Access to treatment and healthcare

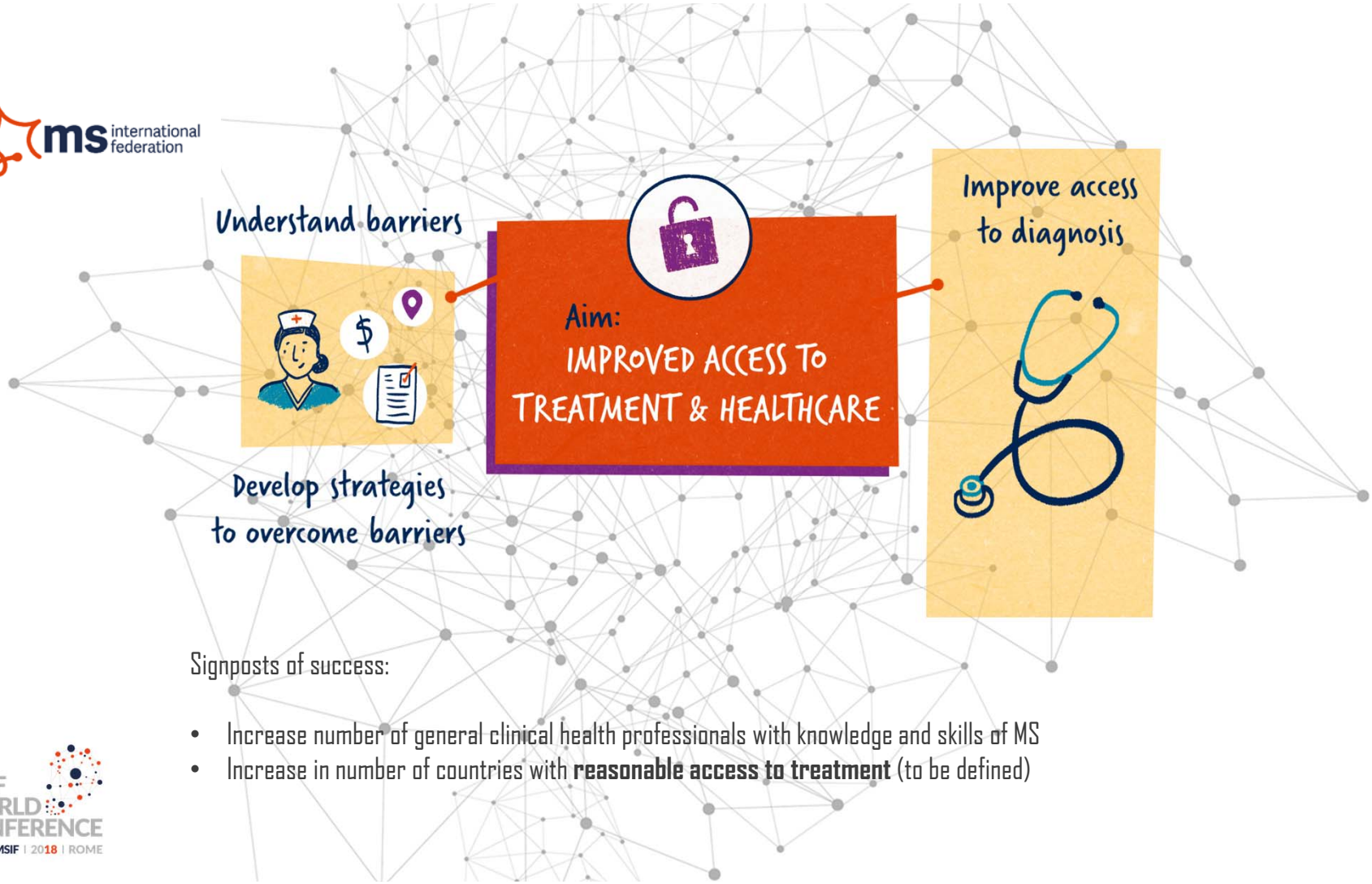
MSIF WORLD CONFERENCE

AISM | MSIF | 2018 | ROME

Benjamin Davis

MS Society of Canada

MSIF International Work Group on Access



Signposts of success:

- Increase number of general clinical health professionals with knowledge and skills of MS
- Increase in number of countries with **reasonable access to treatment** (to be defined)

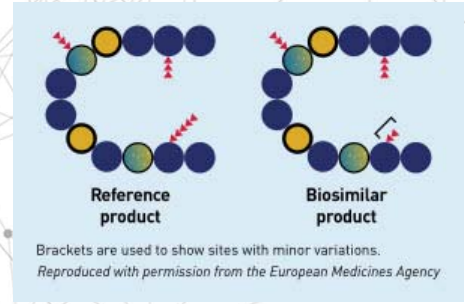
MSIF WORLD CONFERENCE
AISM | MSIF | 2018 | ROME

