Report on the WHO forms for declaration of interests submitted by MSIF Essential Medicine Panel (MEMP) on disease-modifying drugs for multiple sclerosis in low resource-settings

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1. Introduction and background

The Multiple Sclerosis International Federation (MSIF) promotes and coordinates a multidisciplinary international working group called the MSIF Essential Medicine Panel (MEMP) aimed at developing evidence-based recommendations for the choice of disease-modifying drugs for multiple sclerosis in low resource-settings, which will be proposed to the World Health Organization (WHO) for inclusion in the Essential Medicines List (EML), whose periodic update is scheduled for 2023.

The National Center for Clinical Excellence, Quality and Safety of Care (CNEC) of the Istituto Superiore di Sanità was entrusted with assessing the interests declared by all the subjects engaged in the development of the above-mentioned recommendations as an independent institution. See the list of all the subject involved in the process (panel members, evidence review team and observers) in Annex 1.

Each member of the panel and each subject involved declared their interests by using the WHO Declaration of interests form, which includes:

- Identifying information
1. Employment and consulting (items 1a and 1b)
2. Research support (items 2a and 2b)
3. Investments interests (items 3a and 3b)
4. Intellectual property (items 4a and 4b)
5. Public statements, positions (items 5a and 5b)
6. Additional information (items 6a to 6e)
7. Tobacco or tobacco products (item 7a)
- Declarations

The CoI forms were sent to ISS by means of an electronic link to GRADEpro on October 7th 2021 and since then, continuously updated upon specific ISS request for details on the declared interests, until March 7th 2022.

This document presents the result of this assessment process aimed at identifying possible cases of conflict of interest and the measures to be undertaken for their management.

2. The evaluation process and methods

The evaluation process is based on the ISS policy for the conflict of interest management in the development of the ISS guidelines (ISS, 2019) and on the principles set out by the Guidelines International Network G-I-N (Schünemann *et al*. 2015).

2.2 Definition of Conflict of Interest (CoI)

A CoI arises in "any circumstance in which a secondary interest influences or could unduly influence the impartiality of professional judgment" (IOM, 2009).

2.3 Type of interests

In line with the policies of the main organizations that produce clinical practice guidelines[1] and with international standards (NICE 2017; WHO; IOM, 2009; IOM 2011; Schünemann *et al*. 2015) we considered:

- *financial interests* – that is the financial relationships with organizations that invest directly in products or services relevant to the subject matter. It refers to any monetary value related to the direct payment for services, shareholdings, stock options or other shares, intellectual rights properties (patents, copyright royalties). Within his type of intrests, a distinction is made between:
    - *personal financial interest*, referring to opportunities for economic gain for the declaring person;
    - *family financial interest,* referring to opportunities for economic gain for people with whom the declaring person has habitual relationships - including the spouse, cohabitant, minors and adults (cohabiting and not) for whom the subject is legally responsible, relatives or kin up to the second degree;
    - *institutional financial interest*, referring to a payment or other benefit received not personally by the declaring person but by the department or structure in which he/she operates and/or has managerial responsibilities.
- *non-financial or intellectual interests,* which relate to career advancement, social prestige and personal beliefs.

Both *financial* interests and *non-financial or intellectual* interests can be:

- *specific,* or directly associated with the topic on which the subject must give judgement (i.e. relating to the producer or owner of the good or service assessed by the guideline)
- *non-specific*, or not directly associated with the topic on which the subject must give judgement (i.e. related to the sector of the good or service but unrelated to the subject under consideration).

Finally, the interests are considered:

- *current* – that is existing at the time of participation in the work for the preparation of the recommendations;
- *previous* - or present in the last 4 years and concluded.

2.3 The evaluation of the declaration of interests

Declarations of interests were evaluated to assess each individual interest and determine the extent to which the interest could reasonably be expected to influence the expert's judgment. Possible discrepancies were resolved through discussion.

[1] National Institute for Health and Care Excellence (NICE), National Health and Medical Research Council (NHRMC), lo Scottish Intercollegiate Guidelines Network (SIGN), US Preventive Services Task Force (USPSTF), World Health Organization (WHO) and others.

The assessment considered the following information:

- type of interest (*financial*, *non-financial*; *personal*, *family*, *institutional*)
- relevance in terms of specificity with respect to the guideline topic.
- period and duration.
- role of the declaring person in the relevant structure and / or activity and the amount of funding (in the case of institutional interest).

In particular, an interest was considered "*specific*" when referred to the population and to specific disease modifying therapies (DMTs) included in the guideline PICOs (see Annex 2) and "*non-specific*" when the interest was not related to any of the PICOs component and outside the scope of the guideline.

2.4 CoI risk levels and mitigation actions

Based on the evaluation, each interest was assigned one of three risk levels and one of the corresponding measures to be taken for their management, as illustrated in Table 1 and described afterwards:

Table 1 Possible measures to be taken by level of risk

Level of risk		Measure	
1	Minimal or irrelevant	**1a**	None (full participation in the work)
2	Potentially relevant	**2a**	Full participation in the work with public disclosure of interest
		2b	Partial exclusion from the work related to the declared interest
3	Relevant	**3a**	Partial exclusion from the work related to the declared interest
		3b	Total exclusion from the panel

The interest was considered *minimal or irrelevant* (level 1) if it is unlikely to influence the subject's judgment. In this case, no action needs to be taken: *a) No measure*.

In the case of *potentially relevant interest* (level 2), the application of one of the following measures for the management of the conflict is indicated:

- *2a: full participation in the work with public disclosure of the interest* in the final document of the guideline or on the website following the publication of the recommendation to which the interest refers. It applies for interests considered relatively minor (e.g. related to the guideline topic but outside the specific guideline scope).
- *2b: partial exclusion from the work*, such as exclusion from the part of the meeting or work relating to the declared interest and from the related decision-making process. That means they are excluded from formulating judgments on the GRADE Evidence to Decision (EtD) criteria and from the consensus stage or voting on the conclusions and on the recommendation formulation related to the declared interest. It is used to allow Panel members to access the

knowledge or opinion of the most qualified experts, while bearing in mind their potential biases.

In the case of significant interest (level 3), the application of one of the following measures for the management of the conflict is indicated:

- *3a: partial exclusion from the work*, such as exclusion from the part of the meeting or work relating to the declared interest and from the related decision-making process.
- *3b: total exclusion*, i.e. the limitation to participation in any part of the meeting or process. It applies when the nature of the interest is too significant with respect to the general objectives or where limiting the involvement of the expert to a part of the work would not make sense.

In the event that a declared interest is considered potentially or clearly relevant (level 2 and 3), in taking a decision towards mitigation or abstention of a subject, the "balancing test" was applied.

In carrying out such a "balancing test", the reviewers, while fully considering the contribution, tasks and function of the expert as well as the availability of alternative experts with the required expertise, has weighed:

- the nature, type and magnitude of the expert's interest and therefore the degree to which the interest may be reasonably expected to influence the expert's judgment

against:

- the adequacy of measures/options available to protect the independence and integrity of the decision-making process.

3. Results of the assessment

A total of 46 CoI forms were assessed, belonging to panel members, evidence review team, expert consultants and WHO observers. More than a half of the experts, 63% (29) declared one or more interests while the remaining 37% (17) answered "no" to all items of the WHO form.

In total, 202 interests were declared and assessed.

The assessment of the single interests declared by all the subjects involved in the MSIF Essential Medicine Panel (MEMP) guideline was aimed at identifying possible cases of conflict of interest and the measures to be undertaken for their management.

As shown by Figure 1, the level of risk of almost half of the interests, 47% (96), was deemed as "minimal or irrelevant" with no measure to be taken (1a) and the other 48% of the interests was deemed as "potentially relevant", divided by a 25% (50) needing the application of measure 2a "Full participation in the work with public disclosure of interest" and the 23% (46) needing the application of measure 2b "Partial exclusion from the work".

None of the declared interests were deemed as "relevant" (risk level 3).

Ten interests (5%) remained unassessed because of the lack of the necessary information for allowing an assessment.

