaware of this observed. Many healthcare professionals may relevant variances observed. Many healthcare of these clinically relevant he informed of these clinically relevant he informed of these clinically relevant here. observed. Wany healthcare professionals may be unaware of this This inclusion of these clinically relevant the inclusion of these and must be informed of these making for the inclusion aldecision making for the inclusion of these arounders a tool for rational decision making for the inclusion of these arounders arounder a tool for rational decision making for the inclusion of this inclusion of these clinically relevant to the inclusion of th Issue and must be informed of these clinically felevant variances. This article provides a tool for rational decision making defined criterial formulary including defined the best into article provides a tool for rational decision making for the including defined criteria nanomedicines into the hospital formulary, including nanomedicines into the hospital for interchange ability or interchange ability for evaluation of substitutability or interchange and substitutability or interchange ability for evaluation of substitutability or interchange ability for evaluation of substitutability or interchange ability for evaluation of substitutability.

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... y, including defined criteria for evaluation of substitutability or interchangeability. The tool was oy conducting a roundtable with an international panel of experts and follows the same thought process mat was developed and published earlier for the selection of biologicals/biosimilars. In addition to the existing criteria for biosimilars, a set of seven criteria was identified that specifically apply to nanosimilars. These include (1) particle size and size distribution, (2) particle surface characteristics, (3) fraction of uncaptured bioactive moiety, (4) stability on storage, (5) bioactive moiety uptake and (6) distribution, and (7) stability for ready-to-use preparation. Pharmacists should utilize their pharmaceutical expertise to use the appropriate criteria to evaluate the comparability of the drug to decide on interchangeability or substitutability.



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Über uns Ausbildung

Dialog

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Expertentreffen

Jahrestagungen

Patientenpreis

Haupstadt Summit

Statement on the "Interchangeability of drugs with a complex active substance composition"

The non-biological complex drugs (NBCD) consist of four drug groups: the low-molecular-weight heparins, the glatiramoids, the iron carbohydrate complexes and the liposomal parenterals (e.g. containing the active substance doxorubicin). They all share the common feature of being drugs with a complex composition. As they also include the low-molecular-weight heparins, however, which are biological in origin, the term "non-biological complex drug" is a legitimate subject for debate. None of the products is of biotechnological origin (i.e. a biological), however, which is to be conveyed by the internationally introduced name "NBCD".



This statement was prepared on the basis of the results of a consultation of experts organized by the German Pharmaceutical Association [DPhG]) together with the House of Pharma & Healthcare, Frankfurt. The following members of the expert panel contributed to the preparation of the statement and support the recommendations formulated therein:

Prof. Dr. Susanne Alban, Kiel	Prof. Dr. Stefan Laufer, Tübingen
Dr. Michael Binger, Wiesbaden	Dr. Martin Lorenz, Frankfurt
Prof. Dr. Henning Blume, Oberursel	Prof. Dr. Jochen Maas, Frankfurt
Prof. Dr. Wolfgang Brück, Göttingen	Dr. Milan Novakovic, Berlin
Dr. Joachim Burschäpers, Frankfurt	Prof. Dr. Friedemann Paul, Berlin
Prof. Dr. Theodor Dingermann, Frankfurt	Dr. Otto-Quintus Russe, Frankfurt
Dr. Daniel Fendji, Berlin	Prof. Dr. Manfred Schubert-Zsilavecz, Frankfurt
Prof. Dr. Sebastian Harder, Frankfurt	Prof. Dr. Fritz Sörgel, Heroldsberg
Prof. Dr. Eva Herrmann, Frankfurt	Dr. Gerhard Tischler, Berlin
Lothar Jungbluth, Obertreis	Dr. Christian Ude, Darmstadt
Prof. Dr. Michael Lämmerhofer, Tübingen	Dr. Dagmar Walluf-Blume, Berlin





This very complex molecular andlor devotes it acceptable to devote structure develop generic makes it practically impossible with an identical molecular with alternatives, i.e. products with these drugs cook products alternatives, i.e. anematives, i.e. products with these drugs, each production these drugs, list cascial account of the composition. Instead, with the cascial account of the casci makes it practically impossible to composition is determined by its special manufacturing process is the product").

s of biotechnological origin (i.e. a biological), however, which is to be conveyed by the







