



Medical Affairs Survey 2022 (Japan insights edition)

Current situation and issues, and outlook of Japan's medical affairs organisations



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Introduction

Medical affairs (hereinafter 'MA') refers to the functions and organisations of the same name within pharmaceutical and life science companies, whose primary role is medical and scientific communication with external stakeholders including scientific experts, medical doctors, and other healthcare providers. The role of MA, as an industry-specific and relatively new concept, has yet to be clearly established or defined, and can change with the times or vary depending on the specific company or country or region. Recently, the landscape surrounding healthcare and medical science companies is becoming increasingly complex and advanced, while social needs for related information and scientific evidence are on the rise. Under such conditions, the roles and responsibilities of MA organisations are expanding, along with the organisations themselves, in many companies around the world.

In Japan, MA has an even shorter history; the full-scale introduction and adoption of MA as a concept started only in the early 2010s. At present, all major pharmaceutical and life science companies in Japan (including Japanese subsidiaries of global companies) have an MA or equivalent function, but those functions do not yet necessarily play a sufficient role or make a significant contribution, and other departments may not have a sufficient understanding of what they do. For these reasons, many MA organisations are struggling to establish themselves both internally and externally. Furthermore, new and emerging issues in the industry such as the utilisation of data and digital technologies, patient centricity and precision medicine, and highly advanced treatment modality including gene therapy, cell therapy and regenerative medicine pose the additional questions of how MA organisations can display leadership in those fields. In addition, with the recent introduction of new regulations and industry rules around pharma-physician interaction and evidence generation based on clinical studies affecting MA activities in Japan, it has become more difficult for MA organisations to proactively conduct meaningful activities externally and differentiate themselves from other functions internally.

Under these circumstances, PwC Consulting LLC conducted a survey of MA organisations at major pharmaceutical companies in Japan with the goal of understanding the current situation and issues facing MA functions and the outlook of MA as viewed by MA leaders. This report presents the results of the survey along with some of the comments from our discussions with the survey participants. As other member firms of the PwC global network conducted similar surveys of MA organisations in their respective countries at the same time, we plan to compare the results of this survey with the global results in the near future.



Overview of the survey

■ Objectives

- To understand the current situation and issues, and future outlook of medical affairs (MA) organisations at pharmaceutical companies in Japan

■ Survey period

- January to April 2022

■ Respondents

- Heads of MA organisations or other executive-class leaders in charge of MA
- Total of 16 companies (6 Japanese companies; 10 foreign-affiliated companies in Japan)

■ Survey method

- Multiple-choice questionnaire survey with open-ended questions by email, in combination with an explanatory and confirmational interview

■ Survey contents

- Organisational structure of the company's MA function
- Role and responsibility of the MA function
- Satisfaction with current MA activities
- Issues related to MA
- The need for MA organisations to transform MA
- Utilisation of RWD*¹ in MA
- Patient-related activities in MA
- MSL*² activities

Note: The sum of the percentages in the figures in this report may not add up to 100%, as individual results are rounded to the nearest percent.

