

Policy: Working with pharmaceutical companies

This policy was last updated on 3 December 2021. This policy is reviewed regularly. We invite your comments by email to info@mastocytosis.org.au

1. Introduction

1.1 Mast cell diseases

Mast cell diseases (MCDs) are caused by the proliferation and accumulation of genetically altered mast cells and/or the inappropriate release of mast cell mediators, creating symptoms in multiple organ systems.

The two major forms of mast cell diseases are mastocytosis and mast cell activation syndromes (MCAS). Mast cell diseases can cause tremendous suffering and disability due to symptomatology from daily mast cell mediator release, and/or symptoms arising from infiltration and accumulation of mast cells in major organ systems.

Although systemic mastocytosis is a rare disease, those suffering with MCAS have recently been increasingly recognised and diagnosed (however an official diagnostic protocol is yet to be adopted). As a result, patients with MCAS appear to represent a growing proportion of the mast cell disease patient population. It is important to note that the process of mast cell activation can occur in anyone, even without a mast cell disease, as well as in patients with both Mastocytosis and MCAS.

These diseases are incredibly rare, with the Orphanet Report on Rare Diseases of January 2021 listing the prevalence of Systemic Mastocytosis as 1:100,000 using global data. No statistics are available on monoclonal MCAS due to insufficient global data.

Mast cell diseases supported by TAMS include:

- Cutaneous Mastocytosis
- Diffuse Cutaneous Mastocytosis (DCM)
- Maculopapular Cutaneous Mastocytosis (MPCM)
- Systemic Mastocytosis
- Indolent Systemic Mastocytosis (ISM)
- Smoldering Systemic Mastocytosis (SSM)
- Systemic Mastocytosis with an Associated Hematologic Neoplasm
- Aggressive Systemic Mastocytosis (ASM)
- Mast Cell Activation Syndrome (MCAS)
- Urticaria Pigmentosa (UP)
- Bone Marrow Mastocytosis
- Mast Cell Leukemia
- Mast Cell Sarcoma
- Tryptase and Alpha Tryptasemia
- Hereditary Alpha Tryptasemia (HAT)

1.2 About The Australasian Mastocytosis Society (TAMS)

The Australasian Mastocytosis Society (TAMS) is a volunteer-run support, advocacy, education, research body for mastocytosis, mast cell activation syndrome (MCAS) and hereditary alpha tryptasemia (HaT) patients and carers.

TAMS is a member-based organisation, providing additional services to paid members, including monthly member e-newsletters, regular member support groups, discounts to events, advanced access to research, advocacy and more.

TAMS was established due to the overwhelming need for sufferers and their supporters to find a local voice and active support network.

TAMS is an independent not-for-profit incorporated organisation with a committed and functional volunteer committee of individuals – all of whom are sufferers or carers – ensuring your needs will be met.

TAMS members help support TAMS in its mission to support patients and carers with MCDs.

Our mission

TAMS aims to:

- **Provide a network** of support for patients living with mastocytosis or a mast cell activation syndrome (MCAS) and their carers
- **Connect patients** to medical practitioners and specialists with knowledge of mastocytosis and MCAS
- **Link together with associations worldwide** to collectively gather research data, share resources and knowledge in the hope of greater understanding, treatment practices, medications and overall improved health outcomes for those living with mastocytosis or MCAS.

2. Working with pharmaceutical companies

Collaboration between TAMS and pharmaceutical companies may deliver significant benefits for our TAMS members enhancing current and potential development of new treatments to produce better health outcomes. TAMS has an important role to play in increasing mast cell diseases (MCDs) research and development capacity in Australia. TAMS recognises that relationships with pharmaceutical companies should be subject to clear guidelines to ensure openness, independence, transparency and impartiality.

Pharmaceutical companies are also sometimes willing to sponsor and fund certain activities we undertake. Pharmaceutical companies are not charitable organisations and have different interests and objectives from TAMS'. We acknowledge that in many cases, when we work with pharmaceutical companies the partnership is not equal, in that the pharmaceutical company has many more resources at its disposal than TAMS. For these reasons, we take particular care in how our organisation works with pharmaceutical companies and other for-profit health care providers.

We also acknowledge that, because there are a limited number of treatments for MCDs, there are a limited number of pharmaceutical companies with an interest in MCDs. TAMS is also committed to supporting research that leads to new treatments for MCDs.

The purpose of this Policy is to provide clear principles and guidance about how TAMS works with pharmaceutical companies to achieve our objectives, without compromising our integrity and our ability to support our members. Adherence to this policy will ensure that our activities are not in any way influenced by the commercial interests of any for-profit companies we work with.

Policy review

The TAMS Committee will review this policy every two years.

Principles

- TAMS is committed to total transparency in all dealings with pharmaceutical companies.
- TAMS will independently set its own priorities, policies and plans.
- TAMS will not endorse individual pharmaceutical products or suppliers of health care services.
- TAMS will seek to develop relationships with multiple pharmaceutical companies, so as not to develop a special relationship with only one company.
- TAMS will engage in dialogue with pharmaceutical companies about MCDs treatments.

Practice

1. Openness and transparency

This Policy will be published on the TAMS website.

A full list of donations and grants received from pharmaceutical companies will be published in the digital annual report of TAMS in the year in which the money is received.

TAMS will acknowledge financial support for projects with a statement similar to “This project was funded by a grant from <company name>.”

2. Funding of projects

- a. All relationships with pharmaceutical companies will be documented in writing. The agreed roles and responsibilities will be clearly defined for all parties.
- b. TAMS will only encourage funding for projects that have been identified as priorities in the regular TAMS planning process. These will be projects that align with TAMS’ mission and objectives. Funded projects that are not research trials and are initiated by a pharmaceutical company will need to be approved by the TAMS Committee before they proceed. TAMS will not accept support from any pharmaceutical company that is attempting to influence its policy or direction for commercial advantage.
- c. Funding will only be accepted from pharmaceutical companies where the project has a fixed timeframe and outcome. Funding will not be accepted for ongoing costs of operating TAMS.

3. Promotion

- a. TAMS will not endorse or promote any specific drug or treatment. Where possible, when discussing treatments, TAMS will refer to a class of drugs (e.g. “mTOR inhibitors”) rather than a

specific drug or brand name.

- b. TAMS will not accept or distribute promotional products provided by a pharmaceutical company and will not allow distribution of such products at TAMS events.

4. Education

- a. TAMS will keep its key staff and volunteers informed on MCDs research, the drug development process and the way the pharmaceutical industry operates.
- b. TAMS will work with other patient support bodies and learn from their experiences of working with pharmaceutical companies.
- c. TAMS will seek ensure that all medical information it publishes is reviewed by the TAMS medical advisors, who are independent clinicians.

5. Representing families affected by MCDs

a. TAMS understands that in its role as representing the families affected by MCDs in Australia that it may be asked to review patient information material to ensure that it has validity and understanding for its audience. TAMS will not accept any fee for this service. TAMS representatives may, however, be reimbursed for any out-of-pocket expenses associated with this activity.

6. Other

- a. The TAMS Committee will review any offer of hospitality, including travel and accommodation that is provided or funded by a pharmaceutical company.
- b. The TAMS logo and name cannot be used by any pharmaceutical company to promote a product.
- c. In accordance with Medicines Australia's Code of Conduct, companies that provide TAMS with financial support need to disclose this publicly — ideally on their website.
- d. Company logos featured on Supporters page on the TAMS' website will be high resolution and of equal proportion to each company and contributor to TAMS. The logos appear in alphabetical order and are not in order of preference or status of contribution made to TAMS.