Detailed analysis of specific NBCD features leads to the conclusion Detailed analysis of specific NDCD reatures reads to the conclusion that, in view of their particular product features with their very complex that, in view of their particular product features with their particular product features with their particular product features with their very complex that, in view of their particular product features with their very complex that, in view of their particular product features with their very complex that, in view of their particular product features with their very complex that, in view of their particular product features with their very complex that, in view of their particular product features with their very complex that, in view of their particular product features with their very complex that, in view of their particular product features with the complex that the c composition in all cases, a simple authorization referencing another areduct colohycupaerted by aviidance of above colohycupaerted by aviidance of a simple aviidance of product, solely supported by evidence of pharmacokine in the supported by evidence of pharmacokine in the support is a support in the support in the support is a support in the support in the support in the support is a support in the support in bioequivalence pased on a single fingredient, is definitely not a studies acceptable. To ensure safety of treatment in such cases, clinical studies acceptable. To ensure safety of treatment in such cases, confirming of the confirmation of the con bioequivalence based on a single ingredient, is definitely not acceptable. To ensure safety of treatment in such cases, climical site confirming efficacy and safety are essential and should always be confirming efficacy and safety are essential and confirming efficacy and confirming efficiency and confirming efficacy performed in comparison to the originator drug (if necessary, Performed in comparison to the originator or of his supported by comprehensive pharmacodynamic investigations). internationally introduced name "NBCD".







Über uns Ausbildung

Dialog

Forschung

Service

For those NBCDs used in the long-term therapy of a patient whose drug dosage has been carefully titrated, an aut-idem substitution can therefore – analogous to the biosimilars – not be recommended until confirmation of "therapeutic interchangeability" is available has they also include the low-molecular-weight heparins, however, which are rcal in origin, the term "non-biological complex drug" is a legitimate subject for debate. None of the products is of biotechnological origin (i.e. a biological), however, which is to be conveyed by the internationally introduced name "NBCD".



EU Parliament meeting - 'Handling Innovation in nanomedicines: regulatory changes needed to realise new treatment opportunities and ensure patient safety'





Event summary: Innovation in Nanomedicines: Enhancing Patient Safety Through Regulatory Clarity

30 Nov 2020



MEP Maria Carvalho (EPP, Portugal)



The Nanomedicines Regulatory Coalition



THE REGULATORY NANOMEDICINES COALITION

















The Coalition Website

https://eunanomedicinescoalition.eu



News & Publications

Regulatory Coalition

Sign the Petition

Contact





Letter to the EU Commissioner for Health and Food Safety European Alliance for Access to Safe Medicines Brussels, 30 June 2021 Re: Enabling a centralised regulatory system for nanomedicines through the Pharmaceutical 1. Developing a scientific consensus on definitions for nanomedicines in Europe improving education and makers, prescribers. 1. Developing a scientific consensus on definitions for nanomedicines in Europe improving education and patients.

1. Developing a scientific consensus on definitions for nanomedicines in Europe improving education and patients.

1. Developing a scientific consensus on the consensus on definitions for nanomedicines in Europe improving education and patients. 2. Adopting an EMA centralised procedure for all nanomedicines and nanosimilars which would ensure the On behalf of the European Alliance for Access to Safe Medicines (EASSM), the member organisations of the Nanomedicines Resultance Coalition (NRC): and a number of Members of the European Parliament use usual 2. Adopting an **EMA centralised procedure** for all nanomedicines and nanosimilars which would ensure Datient safety;

Amount of these complex products. This is key to nanosimilars which would ensure between On behalf of the European Alliance for Access to Safe Medicines (EAASM), the member organisations of the Nanomedicines Regulatory Coalition (NRC)¹ and a number of Members of the European Parliament, we would like to bring to your attention a regulatory losses which will have a major impact on the E1 health sector in the like to bring to your attention a regulatory losses which will have a major impact on the E1 health sector in the Dear Commissioner for Health and Food Safety, Ms. Stella Kyriakides, Nanomedicines Regulatory Coalition (NRC)¹ and a number of Members of the European Parliament, we would like to bring to your attention a regulatory issue which will have a major impact on the EU health sector in the like to bring to your attention a regulatory issue which will have a major impact on the Follow-on conv. versions and their follow-on conv. versions when the properties of innovative nanomedicines and their follow-on conv. 3. Cleritying regulatory checks for the sporoval of follow on nanovalinilar medicines. As manufacturing exact through clinical medicines. like to bring to your attention a regulatory issue which will have a major impact on the EU health sector in the upcoming years; namely the approval of innovative nanomedicines and their follow-on copy yersions, nanominilars. Strategy for Europe a. Clarifying resultatory criteria for the approval of follow-on/hanosimilar medicines. Is not achievable, therapeutic similarity, will need to be shown through clinical and included in the Popices of hanomedicines is not achievable there is included in the highest possible manufacturing standards must be guaranteed and included in the In the absence of clarity on nanomedicines and nanosimilar regulatory pathways and a efficacy of nan and efficacy of nan efficacy effi Nanotechnology is an emerging innovative technology which has the potential to address unmet medical needs and will offer an emerging innovative technology which has the potential to address unmet medical needs and an address unmet medical needs and an address unmet medical needs and an address unmet medical needs and address unmet medical needs an In the absence of clarity on nanomedicines and ranosimilar regulatory pathwars including payors and health care of clarity on nanomedicines and ranosimilar regulatory pathwars. Nanotechnology is an emerging innovative technology which has the potential to address unmet medical needs and will offer alternatives for several therapeutic areas. Nanomedicines offer potential solutions for a number and will offer alternatives for several therapeutic areas. Nanomedicines offer potential solutions for a number and will offer alternatives for several therapeutic areas. Nanomedicines offer potential solutions for a number of current treatment challenges. Such as cancer. earlieusecular neuvrologenerative also number of current treatment challenges. and will offer alternatives for several therapeutic areas. Nanomedicines offer potential solutions for a number of current treatment challenges, such as cancer, cardiovascular, neurodegenerative disorders, as well as other nanosimilars. Innovative – they enhance the way that medicines target and reach areas of disease within the body, as well as having inhorant therapeutic activity, making treatments highly effective. the organic Prantaceutical Strategy for Ed. or current treatment chairenges, such as cancer, cardiovascular, diseases; the innovative mRNA vaccines contain nanoparticles. Well as having inherent therapeutic activity, making treatments highly effective.