*1 RWD: Real-world data

*2 MSL: Medical science liaison



Survey participants

Figure 1. By company affiliation

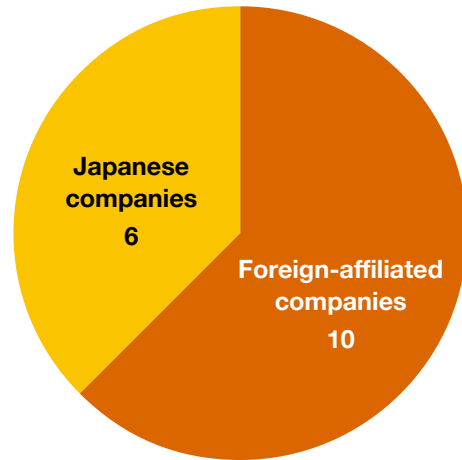


Figure 2. By headcount of MA organisation in Japan

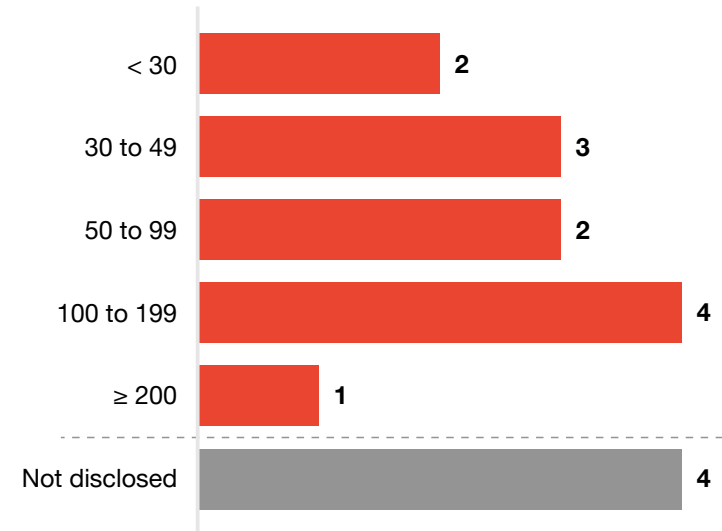


Figure 3. Number of MSLs in the MA organisation in Japan

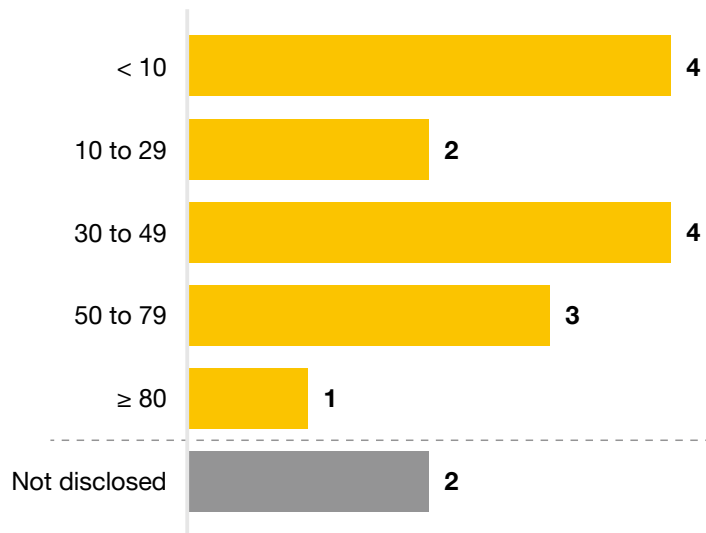
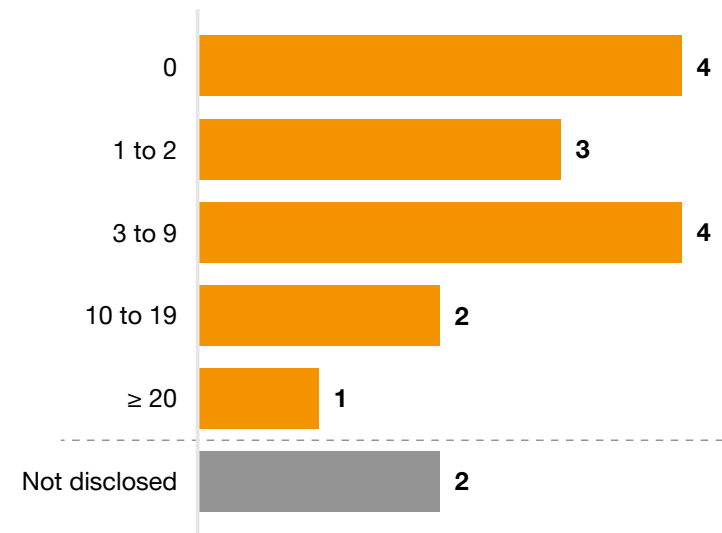