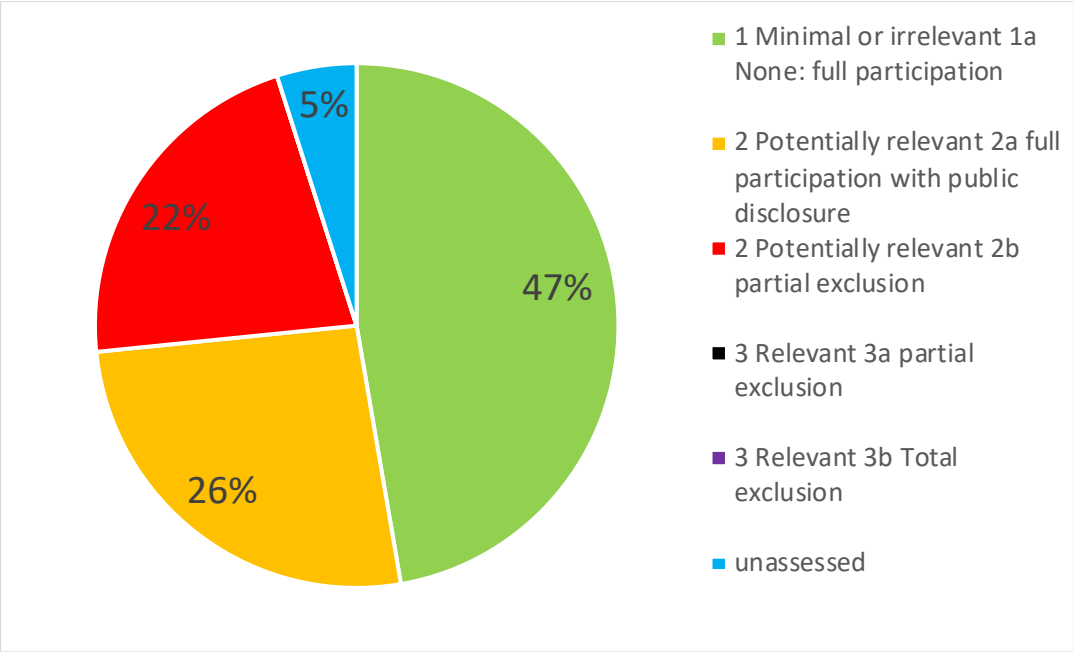

Figure 1. Distribution of the interests by level of risk and measure to be undertaken

The detailed results of the assessment are presented in the following paragraphs.

3.1 Risk level 1 - measure 1a: none, full participation in the work

In Table 2 are listed the interests considered as minimal or irrelevant (risk level 1) because they didn't match with the PICOs and were not specific nor related to the guideline scope.

Therefore, no action needs to be taken for the involved experts.

Table 2. List of interests assessed as Risk level 1 - Measure 1a: None, full participation in the work

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
3	**Traboulsee Anthony**	panel member	1b consulting	MRI guidelines for monitoring MS	Teva Pharmaceutical Industries	personal	$5000	previous
3	**Traboulsee Anthony**	panel member	2a research support	MS Society of Canada: Co-applicant and Principal investigator for cohort study of progression in MS	MS Society of Canada	University of British Columbia	_	current
3	**Traboulsee Anthony**	panel member	2b non monetary support	development and dissemination of MRI guidelines for MS in clinical practice	Consortium of MS Centers:	personal	$5000	current
3	**Traboulsee Anthony**	panel member	6b additional information	Outcome of the meeting could have a negative financial effect on Sanofi Genzyme, Novartis, Biogen, Teva, Roche with whom I've had a financial and research relationship with.	_	_	_	_
5	**Elisa Baldin**	research team	6e additional information	https://orcid.org/0000-0002-3277-5623	_	personal	_	_
7	**Ben Ridley**	research team	6e additional information	Donadieu, M., Le Fur, Y., Maarouf, A., Gherib, S., Ridley, B.,Pini, L., Rapacchi, S., Confort-Gouny, S., Guye, M., Schad, L.R., Maudsley, A.A., Pelletier, J., Audoin, B., Zaaraoui, W., Ranjeva, J.-P., 2017. Metabolic counterparts of sodium accumulation in multiple sclerosis: A whole brain 23Na-MRI and fast 1H-MRSI study. Mult. Scler.	_	personal	_	_
11	**Kathy Costello**	panel member	1b consulting	The objectives of this Advisory Board was to understand diversity, equity and inclusion issues facing people living with MS	Biogen	personal	$ 810 USD	2021

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
20	**Joanna Laurson-Doube**	coordinator	6e additional information	My scientific publications can be found here: https://orcid.org/0000-0001-9619-9170 I have also written this article: https://oneneurology.net/equitable-access/ I gave a talk on MSIF's work on ethical use of off-label treatments in MS at Sri Lanka CTRIMS January 2022.	_	personal	_	_
23	**Aukje Mantel-Teeuwisse**	panel member	2a research support	EC Horizon 2020. we have received a grant for the HTx project, a project that aims to create a framework for the Next Generation Health Technology Assessment (HTA) to support patient-centered, societally oriented, real-time decision-making on access to and reimbursement for health technologies throughout Europe (see https://www.htx-h2020.eu/about-htx-project/). MS is one of the four disease case studies. **I am the academic supervisor for 2 of the PhD students who work within this project. I am not the principle investigator, was not involved in the grant proposal nor responsible for the grant money within our research group**	EC Horizon 2020.	Research unit,	1000k. EC Horizon 2020.	current
27	**Carlos Navas**	panel member	1b consulting	Sanofi: · # 2 advisory boards on implications of highly effective therapies and vaccines, conferences in Central America on highly effective therapies and covid-19, and two conferences in Colombia on Induction and Multiple Sclerosis. I have not received a grant for travel or hotel stays in the last two years.	Sanofi	personal	_	_

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
27	**Carlos Navas**		1b consulting	Roche: grand for lectures: # 3 on Immune Nutrition and Multiple Sclerosis / NMOSD. Conference on Progression and Multiple Sclerosis. I have not received a grant for travel or hotel stays in the last two years.	Roche	personal	_	_
27	**Carlos Navas**		1b consulting	Novartis: grand for lectures # 2 advisory boards. About therapeutic failure and Multiple Sclerosis. conference on post ECTRIMS both 2020 and 2021. I have not received in the last two years a grant for travel or hotel stays.	Novartis	personal	_	_
27	**Carlos Navas**		1b consulting	Principal investigator for studies related to demyelinating disease. Primary Progressive Multiple Sclerosis (PPMS) Study of Bruton's Tyrosine Kinase (BTK) Inhibitor Tolebrutinib (SAR442168) (PERSEUS)	Sanofi	Universidad Sanitas	_	Sanofi study EFC 16035 in recruitment (2020) to date.
32	**Andrea Prato**	lay member	6c additional information	The following Organisations afforded trips for me as an attendant (not to speak on behalf of a specific drug or project), regarding different activities focused on topics that had no direct relation to the current project:- MSIF Global Meetings, to improve networking and awareness about MS, and to inform about MSIF anual work (Rome 2018), paid by MSIF	MSIF	personal	my plane tickets and allocations where covered	_
32	**Andrea Prato**	lay member	6c additional information	MSIF Global Meetings, to improve networking and awareness about MS, and to inform about MSIF annual work (London 2019), paid by MSIF	MSIF	personal	idem	_
32	**Andrea Prato**	lay member	6c additional information	MSIF Global Meetings, to improve networking and awareness about MS, and to inform about MSIF anual work (Athens 2019), paid by MSIF	MSIF	personal	idem	_

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
32	**Andrea Prato**	panel member	6b additional information	There's a potential damage for those MS Latin American Association that may be against off-label treatments, because they are afraid that their local Goverment will just allow off-label treatments in theri contries instead of DMT´s specifically developed for MS. Despite there is no concrete evidence of that consequence, it is still a fear from MS Latin American Association.	NA	NA	NA	NA
34	**Deanna Saylor**	clinical chair	2a research support	$50,000 pilot grant to develop a registry of demyelinating diseases in Zambia. This project collects observational data on current and prior treatment regimens but is not directly investigating the efficacy or appropriateness of these regimens	National Multiple Sclerosis Society	Research unit/institution	$50,000	current
35	**Nicoline Schiess**	observer from WHO Bran Healh Unit	5b public statements and positions	ORCID: 0000-0002-0121-8453 for publications on MS. As a clinician neurologist my career has been spent treating MS patients in clinics until 2018.	_	personal	_	_
38	**Janis Tye**	panel member	1a employment	advanced practice nurse	National Neuroscience Institute	personal	9000 per month	
44	**Riley Bove**	panel member	1b consulting	clinical advances moderator	WebMD	personal	5000	5/28/20
44	**Riley Bove**	panel member	1b consulting	CME talk	WebMD	personal	3000	06/11/20
44	**Riley Bove**	panel member	1b consulting	Medscape Spotlight - Patient’s Perspective in MS (275735.18) - 16 June 2020 at 7:00 PDT	WebMD	personal	4000	6/16/20
44	**Riley Bove**	panel member	1b consulting	MS National Steering Committee half hour safety on covid9	Roche Genentech	personal	300	03/12/20
44	**Riley Bove**	panel member	1b consulting	online survey about general treatment practices	Efficient LLC	personal	500	5/14/20