MSIF access to treatment projects

WHO Essential Medicines List

World Health Organization

Regulation of Biosimilar Drugs



MSIF WORLD CONFERENCE
AISM | MSIF | 2018 | ROME

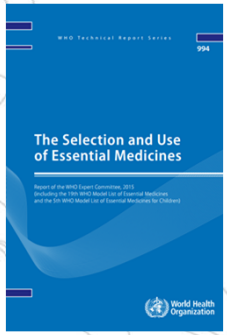
Understanding DMT regulation

- What level of evidence is required by regulatory authorities for the assessment of biosimilar medicines?
- Are these assessments routinely implemented in practice?
- The extent to which healthcare professionals and people affected by MS are engaged in the regulatory assessment of medicines.
- Current pharmacovigilance systems and their effectiveness?

MSIF WORLD CONFERENCE
AISM | MSIF | 2018 | ROME

What is the WHO Essential Medicine List?

- WHO list of selected medicines to help countries prioritise
- Guidance for creating national essential medicines (146 countries)
- Gold-standard list for reimbursement
- Updated every two years, 433 medicines in 2017 for all diseases



- Neurologic disorders are poorly represented on the EML
- No MS treatments
- Unsuccessful azathioprine application in 2015 – review of MS treatments requested

Why is the WHO Essential Medicine List important?

- Raise the profile of MS on an international scale

- Advocacy tool on a national level:
  - Availability
  - Affordability
  - Awareness
  - National healthcare systems

- Allows focus for future:
  - Regions/countries
  - Barriers to access

MSIF WORLD CONFERENCE
AISM | MSIF | 2018 | ROME

Underlying principles

- Ideally, all regulatory approved DMTs should be available for people with MS (pwMS).
- PwMS have unique clinical disease and personal circumstances. A choice of treatment options is paramount.
- Given that the WHO EML can endorse only a few therapies, this FIRST application had to select 3 DMTs only
- To enable a minimum choice of treatment options for pwMS, we used key criteria to select three DMTs.
    - We are NOT attempting to (i) suggest that these are the only 3 therapies of value; (ii) undervalue the many other DMTs that we were unable to propose at this time; or (iii) Create a treatment algorithm.

Criteria to choose DMTs

1. Efficacy/safety profile: recognising different clinical disease course and personal circumstances, different profiles need to be available for pwMS.

2. Risk of adverse events (includes tolerability and liveability) and feasible monitoring needs (important in resource-poor environments).

3. Route of administration: recognising that resource-poor settings may have challenging infrastructure, e.g. infusion centres.

4. Different populations of pwMS: ensuring we cover main sub-populations of pwMS, e.g. use in pregnancy, family planning, use in paediatrics and potential for PPMS.

5. Price: if there is no clear advantage on the other criteria, we consider price; including patent status, available and/or emerging generics/biosimilars and off-label alternatives currently in use and supported by evidence published in peer-reviewed journals

Three catgories of DMTs should be available

1. Moderate efficacy/high safety (IFN, glatiramer acetate)

2. Moderate to high efficacy oral therapy (dimethyl fumerate, terifluonomide, cladribine and fingolimod)

3. High efficacy monoclonal therapy (natalizumab, alemtuzumab, ocrelizumab)

MSIF WORLD CONFERENCE
AISM | MSIF | 2018 | ROME

Draft shortlist of candidates

- Glatiramer acetate – high safety profile and use in pregnancy, availability of high quality generics
- Fingolimod – paediatric indication, tolerability past first dose and short patent life outside of the US, which may allow generics to be developed in the near future
- Ocrelizumab – low monitoring requirements, high safety profile, rituximab is used off-label in some areas of the world

Draft shortlist of DMT:
Glatiramer acetate, fingolimod, ocrelizumab

- We propose that these DMTs provide a REASONABLE selection for MS care
- With these DMTs, we suggest that we cover most populations of pwMS
- With these DMTs, we feel that we advocate choice for pwMS and clinicians

MSIF WORLD CONFERENCE
AISM | MSIF | 2018 | ROME

Over to you...

- Is there anything else we should consider relating to the application?
- Do you have any further advice for us?
- Are you aware of the WHO EML being used to improve access to medicines in your country?

MSIF WORLD CONFERENCE
AISM | MSIF | 2018 | ROME

What can you do to support us?

1. Let us know if your Ministry of Health uses the WHO EML for their national Essential Medicines List and help us gather support from them

2. Let us know if pwMS in your country do not have access to the three categories of DMTs

3. Let us know what the main barriers to access to treatment are

Please talk to Ben or Anne after the session or contact: Joanna@msif.org

MSIF WORLD CONFERENCE
AISM | MSIF | 2018 | ROME