

February 2022

MOLT – additional Conflict of Interest (COI) assessment related to interferon products

The COI of the MOLT panel members was assessed by the European Academy of Neurology (EAN) Ethics and Quality Task Force in 2020 - 2021. In January 2022, the MOLT panel reconvened to discuss a specific question relating to the multi-comparison relating to azathioprine vs interferon. Due to the nature of the discussion relating to interferon specifically, it was deemed necessary to reassess COI in relation to interferon. All panel members were asked to submit a WHO COI form to MSIF declaring any COI in relation to interferon products. The pharmaceutical companies producing interferon products for MS include (but are not limited to) Biogen, Bayer, Novartis and Merck. Other manufacturers may exist in different regions or countries. The following COI assessment was prepared by MSIF and confirmed by the EAN Ethics and Quality Task Force to be accurate.

The assessment will inform which MOLT panel members can take part in voting on the recommendations.

Panel members assessed:

Tapas Banerjee (India)
Kathleen Costello (US)
Najoua El Abkari (Morocco)
Aukje Mantel-Teeuwisse (Netherlands)
Andrea Prato (Uruguay)
Nick Rijke (MSIF)
Mohammad Sahraian (Iran)
Deanna Saylor (Zambia)
Holger Schünemann (Canada)
Shanthi Viswanathan (Malaysia)
Bassem Yamout (Lebanon/UAE)
Maya Zeineddine (Lebanon)
Fatima Suleman (South Africa)

EAN internal document:

Managing conflicts of interest for the task forces for Guideline Production (version 26.03.2019)

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The purpose of managing conflicts of interest (COI) is to exclude unwanted influence from all kind of unauthorized stakeholders in the field of managing patient care. This may be typically industry wanting its products to receive favourable judgment by the final guideline product, but also non-physician managers dealing with healthcare in hospitals, governmental bodies judging on healthcare approval of medical products or services, health insurance companies and other stakeholders in the broader field of healthcare.

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Typically, an individual having a CoI in a special area should have the right to speak on this topic and to help writing the specific topics but not to vote on the final acceptance of the recommendation. There is also the possibility that the GL-member who is involved in a specific question should not write the appropriate part of the GL.

Conflict of Interest (COI) statements:

All panel members answered NO to all items of the WHO forms except:

- Tapas Banerjee (India)

2a. Conducted the study on Multiple Sclerosis, using Investigator initiated research grant
The research paper "Conversion of clinically isolated syndrome...." published in "Mult Scler J Ex Transl Clin 2019; 5(2): 2055217319849721.

Name of company: Biogen

Belongs to: National Neurosciences Centre Calcutta

Amount: Nearly INR 470 000

Current interest (or year ceased): Ceased in 2019.

2b. Received honoraria for lectures on Multiple Sclerosis and its treatment.

Name of company: Biogen, Merck

Belongs to: self

Amount: approximately INR 50 000

Current interested (or year ceased): Last received 2019

- Kathleen Costello (US)

1a. Advisory board:

- Janssen: I participated in an initiative called "MUSE" or MUltiple Sclerosis Expert, or MUSE, team. We participated in several advisory meetings and consulting activities, both promotional and educational, over the course of 2021 to help support the launch of a new therapy for relapsing multiple sclerosis (RMS); an S1P receptor modulator.
- Biogen: The objectives of this Advisory Board was to understand diversity, equity and inclusion issues facing people living with MS and did not discuss specific DMT's.

Name of company: Janssen, Biogen

Belongs to: me

Amount: Janssen \$450 USD, Biogen \$810 USD

Current interested (or year ceased): 2021

2b. Sponsorship: Can Do Multiple Sclerosis has received multiple grants and sponsorships over the past several years from Pharma. The Pharma companies listed sponsor programs and events for Can Do Multiple Sclerosis, a 501 C3 non -profit.