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
44	**Riley Bove**	panel member	1b consulting	talk	Medscape	personal	_	5/15/20
44	**Riley Bove**	panel member	1b consulting	Advisroy board on pregnancy	Merck	personal	2160	May-20
44	**Riley Bove**	panel member	1b consulting	virtual CME lecture	The Corpus lecture	personal	_	6/30/20
44	**Riley Bove**	panel member	1b consulting	virtual CME lecture	The Corpus lecture	personal	_	08/06/20
44	**Riley Bove**	panel member	1b consulting		Medscape steering committee	personal	_	9/17/20
44	**Riley Bove**	panel member	1b consulting	NMOSD advisory board	Alexion NMOSD advisory board	personal	1020	10/09/20
44	**Riley Bove**	panel member	1b consulting	advisory board on women's health	Momenta advisory board	personal	2000	11/14/20
44	**Riley Bove**	panel member	1b consulting	My life with MS - webMD talk	WebMD	personal	_	11/06/20
44	**Riley Bove**	panel member	1b consulting	seminar on neurorehabilitatino	Biogen	personal	_	_
44	**Riley Bove**	panel member	1b consulting	Medscape activity in pregnancy	Medscape	personal	2000	4/23/21
44	**Riley Bove**	panel member	1b consulting	University of MS Webinar on covid19	Novartis	personal	1596	06/08/21
44	**Riley Bove**	panel member	1b consulting	Ref: Delphi Consensus Programme: Expert Opinion on Contraception and MS	merck	personal	5500	11/05/21
44	**Riley Bove**	panel member	1b consulting	lecture on state of the art in MS treatment	webmd	personal	3500	11/30/21
44	**Riley Bove**	panel member	1b consulting	virtual CME lecture	The Corpus lecture	personal	_	11/04/21

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
44	**Riley Bove**	panel member	1b consulting	virtual CME lecture	The Corpus lecture	personal	_	12/19/21
44	**Riley Bove**	panel member	1b consulting	Caring for patients during the pandemic lecture	Medscape	personal	_	1/26/22
44	**Riley Bove**	panel member	2a research support	Digital Neurological Examination	Roche	UCSF	_	1/1/22-12/31/2023
44	**Riley Bove**	panel member	2a research support	Real World Data: Silent progression monitoring in RR-MS patients (CA-0169643)	Roche	UCSF	1,589,595	1/1/2022-12/31/2026
44	**Riley Bove**	panel member	2a research support	PROSPECTIVE ASCERTAINMENT OF PERI-CHILDBIRTH DEPRESSION AND ITS RELATIONSHIP WITH POSTPARTUM INFLAMMATORY ACTIVITY IN WOMEN WITH MS	Biogen	UCSF	_	10/1/20-9/30/23
45	**Dina Jacobs**	panel member	1b consulting	Novartis (Women in Neurology)	Novartis	personal	$2500	3. 2021
46	**Bianca Ozcan**	panel member	5b public statements and positions	I am the founder of Multiple Sclerosis Namibia and a MS Patient	_	personal	_	_
46	**Bianca Ozcan**	panel member	6e additional information	I am a MS Patient and the founder of the MS Namibia organization.	_	personal	_	_
47	**Tomas Kalincik**	panel member	1b consulting	Recording of an educational video for neurologsits - a discussion of the state of the art in neurological assessment and follow-up in MS.	Biogen	personal	2252	mar-22
47	**Tomas Kalincik**	panel member	1b consulting	Advisory board: role for registries in clinical care for MS. (Australia, Japan, China)	Biogen	personal	2252	feb-22
47	**Tomas Kalincik**	panel member	1b consulting	Lecture (Croatian Neurological Society): Real world evidence in the management of MS	Novartis	personal	1921	apr-22
47	**Tomas Kalincik**	panel member	1b consulting	Webinar: MS and COVID19	Novartis	personal	2562	nov-21

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
47	**Tomas Kalincik**	panel member	1b consulting	Consultancy: Australian treatment landscape in MS	Merck	personal	3200	ott-21
47	**Tomas Kalincik**	panel member	1b consulting	Expert commentary: Real world evidence in MS	Research Review	personal	700	set-21
47	**Tomas Kalincik**	panel member	1b consulting	Consultancy: neuroimmunological markers of personalised therapy for MS	Novartis	personal	1708	gen-22
47	**Tomas Kalincik**	panel member	1b consulting	Advisory board: treatment for MOG associated disease	Jansen Cilag	personal	1800	set-21
47	**Tomas Kalincik**	panel member	1b consulting	Lecture: Real world evidence in MS	Novartis	personal	1825	nov-21
47	**Tomas Kalincik**	panel member	1b consulting	Lecture: Real world evidence in MS	Eisai and Neurological Society of Taiwan	personal	3500	set-21
47	**Tomas Kalincik**	panel member	1b consulting	Lecture: annual teaching course in MS neurology	MS For Neurology Trainees	personal	2000	ott-21
47	**Tomas Kalincik**	panel member	1b consulting	Lecture: MS Masters symposium, real world evidence in MS	Merck	personal	2800	nov-20
47	**Tomas Kalincik**	panel member	1b consulting	Lecture: Overview of MS management during COVID19 for nurses	Merck	personal	3190	mag-21
47	**Tomas Kalincik**	panel member	1b consulting	Podcast: role of registries in management of MS	Biogen	personal	2252	lug-20
47	**Tomas Kalincik**	panel member	1b consulting	Webinar: Summary of the ECTRIMS 2021 meeting	The Limbic	personal	2000	set-20
47	**Tomas Kalincik**	panel member	1b consulting	Lecture: Real world evidence Summit	Novartis	personal	1964	ago-20
47	**Tomas Kalincik**	panel member	1b consulting	Lecture: timing of treatment in MS	Novartis	personal	1281	ago-20

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
47	**Tomas Kalincik**	panel member	1b consulting	Lecture: timing of treatment in MS	Biogen	personal	1971	lug-20
47	**Tomas Kalincik**	panel member	1b consulting	Lecture (Slovakia): timing of treatment in MS	Biogen	personal	3097	giu-20
47	**Tomas Kalincik**	panel member	1b consulting	Onine seminar: session chair (COVID19 and MS)	Merck	personal	1400	giu-20
47	**Tomas Kalincik**	panel member	1b consulting	Virtual lecture series (China): timing of high-efficacy MS therapies, real-world evidence	Novartis	personal	8450	mag-20
47	**Tomas Kalincik**	panel member	1b consulting	Scientific committee (online conference)	triMS.online	personal	1815	apr-21
47	**Tomas Kalincik**	panel member	1b consulting	Lecture (Neurological Society Hong Kong): timing of high-efficacy therapy in MS	Merck	personal	1600	nov-19
47	**Tomas Kalincik**	panel member	1b consulting	Seminar: statistics in observational data	Merck	personal	1600	lug-19
47	**Tomas Kalincik**	panel member	1b consulting	Lecture series (Portugal): interpreting results of real-world studies	Biogen	personal	11823	mag-19
47	**Tomas Kalincik**	panel member	1b consulting	Lecture (PACTRIMS): oral therapies in the management of MS	Merck	personal	1600	nov-18
47	**Tomas Kalincik**	panel member	1b consulting	Lecture: examples of real world evidence in MS	WebMD	personal	3185	ott-18
47	**Tomas Kalincik**	panel member	1b consulting	Lecture (Taiwan): effect of MS therapy on long-term disability outcomes; personalised medicine	Merck	personal	2600	nov-18
47	**Tomas Kalincik**	panel member	1b consulting	Scientific committee (online conference), chairing, presentation	triMS.online	personal	5500	nov-18
47	**Tomas Kalincik**	panel member	1b consulting	Lecture (MS Masters)	Merck	personal	1600	set-18

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
47	**Tomas Kalincik**	panel member	1b consulting	Lecture: hematopoietic stem cells in the treatment of MS	Cairns society	personal	1500	mag-18
47	**Tomas Kalincik**	panel member	1b consulting	Lecture (ECTRIMS): timing of high-efficacy treatment in MS	Novartis	personal	1760	mag-18
47	**Tomas Kalincik**	panel member	2a research support	Teaching preceptorship for neurologists: principles of management of MS, including COVID19 and other infections	Novartis	Royal Melbourne Hospital Neuroscience Foundation	15799	dic-21
47	**Tomas Kalincik**	panel member	2a research support	Research grant: education for patients with MS	Biogen	Royal Melbourne Hospital	90000	dic-22
47	**Tomas Kalincik**	panel member	2a research support	Research grant: therapeutic lag in MS	Biogen	Royal Melbourne Hospital Neuroscience Foundation	75000	dic-21
47	**Tomas Kalincik**	panel member	2a research support	Research fellowship: latitude and MS severity	Biogen	Royal Melbourne Hospital Neuroscience Foundation	68000	mar-19
47	**Tomas Kalincik**	panel member	2a research support	Training fellowship: Neuroimmunology and MS	Biogen	Royal Melbourne Hospital Neuroscience Foundation	50000	gen-23
47	**Tomas Kalincik**	panel member	2a research support	Teaching course: CORe Advanced Statistics Course	Biogen, Celgene, Genzyme, Merck, Roche, Teva	Royal Melbourne Hospital Neuroscience Foundation	66000	feb-21

