Consensus group on Follow-on DMTs

Pre-Read for the Voting Panel Consensus Meeting on 6 September 2021: Agenda, overarching principles and statements

Follow-on DMTs in MS

Agenda

17:00 CET	Welcome, rationale, and objectives	Wallace Brownlee
17:30	Further information - Systematic literature review - Trends in regulatory requirements for biosimilars	 Christian Wolf Gabriele Dallmann
18:00	Q & A on process and content	All
18:15	Overarching principles and consensus statements	Jeffrey Cohen
18:45	Q&A on statements	All
19:00	Technical introduction into the voting process	Christian Wolf
	Voting	All
19:15	Results, final discussion and closing remarks	Wallace Brownlee
19:30	End of the meeting	

Overarching working principles

Follow-on DMTs in MS

Overarching working principles

a. PwMS and clinicians should jointly decide on drug treatment for MS.
b. Treatment decisions should consider the context of the specific healthcare system to increase affordability and overall access to DMTs.
c. PwMS and clinicians should be offered clear information about the basics of the approval processes for FO-DMTs in their area.
d. Registration of a FO-DMT in a highly regulated area means that it is as efficacious and safe as the reference product when used in accordance with the label information.
e. Pre-approval analytical, biofunctional and clinical data, as well as post-approval pharmacovigilance data, should be available publicly.

Statements

Follow-on DMTs in MS

Clinical data

1. FO-DMTs should be supported by rigorous analytical, biofunctional, and clinical data, as appropriate, for the therapeutic target(s) of each compound.
2. The data generated to characterise the FO-DMT should be published in peer-reviewed journals.

Treatment and access

3. FO-DMTs represent an effective option for the management of MS, intended to reduce treatment costs and improve access to DMTs for PwMS.
4. FO-DMTs approved in highly regulated areas are intended to be used in the same way as the reference product.
5. Adverse reactions and inadequate treatment response to an FO-DMT are anticipated to occur at the same frequency as with the reference product.
6. Switching from the reference product to a FO-DMT is appropriate when the FO-DMT has undergone appropriate testing and regulatory review in a highly regulated area.
7. Scientific and clinical evidence is lacking for multiple switching and cross-switching among FO-DMTs containing the same compound.
8. Purported FO-DMTs only approved outside of highly regulated areas might not have undergone rigorous testing and review.
9. At minimum, any decision to substitute DMTs at the pharmacy level should be actively communicated to the PwMS and the prescribing clinician.

Vigilance and acquisition of new scientific data

10. Pharmacovigilance data should be sought in the same way for FO-DMTs and the reference product, and reported transparently in a timely manner.
11. The trade name of any DMT formulation should be recorded in the patient files to allow tracking of adverse reactions or inadequate treatment response.
12. FO-DMTs should be supported by long-term pharmacovigilance data. This should be supplemented by registries involving the relevant stakeholders (manufacturer, healthcare professionals and patients' associations).
13. Companies bringing FO-DMTs to the market should commit to improving patient care by acquiring new scientific data beyond that which is required as a minimum to satisfy regulatory authorities, namely on long-term outcomes and switching.

Pre-instructions for voting

- Tool: Survey Hero
- Steering committee and voting panel members will receive an individual access link by Pieter van Galen or Martina Sintzel
- **ALL** questions should be answered – answer options are
  - I agree
  - I do not agree
  - I do not wish to answer
- Further instructions during the meeting