Name of company: Biogen, EMD Serono

Belongs to: Can Do MS

Amount:

Biogen	\$355,560	\$328,206	\$354,000 USD
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Serono	\$166,710	\$124,875	\$109,175 USD
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Genentec	\$294,650	\$289,500	\$219,000 USD
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Novartis	\$165,000	\$303,000	\$288,000 USD
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Mallinckrodt	\$25,000	\$25,000	USD
Sanofi Gen	\$26900	\$212,000	\$264,000 USD
Celgene	\$325,900	\$363,655	\$307,459 USD
Janssen	\$30,000	\$155,000	USD
TOTALS	\$1,601,820	\$1,676,236	\$1,696,634

Current interested (or year ceased): 2019, 2020, 2021 quoted above

- Andrea Prato (Uruguay)

6b, 6c and 6e

Nos. 5-6: Describe the subject, specific circumstances, parties involved, time frame and other relevant details

// Regarding question 6b: To my knowledge, some Latin American MS Associations are against off-label treatments as they are afraid that Governments and Health Authorities of some countries may consider that by having off-label DMTs options, on-label drugs may not be prioritised. Thus, introducing more disparities in low and middle resources settings. // Regarding question 6c: I received travel cost support to attend the following meetings: - MSIF Global Meeting in 2018 (Rome) and 2019 (London and Athens), paid by MSIF; - 4th Latin American Meeting of MS Associations in 2018 (Paraguay), paid by Nolver; - International MS patient summit about patient engagement in 2019 (Athens), paid by Roche. I only attended these meetings, not speaking on behalf of a specific drug or DMT. I can not declare a precise amount of money, as I only receive plane tickets and accomodation indications. // Regarding question 6e: In 2020, Roche donated a grant to the Uruguayan MS Association (EMUR) where I was a volunteer. This grant was intended to improve volunteer staff skills, thus, in my case I received two trainings from independent organisations: 1) introduction to HTA (delivered by IECS: Institute of Clinical and Healthcare Effectiveness; price: USD 299); 2) English expression course which I finally took in 2021 (delivered by In Situ Languages; price: 72.224 uruguayan pesos, taxes included)

- Mohammad Sahraian (Iran)

1b, 2a, 2b

I have received travel support to attend international congresses from Merck, Bayer, Biogen, Novartis, Roche and Cinnagen

I have received speaker Honoraria from Merck, Biogen, Cinnagen and Roche,

I have been involved in research projects supported by Merck, Cinnagen and Novartis.

I have received consulting fee to attend advisory boards from Merck, Cinnagen

- Deanna Saylor (Zambia)

2a. Research grant to develop a registry of patients with demyelinating diseases in Zambia.

There is no direct link to interferon or any other MS DMT with this grant.

Name of organisation: National Multiple Sclerosis Society (USA)

Belongs to: Research Unit

Amount: \$50 000

Current interest (or year ceased): current

- Bassem Yamout (Lebanon/UAE)

1b, 2a

Board meetings, speaker honoraria, research grants from Merck, Bayer, Biogen.

Belongs to: myself

Current interested (or year ceased): current

- Maya Zeineddine (Lebanon)

2b

My travel to ECTRIMS 2018 (Berlin, Germany) and ECTRIMS 2019 (Stockholm, Sweden) was paid by Merck Serono Lebanon (Flight, accommodation and registration to the congress).

The following people declared relevant COI to interferon:

Tapas Banerjee (India)

Kathleen Costello (US)

Mohammad Sahraian (Iran)

Bassem Yamout (Lebanon/UAE)

The following people declared COI but which were not specific to interferon products:

Andrea Prato (Uruguay) – conflicts relating to Roche, but to our knowledge Roche is not involved in interferon products for MS.

Deanna Saylor (Zambia) – conflicts not related to pharmaceutical companies.

Maya Zeineddine (Lebanon) – ceased travel grant not related to specific DMTs from Merck.

Conclusion

Three panellist, Tapas Banerjee, Mohammad Sahraian and Bassem Yamout, mention having received honoraria from the companies (Biogen, Merck, Bayer, Novartis, Cinnagen) who have interferon products for MS on the market. Kathleen Costello mentioned being on an advisory board for Biogen.

Panellists Tapas Banerjee, Mohammad Sahraian, Bassem Yamout and Kathleen Costello should have the right to speak on the topic but not to write the corresponding part of the panel report nor to vote on the final acceptance of the panel recommendation.

Panel members who would be able to vote on the recommendation:

Najoua El Abkari (Morocco)

Aukje Mantel-Teeuwisse (Netherlands)

Andrea Prato (Uruguay)

Nick Rijke (MSIF)

Deanna Saylor (Zambia)

Holger Schünemann (Canada)

Shanthi Viswanathan (Malaysia)

Maya Zeineddine (Lebanon)