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
47	**Tomas Kalincik**	panel member	2a research support	Training fellowship: Neuroimmunology and MS	Merck	Royal Melbourne Hospital Neuroscience Foundation	75000	feb-22
47	**Tomas Kalincik**	panel member	2a research support	Training fellowship: Neuroimmunology and MS	BMS/Celgene	Royal Melbourne Hospital	75000	feb-23
47	**Tomas Kalincik**	panel member	2a research support	Project grant: RMH MS Centre	Roche	Royal Melbourne Hospital	100000	feb-23
47	**Tomas Kalincik**	panel member	2a research support	Training fellowship: Neuroimmunology and MS	Alexion	Royal Melbourne Hospital	51500	feb-23
47	**Tomas Kalincik**	panel member	2b non monetary support	Conference: travel, accommodation, registration	Merck	personal	2000	feb-22
47	**Tomas Kalincik**	panel member	2b non monetary support	Conference: travel, accommodation, registration	Merck	personal	9000	ott-19
47	**Tomas Kalincik**	panel member	2b non monetary support	Conference: virtual registration	Roche	personal	800	ott-21
47	**Tomas Kalincik**	panel member	2b non monetary support	Conference: virtual registration	Biogen	personal	800	ott-20
47	**Tomas Kalincik**	panel member	2b non monetary support	Conference: virtual registration	Roche	personal	1000	feb-21
47	**Tomas Kalincik**	panel member	2b non monetary support	Conference: travel, accommodation, registration	Novartis	personal	9000	set-18
47	**Tomas Kalincik**	panel member	2b non monetary support	Conference: virtual registration	Merck	personal	500	mag-20

3.2 Risk level 2 - measure 2a: full participation in the work with public disclosure of interest

In Table 3 are listed the interests considered as potentially relevant (risk level 2) with application of measure 2a (participation with disclosure).

That is mainly because although the interests are specific to the guideline scope, they are nevertheless related to research team members or other subjects with no voting right. When related to panel members, these interests refer mainly to activities such as Advisory Boards, speaking at meetings, travel and accommodation paid by Pharma but not related to the specific DTMs evaluated by the guideline. Registry studies, out of scope disease areas (even if relevant DMT) and out of scope population (such as children) are also assessed as potentially relevant with application of measure 2a.

Therefore, the involved experts are entitled to fully participate in the guideline work with public disclosure of the relevant interests in the guideline document or on the website following the publication of the recommendation.

Table 3 List of interests assessed as Risk level 2 - measure 2a: full participation in the work with public disclosure of the interest

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
3	**Traboulsee Anthony**	panel member	5a public statements and positions	Province of Saskatchewan (Canada) Ministry of Health advisory panel on treatment of Multiple Sclerosis	_	personal	_	_
4	**Jagannadha Avasarala**	panel member	1b consulting	AD BOARDS	Genentech, Viela Bio	personal	1500 dollars each plus airfare	2017 and 2019 for NMOSD Ad board, the best I can tell
5	**Elisa Baldin**	research team	2b non monetary	paid travel to meetings (European Academy of Neurology-EAN: Lisbon, Oslo- ECTRIMS : Stockholm, Paris)	Roche, Sanofi-Genzime, Biogen	personal	paid travel to meetings	before 2020
7	**Ben Ridley**	research team	6e additional information	Nonino F, Baldin E, Ridley B, Casetta I, Iuliano G, Filippini G. 2021 Azathioprine for people with multiple sclerosis (Protocol). Cochrane Database of Systematic Reviews 2021, Issue 7. Art. No.: CD015005. DOI: 10.1002/14651858.CD015005.	Multiple Sclerosis International Federation, ARSEP Fondation, Association SEP Pays d'Aix, Agence Nationale de la Recherche	personal	_	_
11	**Kathy Costello**	panel member	2a research support	Can Do Multiple Sclerosis has received multiple grants and sponsorships over the past several years from Pharma. See column 3 for details. The Pharma companies listed sponsor programs and events for Can Do Multiple Sclerosis, a 501 C3 non -profit organizations. We have health and	Pharma: Biogen, Serono, Genentec,Novartis,Mallinckrodt, Sanofi	Can Do Multiple Sclerosis	Total of: $1,601,820 for 2019; $1,676,236 for 2020; $1,696,634	2019-2021

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
				wellness educational programs, including webinars, podcasts, and multi-day programs where health and wellness strategies are discussed. The support has been for wellness and lifestyle programs, and not programs related to DMTs or other pharmaceutical products	Gen, Celgene, janssen		for 2021. See the CoI form	
13	**Cinzia Delgiovane**	research team	1b consulting		MSIF	personal	12.000 euro	current
13	**Cinzia Delgiovane**	research team	2a research support	Swiss MS Register (DOI: 10.1002/14651858.CD012200.pub2) Treatment with disease-modifying drugs for people with a first clinical attack suggestive of multiple sclerosis. Database Syst Rev. 2017 Apr 25;4(4):CD012200.	_	personal	64.000 CHF	ceased
13	**Cinzia Delgiovane**	research team	2a research support	DOI: 10.1002/14651858.CD011381.pub2. DOI: 10.1002/14651858.CD012186. DOI: 10.1002/14651858.CD008933.pub2. Project included in the Strategic Program "Therapy for MS, Italy.	Fondazione Istituto Neurologico Carlo Besta - Milan, Italy and Ministero della salute, Italia or Ministero della Salute - Direzione Generale della Ricerca Scientifica e Tecnologica	personal	I did not receive any fund for that	ceased
14	**Graziella Filippini**	research team	6e additional information	My MS related publications (orcid.org/0000-0002-6682-4307)	funded by the Italian Ministry of Health and the Italian MS Society, or not	personal	_	_

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
					funded, and not supported by industry.			
16	**Marien Gonzalez Lorenzo**	research team	6e additional information	author in the Cochrane systematic review entitled "Adverse effects of immunotherapies for multiple sclerosis: a network meta-analysis".	not funded by Industry,	personal	not funded by Industry,	current
19	**Tapas Kumar**	panel member	2a research support	Biogen-investigator initiated trial grant. I delivered several lectures on "Multiple Sclerosis and disease-modifying therapies" organised by the above company. I was NOT involved with any clinical trial with pharmaceutical intervention for the said company.	Biogen	My Employer: National Neurosciences Centre Calcutta	_	Ceased in the year 2018.
20	**Joanna Laurson-Doube**	coordinator	2b non monetary support	MENACTRIMS paid for travel cost to attend meeting (flight and hotel) and give a talk about my work for MSIF.	MENACTRIMS	personal	less than 3000 USD	December 2021
20	**Joanna Laurson-Doube**	coordinator	6e additional information	The MSIF Essential Medicines (MEM) project is funded and co-ordinated by MSIF. **I was employed by MSIF** October 2017 - July 2018. From August 2018 I have been working with MSIF on a **consultancy contract**, co-ordinating this project. MSIF's Declaration of Conflicting Interests: Multiple Sclerosis International Federation (MSIF) is an alliance of national MS organizations. MSIF receives income from a wide range of sources, including healthcare and other companies, individuals, member organizations, campaigns, foundations, and trusts. Over the last five years, **MSIF received funding from the following companies:** Biogen, Bristol Myers Squibb (formerly Celgene), MedDay, Merck, Mylan, Novartis, Roche, Sanofi Genzyme, and Teva. Our independence and all our donations from the healthcare industry are governed by our policy: http://www.msif.org/wp-	MSIF	employer (MSIF)	_	_