Complex—they consist of multifaceted nanoparticles engineered to have favourable biological, chemical, complex—they consist of multifaceted nanoparticles engineered to have favourable biological as immunological properties. The pharmacological as well as immunological properties. pharmacological as well as immunological properties.

Manufacture dependant – assembling different chemical parts into complex nanoparticles requires highly standardized dependant – assembling different chemical parts into complex nanoparticles requires highly standardized and complex manufacturing orocesses to guarantee consistent quality and clinical effectives standardized and complex manufacturing orocesses to guarantee consistent quality and clinical effectives. Manufacture dependant – assembling different chemical parts into complex nanoparticles requires highly standardised and complex manufacturing processes to guarantee consistent quality and clinical effectives and content quality and clinical effectives. European Alliance for why a centralised regulatory framework for nanomedicines is Access to Safe Medicines EAASM Director Mike Isles and the Members of the Nanomedicines Regulatory Coalition (NRC) are of the issues and safety. 5 MEPS uld be reviewed needed authorities, and European Cancer a separate regulatory framework for follow-on products is also required — as it has been blosimilars over the past years — or as alternative, additional guidelines on how the centralised hybrid regulatory pathway should be used to approve these medicines. Currently, the through a centralised procedure to prevent different approaches by Memo-a separate regulatory framework for follow-on products is also required — as it has been tramework for this class of products is needed at EU level. Nathernough a centralised procedure to prevent different approaches by Menti has potentia In order to fully harness the potential of nanome surrounding nanomi The Alliance of Socialists and Democratis European Alliance for Access to Safe Medicines pathway should be used to approve these medicines. Access to Safe Medicines www.eaasm.eu

European Parliament

2019-2024



Plenary sitting



A9-0317/2021

08.11.2021

REPORT

on a pharmaceutical strategy for Europe (2021/2013(INI))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Dolors Montserrat

Rapporteur for the opinion (*): Marc Botenga, Committee on Industry, Research and Energy



European Parliament

2019-2024

20....highlights that these innovative fields of medicine should be authorised by the centralised approval framework for nanomedicines;

as can or and cardiova nanomedicines, ild be authorise

medi

01. ...calls on the Commission to establish a regulatory framework for nanomedicines and nanosimilar not medicines, and calls for these products to be approved through a compulsory centralised procedure;

porteur: Dolors Montserrat

ting Cancer Plan and for R&D in emerging, echnologies, such as it challenges in areas such movative fields of framework for

der the full lifecycle of all innovative nun medicine, personalised medicine, fit-for-purpose framework on the Commission to ilar medicines, and ntralised procedure,



Nanomedicines – ensuring patient safety through regulatory clarity

Mike Isles
Executive Director,
European Alliance for Access to Safe Medicines













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By Petar Vitanov

Petar Vitanov (BG, S&D) is a member of the European Parliament's Environment, Public Health and Food Safety Committee

26 Jul 2021

梦 @PetarVitanovMEP



Nanomedicines and Nanosimilars: Building a robust legislative framework

The EU has the chance to lead the world in developing a centralised regulatory procedure for nanomedicines and nanosimilars, argues Petar Vitanov



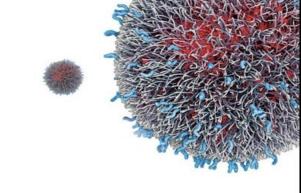


EVENT PROGRAMME

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Nanomedicines and nanosimilars: the medical need for a centralised EMA regulatory process

Concluding remarks