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
				content/uploads/2017/09/Policyand-Practices-in-Relationships-with-the-Healthcare-Industry-2017.pdf. MSIF has not received any funding from industry for its access to medicines work (including this project) in 2019, 2020 or 2021 and does not intend to do so in 2022.				
25	**Jennifer McDonell**	panel member	1a employment	The MS Society of Canada is a national voluntary organization that supports MS research and services for people affected by MS. The MS Society of Canada receives income from various sources: individual donors, campaigns, direct marketing, fundraising events, foundations, corporate partners, pharmaceutical companies and government. The MS Society of Canada's total revenue from pharmaceutical companies is less than one per cent of the amount of money the organization receives annually. Over the past five years the MS Society of Canada **received funding from the following companies:** Biogen, Bristol Myers Squibb (formerly Celgene), Sanofi-Genzyme, EMD Serono, Novartis, Roche, Janssen, Pendopharm, a Division of Pharmascience Inc. , Alexion and Teva. Any pharmaceutical funding received by the MS Society of Canada is subject to the MS Society's strict policies that prevent any control or influence by the donor on our decision-making. This is consistent with the ethical principles of Canada's research-based pharmaceutical companies which require that they assure the independence and integrity of stakeholders, in terms of their operations, policies and activities.	MS Society of Canada.	employer MS Society of Canada.	_	ongoing
25	**Jennifer McDonell**	panel member	4a intellectual property	Article published in MS Journal (Sage) - Blog post published by MS Journal (Sage)		personal	None	

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
				World Health Organization Essential Medicines List: Multiple sclerosis disease-modifying therapies application. https://journals.sagepub.com/doi/full/10.1177/1352458519898340, World Health Organisation Essential Medicines List: multiple sclerosis disease-modifying therapies application process https://perspectivesblog.sagepub.com/blog/msj-blog-post				
26	**Silvia Minozzi**	research team	6e additional information	1. Filippini G, Lasserson TJ, Dwan K, D'Amico R, Borrelli F, Izzo AA, Minozzi S. Cannabis and cannabinoids for people with multiple sclerosis. Cochrane Database of Systematic Reviews 2019, Issue 10. Art. No.: CD013444. DOI: 10.1002/14651858.CD013444. 2. Laura Amato, Silvia Minozzi, Zuzana Mitrova, Elena Parmelli, Rosella Saulle, Fabio Cruciani, Simona Vecchi, Marina Davoli Systematic review of safeness and therapeutic efficacy of cannabis in patients with multiple sclerosis, neuropathic pain, and in oncological patients treated with chemotherapy. Epidemiol Prev 2017; 41 (5-6). doi: 10.19191/EP17.5-6.AD01.069 3. Pucci E, Giuliani G, Solari A, Simi S, Minozzi S, Di Pietrantonj C, Galea I. Natalizumab for relapsing remitting multiple sclerosis. Cochrane Database of Systematic Reviews 2011, Issue 10 Efficacy and safety of pharmacological interventions for the treatment of the Alcohol Withdrawal Syndrome	_	personal	these projiects were not funded by industry.	_
28	**Francesco Nonino**	research team	2a research support		MSIF, Multiple Sclerosis International Federation	The Unit of Epidemiology and Statistics of which I am the director	12,500 euro for evidence synthesis and	current

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
							methodological support on the Multiple Sclerosis Off-Label Task Force (MOLT) project	
32	**Andrea Prato**	lay member	6c additional information	4th Latin American Meeting of MS Associations (Paraguay 2018), paid by Nolver	Nolver	personal	idem	
32	**Andrea Prato**	lay member	6c additional information	International MS patient summit, regarding patient engagement (Athens 2019), paid by Roche	Roche	personal	idem	
32	**Andrea Prato**	lay member	6e additional information	In 2020 Roche donated a grant to the Uruguayan MS Association to train its volunteers on different topics; I received training on HTA and English, both delivered by independent organisations. 1. HTA: IECS (www.iecs.org.ar) - amount: USD 299 2. English: In Situ Languages (https://www.facebook.com/IN-SITU-LANGUAGES-CAPACITACI%C3%93N-EN-IDIOMAS-URUGUAY-111488525528997/about/) - amount: USD 200 per month (8 months total)	Roche	personal	_	_
33	**Nick Rijke**	panel member	6e additional information	The MSIF Essential Medicines (MEM) project is funded and co-ordinated by MSIF.I was employed by MSIF May 2017 - January 2022. I continue to work as a consultant to MSIF for one day a week. MSIF's Declaration of Conflicting Interests: Multiple Sclerosis International Federation (MSIF) is an alliance of national MS organizations. MSIF receives income from a wide range of sources,	MSIF	MSIF	_	_

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
				including healthcare and other companies, individuals, member organizations, campaigns, foundations, and trusts. Over the last five years, **MSIF received funding from the following companies**: Biogen, Bristol Myers Squibb (formerly Celgene), MedDay, Merck, Mylan, Novartis, Roche, Sanofi Genzyme, and Teva. Our independence and all our donations from the healthcare industry are governed by our policy: http://www.msif.org/wp-content/uploads/2017/09/Policyand-Practices-in-Relationships-with-the-Healthcare-Industry-2017.pdf. MSIF has not received any funding from industry for its access to medicines work (including this project) in 2019, 2020 or 2021 and does not intend to do so in 2022. My scientific publications can be found here: https://orcid.org/0000-0002-0328-1309				
34	**Deanna Saylor**	clinical chair	1b consulting	non-remunerated position as committee member in the **ACTRIMS MS Differential Diagnosis in Non-Western Settings Working Group**	ACTRIMS MS	personal	Non-remunerated	current
34	**Deanna Saylor**	clinical chair	1b consulting	Non-remunerated position as **committee member on MSIF working groups** including International Working Group for Access and Off-Label Treatment Group;	Multiple Sclerosis International Federation (MSIF)	personal	Non-remunerated	current
40	**Shanthi Viswanathan**	panel member	5a public statements and positions	I have been involved as a public servant in coming up with **treatment guidelines** on the management of Multiple sclerosis and related disorders in Malaysia as Chair without any remuneration or sponsorship and have given talks on the guidelines to other neurologists,physicians and other members of the public.	_	personal	_	_

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
40	**Shanthi Viswanathan**	panel member	5b public statements and positions	I have been involved as a public servant in coming up with t**reatment guidelines** on the management of Multiple sclerosis and related disorders in Malaysia as Chair without any remuneration or sponsorship and have given talks on the guidelines to other neurologists,physicians and other members of the public. 2016CPG.pdf - Malaysian Society of Neurosciences	Malaysian Society of Neurosciences	personal	non-remunerated	ceased
42	**Bassem Yamout**	panel member	2a research support	Novartis, Merck: I sat on scientific advisory boards, and received speaker honoraria from both companies.	Novartis, Merck	personal	_	_
42	**Bassem Yamout**	panel member	from bio-sketch	president of MENACTRIMS	_	personal	_	_
43	**Maya Zeineddine**	panel member	2b non monetary	Merck sponsored my travel to attend ECTRIMS congress from 2012 until 2018 (on yearly basis). They covered my travel expenses including flight; ECTRIMS registration and accomodation. The Objective was to update our knowledge regarding MS so we can elevate the clinical care of MS in the region to a higher level.	Merck	personal	_	_
43	**Maya Zeineddine**	panel member	2a research support	Honorarium fees for me from Novartis, Merck, Roche, Biologix and Sanofi-genzyme. Deliver clinical lectures about multiple sclerosis (epidemiology; pathophysiology; treatment; economic burden;adverse events management; safety and efficacy of DMTs etc...) to health care professionals in the ME region to increase awareness and educate them about the disease and its available therapies.	Novartis, Merck, Roche, Biologix and Sanofi-genzyme	personal	not more than 1000 USD per lecture	current
43	**Maya Zeineddine**	panel member	declaration elicited	Gilenya Pregnancy Registry	Novartis	personal		
43	**Maya Zeineddine**	panel member	declaration elicited	TERIKIDS (Teriflunomide in Pediatrics)	_	personal	_	_

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
43	**Maya Zeineddine**	panel member	declaration elicited	FOCUS and CONNECT Trials (Dimethyl Fumarate in Pediatrics)	_	personal	_	_
44	**Riley Bove**	panel member	1b consulting	opicinumab advisory board	Biogen	_	1050	4/28/20
44	**Riley Bove**	panel member	1b consulting	MS National Steering Committee #1 Advisory Board	Roche	_	2898	5/16/20
44	**Riley Bove**	panel member	2a research support	ML43942 Evaluating pregnancy outcomes in minority women with MS: A multicenter care series[2]	Genentech	University of California, San Francisco UCSF	246,147	Pending (1 year)
44	**Riley Bove**	panel member	6e	Pregnancy Management in Multiple Sclerosis and Other Demyelinating Diseases. Continuum (Minneap Minn). 2022 Feb 01; 28(1):12-33. Bove RM, Houtchens MK. PMID: 35133309. (It reviews the current state of knowledge)	_	personal	_	_
44	**Riley Bove**	**panel member**	**6e**	Hypogammaglobulinemia in Patients with Neuromyelitis Optica (NMO). Journal of Allergy and Clinical Immunology. 2020 Feb 1; 145(2):ab215. Tsao TL, Bove BR, Krishnakumar KT, Otani OI. .	_	personal	_	_
44	**Riley Bove**	panel member	6e	1. We need to conduct clinical trials of disease-modifying therapy in pregnancy to optimize care of women with MS - Commentary. Mult Scler. 2019 02; 25(2):190-192. Bove R. PMID: 30346219.	_	personal	_	_
44	**Riley Bove**	panel member	6e	A case for gender-based approach to multiple sclerosis therapeutics. Front Neuroendocrinol. 2018 07; 50:123-134. Houtchens MK, Bove R. PMID: 30040969.	_	personal	_	_
45	**Dina Jacobs**	panel member	1b consulting	Horizon (Inebilizumab-cdon)	Horizon Therapeutics	personal	$2500	7. 2021
45	**Dina Jacobs**	panel member	1b consulting	Biogen (Women in Neuroscience)	Biogen	personal	Less than $10,000	2. 2021

[2] The measure 2a was taken because the study title dies not mention exposure to specific DMTs. In case specific DMTs are evaluated in the study, measure 2b should be applied and the expert will have to be excluded for those specific DMTs.

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period
47	**Tomas Kalincik**	panel member	1b consulting	Advisory board (aim of providing impartial clinical input, and support for presenting lectures with content developed and controlled by myself)	BMS / Celgene	personal	2252	nov-20
47	**Tomas Kalincik**	panel member	1b consulting	Advisory board (aim of providing impartial clinical input, and support for presenting lectures with content developed and controlled by myself)	Novartis	personal	2135	nov-20
47	**Tomas Kalincik**	panel member	1b consulting	Advisory board (aim of providing impartial clinical input, and support for presenting lectures with content developed and controlled by myself)	Roche	personal	1220	ott-20
47	**Tomas Kalincik**	panel member	1b consulting	Advisory board (aim of providing impartial clinical input, and support for presenting lectures with content developed and controlled by myself)	Celgene	personal	3290	ago-19
47	**Tomas Kalincik**	panel member	1b consulting	Advisory board (aim of providing impartial clinical input, and support for presenting lectures with content developed and controlled by myself)	Novartis	personal	2562	feb-19
47	**Tomas Kalincik**	panel member	1b consulting	Advisory board (aim of providing impartial clinical input, and support for presenting lectures with content developed and controlled by myself)	Roche	personal	2385	gen-19
47	**Tomas Kalincik**	panel member	1b consulting	Advisory board (aim of providing impartial clinical input, and support for presenting lectures with content developed and controlled by myself)	Novartis	personal	1660	dic-18
47	**Tomas Kalincik**	panel member	1b consulting	Advisory board (aim of providing impartial clinical input, and support for presenting lectures with content developed and controlled by myself)	Merck	personal	2800	set-18
47	**Tomas Kalincik**	panel member	1b consulting	Lecture series (Europe): sequencing of therapies	Biogen	personal	13580	nov-18

3.3 Risk level 2 - measure 2b: partial exclusion from the work

In Table 4 are listed the interests deemed as “potentially relevant” (risk level 2) with application of measure 2b “partial exclusion from the guideline work” because the declared interests are relative to DMTs included in the list of the pharmacological interventions to be evaluated by the guideline (see Annex 2 for this list).

Therefore, the involved experts should have the right to participate in the discussion and in the critical evaluation of the evidence but should be excluded from participation in the expression of judgments on the GRADE EtD criteria and recommendations’ formulation for those PICOs related to the specific DMTs to which the interest is referred.

The specific DMTs to which the interest is referred indicated in the last column of Table 4,

Table 4 List of interests assessed as Risk level 2 - Measure 2b: Partial exclusion from the work

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period	DMT
3	**Traboulsee Anthony**	panel member	1b consulting	ocrelizumab for RRMS and PPMS; satralizuamb for NMOSD;	Roche	personal	$15,000	current	**ocrelizumab**
3	**Traboulsee Anthony**	panel member	1b consulting	Alemtuzumab for RRMS; tolebrutinib for RRMS, PPMS, SPMS	Sanofi Genzyme	personal	$15,000	current	**Alemtuzumab**
3	**Traboulsee Anthony**	panel member	1b consulting	Natalizumab for RRMS	Biogen	personal	$5000	previous	**Natalizumab**
3	**Traboulsee Anthony**	panel member	1b consulting	Ofatumamab for RRMS, siponimod for SPMS	Novartis	personal	$5000	previous	**Ofatumamab**
3	**Traboulsee Anthony**	panel member	2a research support	Principal investigator for ocreulizumab for RRMS and PPMS phase 3 and phase 4 clinical trials and MRI research. Principal investigator for satralizumab for NMOSD	Roche	University of British Columbia	_	current	**ocrelizumab**
3	**Traboulsee Anthony**	panel member	2a research support	Principal investigator for alemtuzumab for RRMS phase III and clinical trial, investigator sponsored study and MRI research of alemtuzumab	Sanofi Genzyme	University of British Columbia	_	current	**Alemtuzumab**
3	**Traboulsee Anthony**	panel member	5a expert testimony	Mavenclad review	Canadian Agency for Drugs And Technology in Health (CADTH)	personal	_	_	**Mavenclad = cladribine**
4	**Jagannadha Avasarala**	panel member	5b	I have participated in Advisory Boards (2), one related to Genentech (I think it was Ocrevus) and one with Viela Bio (Uplizna, approved for NMOSD, NOT MS)	Genentech, Viela Bio	personal	_	_	**Ovrevus = ocrelizumab**

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period	DMT
11	**Kathy Costello**	panel member	1b consulting	initiative called 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.	Janssen	personal	$ 450 USD	2021	**S1P receptor modulator such as Fingolimod**
27	**Carlos Navas**	panel member	1b consulting	Principal investigator for studies related to demyelinating disease. Novartis study CFTY20D2406 (completed 2016-2020): The primary objective of this study is to evaluate the long-term safety and tolerability of fingolimod for the treatment of Relapsing Remitting Multiple Sclerosis (RRMS).	Novartis	Universidad Sanitas	_	Novartis study CFTY20D2406 (completed 2016-2020)	**fingolimod**
27	**Carlos Navas**	panel member	1b consulting	Principal investigator for studies related to demyelinating diseaseBut the relationship of the laboratories is with the research center, not directly with the researchers (I am part of the group but I am not the director nor am I part of its administration). Roche study WA40404 and MN39159.	Roche	Universidad Sanitas	_	Roche study WA40404 (in recruitment) , 2020 to the present; MN39159 (in its third year of evolution) 2018 to the present.	**Roche study WA40404 and MN39159 = ocrelizumab**
40	**Shanthi Viswanathan**	panel member	5a expert testimony	I have also published investigator initiated papers on the epidemiology of multiple sclerosis, neuromyelitis optica spectrum disorder and its	_	personal	_	_	**Fingolimod, IVIG e Rituximab**

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period	DMT
				treatment. The papers I have published do not include any of the drugs that we are currently discussing except fo**r** an investigator initiated publication on **Fingolimod** in Multiple sclerosis**, IVIG** in NMOSD and the use of **rituximab** in neuromyelitis optica spectrum disorder as induction therapy. SEE LIST OF PUBLICATIONS. My Orcid ID is https://orcid.org/ 0000-0002-0094-0540					
42	**Bassem Yamout**	panel member	2a research support	In the past I was a principal investigator in the following international Phase III trials sponsored by MERCK: CLARITY, ORACLE, REFLEX.	Merck	personal	_	_	**Clarity e Oracle = cladribile. Reflex study on treatment with Rebif®(interferone beta-1a)**
42	**Bassem Yamout**	panel member	2a research support	I am currently on the steering committee of CLASSIC-MS, an international study sponsored by Merck.	Merck	personal	_	_	**CLASSIC-MS on Cladribine**
43	**Maya Zeineddine**	panel member	declaration elicited	ENSEMBLE, ENSEMBLE PLUS and CONSONANCE Trials (Ocrelizumab in progressive MS)	_	personal	_	_	**Ocrelizumab**
44	**Riley Bove**	panel member	1b consulting	ARTIOS ofatumumab trial	Novartis Artios	personal	532	5/13/20	**ofatumumab**
44	**Riley Bove**	panel member	1b consulting	teriflunomide advisory board: women and children, virtual	Genzyme Sanofi	personal	2730	06/05/20	**teriflunomide**
44	**Riley Bove**	panel member	1b consulting	Ocrevus pregnancy ad board	Genentech	personal	3600	7/23/20	**Ovrevus = ocrelizumab**
44	**Riley Bove**	panel member	1b consulting	Ofatumumab Expert panel	Novartis	personal	1596	10/29/20	**Ofatumumab**
44	**Riley Bove**	panel member	1b consulting	Artios Study Steering Committee	Novartis	personal	1064	11/18/20	**Artios Study evaluate**

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period	DMT
									effectiveness of treatment with ofatumumab in patients transitioning from commonly used oral MS therapies - fingolimod or dimethyl fumarate, due to breakthrough disease.
44	**Riley Bove**	panel member	1b consulting	Artios Study Steering Committee	Novartis	personal	798	06/03/21	**Artios Study evaluate effectiveness of treatment with ofatumumab**
44	**Riley Bove**	panel member	2a research support	PRE CSA - COVID19/Vaccination treated with Ofatumumab and Other DMTs	Novartis	UCSF	478,912	7/1/2021-9/3/2022	**Ofatumumab**
44	**Riley Bove**	panel member	2a research support	A PHASE IV MULTICENTER, OPEN-LABEL STUDY EVALUATING B CELL LEVELS IN INFANTS POTENTIALLY EXPOSED TO OCRELIZUMAB DURING PREGNANCY THE MINORE STUDY	Roche	UCSF	907,162	8/13/21-8/13/26	**Ocrelizumab**
44	**Riley Bove**	panel member	2a research support	A PHASE IV MULTICENTER, OPEN-LABEL STUDY EVALUATING B CELL LEVELS IN INFANTS OF LACTATING WOMEN WITH CIS OR MS RECEIVING OCRELIZUMAB THE SOPRANINO STUDY	Roche	UCSF	332,532	8/15/21-9/1/24	**Ocrelizumab**
44	**Riley Bove**	panel member	2a research support	Measurement of ocrelizumab in human breastmilk - Bove/Genentech	Genentech	UCSF	322,463$	08/10/2020-02/14/2022	**Ocrelizumab**

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period	DMT
44	**Riley Bove**	panel member	6e	Multiple sclerosis therapies differentially impact SARS-CoV-2 vaccine-induced antibody and T cell immunity and function. JCI Insight. 2022 Jan 14. Sabatino JJ, Mittl K, Rowles WM, McPolin K, Rajan JV, Laurie MT, Zamecnik CR, Dandekar R, Alvarenga BD, Loudermilk RP, Gerungan C, Spencer CM, Sagan SA, Augusto DG, Alexander JR, DeRisi JL, Hollenbach JA, Wilson MR, Zamvil SS, Bove R. PMID: 35030101	_	personal	_	_	**glatiramer acetate, dimethyl fumarate, natalizumab, sphingosine-1-phosphate (S1P) receptor modulators and anti-CD20 mAbs**
44	**Riley Bove**	panel member	6e	Impact of multiple sclerosis disease-modifying therapies on SARS-CoV-2 vaccine-induced antibody and T cell immunity. medRxiv. 2021 Sep 20. Sabatino JJ, Mittl K, Rowles W, Mcpolin K, Rajan JV, Zamecnik CR, Dandekar R, Alvarenga BD, Loudermilk RP, Gerungan C, Spencer CM, Sagan SA, Augusto DG, Alexander J, Hollenbach JA, Wilson MR, Zamvil SS, Bove R, Sabatino JJ, Mittl K, Rowles W, Mcpolin K, Rajan JV, Zamecnik CR, Dandekar R, Alvarenga BD, Loudermilk RP, Gerungan C, Spencer CM, Sagan SA, Augusto DG, Alexander J, Hollenbach JA, Wilson MR, Zamvil SS, Bove R. PMID: 34580672; PMCID: PMC8475959	_	personal	_	_	**sphingosine-1-phosphate (S1P) receptor modulators and anti-CD20 monoclonal antibodies (mAb)**
44	**Riley Bove**	panel member	6e	Humoral immune response following SARS-CoV-2 mRNA vaccination concomitant to anti-	_	personal	_	_	**on anti-CD20 monoclonal antibody treatment**

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period	DMT
				CD20 therapy in multiple sclerosis. Mult Scler Relat Disord. 2021 Sep 09; 56:103251. Novak F, Nilsson AC, Nielsen C, Holm DK, Østergaard K, Bystrup A, Byg KE, Johansen IS, Mittl K, Rowles W, Mcpolin K, Spencer C, Sagan S, Gerungan C, Wilson MR, Zamvil SS, Bove R, Sabatino JJ, Sejbaek T. PMID: 34571415; PMCID: PMC8426319					**such as ofatumumab, Ocrelizumab, rituximab .**
44	**Riley Bove**	panel member	6e	Traitement de la sclérose en plaques (SEP) par ocrelizumab (OCR) et grossesses : actualisation des données. Revue Neurologique. 2021 Apr 1; 177:s106. Bove BR, Oreja-Guevara OC, Hellwig HK, Buffels BR, Pasquarelli PN, Zecevic ZD, Vukusic VS.	__	personal	_	_	**ocrelizumab**
44	**Riley Bove**	panel member	6e	Treatment of Women with Multiple Sclerosis Planning Pregnancy. Curr Treat Options Neurol. 2021; 23(4):11. Krysko KM, Bove R, Dobson R, Jokubaitis V, Hellwig K. PMID: 33814892; PMCID: PMC8008016	_	personal	_	_	**glatiramer acetate, interferon-beta, rituximab, natalizumab**
44	**Riley Bove**	panel member	6e	1. Transfer of monoclonal antibodies into breastmilk in neurologic and non-neurologic diseases. Neurol Neuroimmunol Neuroinflamm. 2020 07; 7(4). LaHue SC, Anderson A, Krysko KM, Rutatangwa A, Dorsey MJ, Hale T, Mahadevan U, Rogers EE, Rosenstein MG, Bove R.	_	personal	_	_	**rituximab, natalizumab**

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period	DMT
				PMID: 32461351; PMCID: PMC7286664.					
44	**Riley Bove**	panel member	**6e**	Minimal breast milk transfer of rituximab, a monoclonal antibody used in neurological conditions. Neurol Neuroimmunol Neuroinflamm. 2020 01; 7(1). Krysko KM, LaHue SC, Anderson A, Rutatangwa A, Rowles W, Schubert RD, Marcus J, Riley CS, Bevan C, Hale TW, Bove R. PMID: 31719115; PMCID: PMC6857908	_	personal	_	_	**rituximab**
44	**Riley Bove**	panel member	6e	Navigating monoclonal antibody use in breastfeeding women: Do no harm or do little good? Neurology. 2019 10 08; 93(15):668-672. LaHue SC, Gelfand AA, Bove RM. PMID: 31492717.	_	personal	_	_	**monoclonal antibodies (mAbs)**
44	**Riley Bove**	panel member	6e	1. Hypogammaglobulinemia in Multiple Sclerosis Patients Receiving Disease-Modifying Immunomodulatory Agents. Journal of Allergy and Clinical Immunology. 2019 Feb 1; 143(2):ab16. Tsao TL, Otani OI, Bove BR. .	_	personal	_	_	**immunomodulatory agents: interferon beta-1a, interferon beta-1b, peginterferon beta-1a, glatiramer acetate, teriflunomide, dimethyl fumarate, fingolimod, cyclophosphamide, mycophenolate mofetil, mitoxantrone, daclizumab, alemtuzumab,**

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period	DMT
									rituximab, natalizumab, and ocrelizumab.
44	**Riley Bove**	panel member	6e	Clinical and Radiologic Disease Activity in Pregnancy and Postpartum in MS. Neurol Neuroimmunol Neuroinflamm. 2021 03; 8(2). Anderson A, Krysko KM, Rutatangwa A, Krishnakumar T, Chen C, Rowles W, Zhao C, Houtchens MK, Bove R. PMID: 33608303; PMCID: PMC8105896.	_	personal	_	_	**fingolimod. natalizumab, glatiramer acetate, interferon-β, anti-CD20 mAbs**
44	**Riley Bove**	**panel member**	6e	MRI activity in MS and completed pregnancy: Data from a tertiary academic center. Neurol Neuroimmunol Neuroinflamm. 2020 11 05; 7(6). Houtchens M, Bove R, Healy B, Houtchens S, Kaplan TB, Mahlanza T, Chitnis T, Bakshi R. PMID: 32917773; PMCID: PMC7643615	_	personal	_	_	**fingolimod, natalizumab and interferon are mentioned.** Other DMTs to be elicited by the expert.
44	**Riley Bove**	panel member	6e	Rituximab before and during pregnancy: A systematic review, and a case series in MS and NMOSD. Neurol Neuroimmunol Neuroinflamm. 2018 May; 5(3):e453. Das G, Damotte V, Gelfand JM, Bevan C, Cree BAC, Do L, Green AJ, Hauser SL, Bove R. PMID: 29564373; PMCID: PMC5858951	_	personal	_	_	**rituximab**
44	**Riley Bove**	panel member	6e	Management of multiple sclerosis during pregnancy and the reproductive years: a systematic review. Obstet Gynecol. 2014 Dec; 124(6):1157-1168. Bove R,	_	personal	_	_	**specific DMTs to be elicited by the expert**

Expert N.	Name	Role	CoI form item	Declared interest	Organization	Belongs to	Amount	Period	DMT
				Alwan S, Friedman JM, Hellwig K, Houtchens M, Koren G, Lu E, McElrath TF, Smyth P, Tremlett H, Sadovnick AD. PMID: 25415167					
45	**Dina Jacobs**	panel member	1b consulting	EMD Serono (Cladribine)	EMD Serono	personal	Less than $4000	4. 2020	**Cladribine**
45	**Dina Jacobs**	panel member	1b consulting	Bristol Myers Squibb (Ozanimod)	Bristol Myers Squibb	personal	$2500	6. 2021	**Ozanimod**
45	**Dina Jacobs**	panel member	1b consulting	Banner Life Sciences (Bafiertam)	Banner Life Sciences	_	$2500	5. 2021	**Monomethyl fumarate is under evaluation in the guideline**
45	**Dina Jacobs**	panel member	1b consulting	Sanofi Genzyme (Teriflunomide)	Sanofi Genzyme	personal	Less than $5000	8. 2020	**Teriflunomide**
45	**Dina Jacobs**	panel member	1b consulting	Genentech (Ocrelizumab, Women's Issues in MS)	Genentech	personal	less than $5000	1. 2022	**Ocrelizumab**
45	**Dina Jacobs**	panel member	2a research support	multi-site trial OCARINA; I am the site PI	Genentech	Penn MS and Related Disorders Research Program	_	ongoing	**ocrelizumab**
45	**Dina Jacobs**	panel member	2a research support	multi-site trial MINORE/SOPRANINO; I am the site PI	Genentech	Penn MS and Related Disorders Research Program	_	ongoing	**ocrelizumab**
45	**Dina Jacobs**	panel member	2a research support	multi-site trial CONSONANCE; I am the site PI	Genentech	Penn MS and Related Disorders Research Program	_	ongoing	**ocrelizumab**

3.5 Interests not assessed

In Table 5 are listed those interests which remained unassessed because of the lack of necessary details.

Table 5. List of unassessed interests

Expert N.	Name	Role	CoI form item	declared interest	organization	belogs to	amount	period
3	**Traboulsee Anthony**	panel member	2a research support	Principal investigator for phase 2 clinical trial for RRMS	Clene	University of British Columbia	_	current
17	**Hans-Peter Hartung**	panel member	1b consulting	?	BMS Celgene		less than 10.000€	current
17	**Hans-Peter Hartung**	panel member	1b consulting	?	TG Therapeutics		less than 10.000€	current
17	**Hans-Peter Hartung**	panel member	1b consulting	?	Biogen		less than 10.000€	ceased
17	**Hans-Peter Hartung**	panel member	1b consulting	?	VielaBio		less than 10.000€	
44	**Riley Bove**	panel member	1b consulting	Talk on my research	Genzyme Sanofi		2947.5	06/03/20
44	**Riley Bove**	panel member	1b consulting	?	WebMD		4000	7/17/20
44	**Riley Bove**	panel member	1b consulting		M		2951.74	11/23/20
44	**Riley Bove**	panel member	1b consulting		ortleybio		1800	11/02/21
44	**Riley Bove**	panel member	1b consulting	us medical neurology franchisce ad board			2825	11/12/21

References

Institute of Medicine. Conflict of Interest in Medical Research, Education, and Practice. Washington, DC: National Academies Press; 2009.

Institute of Medicine. Clinical practice guidelines we can trust. Standards for developing trustworthy clinical practice guidelines. Washington, DC: National Academies Press; 2011.

ISS. Methodological Manual for the production of clinical practice guidelines (available at https://snlg.iss.it/wp-content/uploads/2021/08/MM_v1.3.2_apr_2019.pdf)

National Institute for Health and Care Excellence. Policy on Conflicts of Interest. version 2.5 2017 https://www.nice.org.uk/Media/Default/Get-involved/Fellows%20and%20scholars%20unsecure/Conflicts-of-interest-policy.pdf.

Schünemann HJ, Al-Ansary LA, Forland F, Kersten S, Komulainen J, Kopp IB, Macbeth F, Phillips SM, Robbins C, van der Wees P, Qaseem A; Board of Trustees of the Guidelines International Network. Guidelines International Network: Principles for Disclosure of Interests and Management of Conflicts in Guidelines. Ann Intern Med. 2015 Oct 6;163(7):548-53. doi: 10.7326/M14-1885. PMID: 26436619.

World Health Oorganization. Guidelines for Declaration of interests (WHO experts) Available at https://www.who.int/about/ethics/declarations-of-interest.

List of Annexes

Annex 1 – List of all the subject involved in developing recommendations on disease-modifying drugs for multiple sclerosis in low resource-settings
Annex 2 – MSIF Essential medicines Panel (MEMP) guideline PICO questions

Annex 1

List of all the subject involved in developing recommendations on disease-modifying drugs for multiple sclerosis in low resource-settings (panel members, evidence review team and observers)

Expert N.	Expert Name
1	Najoua Abkari
2	Laura Amato
3	Traboulsee Anthony
4	Jagannadha Avasarala
5	Elisa Baldin
6	Maria Chiara Bassi
7	Ben Ridley
8	Maria Chiara Bassi
9	Ivana Bogdanovic
10	Kimberley Chawla
11	Kathy Costello
12	Franco De Crescenzo
13	Cinzia Delgiovane
14	Graziella Filippini
15	Roberta Giroldini
16	Marien Gonzalez Lorenzo
17	Hans-Peter Hartung
19	Tapas Kumar
20	Joanna Laurson-Doube
21	Enrica Lavezzini
22	Lucia Magnano
23	Aukje Mantel-Teeuwisse
24	Anna Maria Marata
25	Jennifer McDonell
26	Sivia Minozzi
27	Carlos Navas
28	Francesco Nonino
29	Lara Ojo
30	Elisabetta Pasi
31	Thomas Piggott
32	Andrea Prato
33	Nick Rijke
34	Deanna Saylor
35	Nicoline Schiess
36	Holger Schunemann
37	Dilraj Sokhi
38	Janis Tye
39	Simona Vecchi
40	Shanthi Viswanathan
41	Feng Xie
42	Bassem Yamout
43	Maya Zeineddine
44	Riley Bove
45	Dina Jacobs
46	Bianca Ozcan
47	Tomas Kalincik

Annex 2

12/10/2021

MSIF Essential medicines Panel (MEMP) guideline PICO questions

Populations (P)

1. Relapsing, active and/or worsening
2. Relapsing, not active and stable or indeterminate
3. Relapsing, active and/or worsening when there is a lack of treatment response

4. Progressive, active and/or progressing
5. Progressive, not active and not progressing or indeterminate
6. Progressive, active and/or progressing when there is a lack of treatment response

Interventions (I) and comparators (C)

These pharmacological interventions (disease modifying therapies [DMTs]) will be considered:

1 - Interferon beta-1a
2 - Interferon beta-1b
3 - PEG IFN-beta-1a
4 - Mitoxantrone
5 - Glatiramer acetate
6 - Natalizumab
7 - Fingolimod
8 - Teriflunomide
9 - Leflunomide
10 - Dimethylfumarate
11 - Diroximel fumarate
12 - Alemtuzumab
13 - Laquinimod
14 - Azathioprine
15 - Immunoglobulin
16 - Steroid
17 - Ocrelizumab
18 - Cladribine
19 - Siponimod
20 - Ozanimod
21 - Ponesimod
22 – Ofatumumab
23 - Daclizumab
24 - Rituximab
25 - Cyclophosphamide
26 - Fludarabine
27 - Methotrexate

28 - Minocycline
29 - Mycophenolate mofetil

Out of scope: stem-cell approaches

Outcomes

CRITICAL

1. *Mortality*
2. *Quality of Life (QoL) impairment*
3. *Relapse of multiple sclerosis (>=12 months)*
4. *Disability or dependency (EDSS) (>= 24 months)*
5. *Cognitive decline*
6. *New gadolinium-enhancing positive T1 weighted MRI lesions*
7. *New or enlarging T2 weighted MRI lesions*
8. *Serious Adverse Events*
9. *Discontinuation of treatment due to adverse events (tolerability)*

Note: Brain atrophy was considered but excluded as it is a surrogate for disability, QoL and cognition, which are already captured in other outcomes.