Figure 4. Number of physicians in the MA organisation in Japan



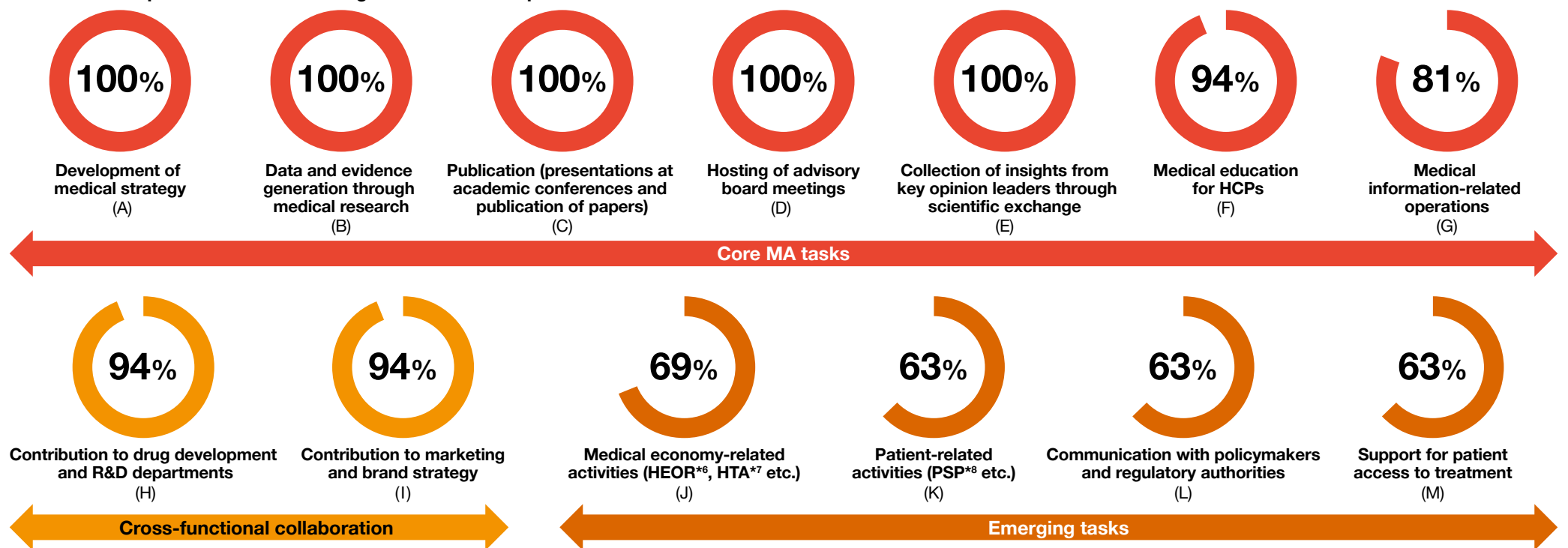
Roles and responsibilities of MA organisations

While the core MA tasks are the same at all companies, the handling of broader areas varies

- The fundamental role of MA is to communicate with KOLs*³ and other healthcare professionals*⁴. MA organisations at all respondent companies, are engaged in various forms of information provision, medical education (Fig. 5. C-G) and insight collection focusing on UMNs*⁵ (D, E).
- The results showed that, together with the above activities, evidence generation (B) and medical strategy development (A) are also conducted by MA organisations at all respondents' companies, and can be viewed as core MA tasks in Japan.
- For tasks other than these core MA tasks, most MA departments are also engaged in support activities for other major internal divisions (such as R&D and commercial divisions) (H, I), while involvement in emerging tasks related to meeting new patient and societal demands varied from company to company (J-M).

Figure 5. Scope of responsibility of MA organisations

Percent of respondents whose MA organisations are responsible for each task



*3: Healthcare professional
*4: Unmet medical need

*5: Key opinion leader
*6: Health economics & outcomes research

*7: Health technology assessment
*8: Patient support program

Self-assessment of MA organisations' activities

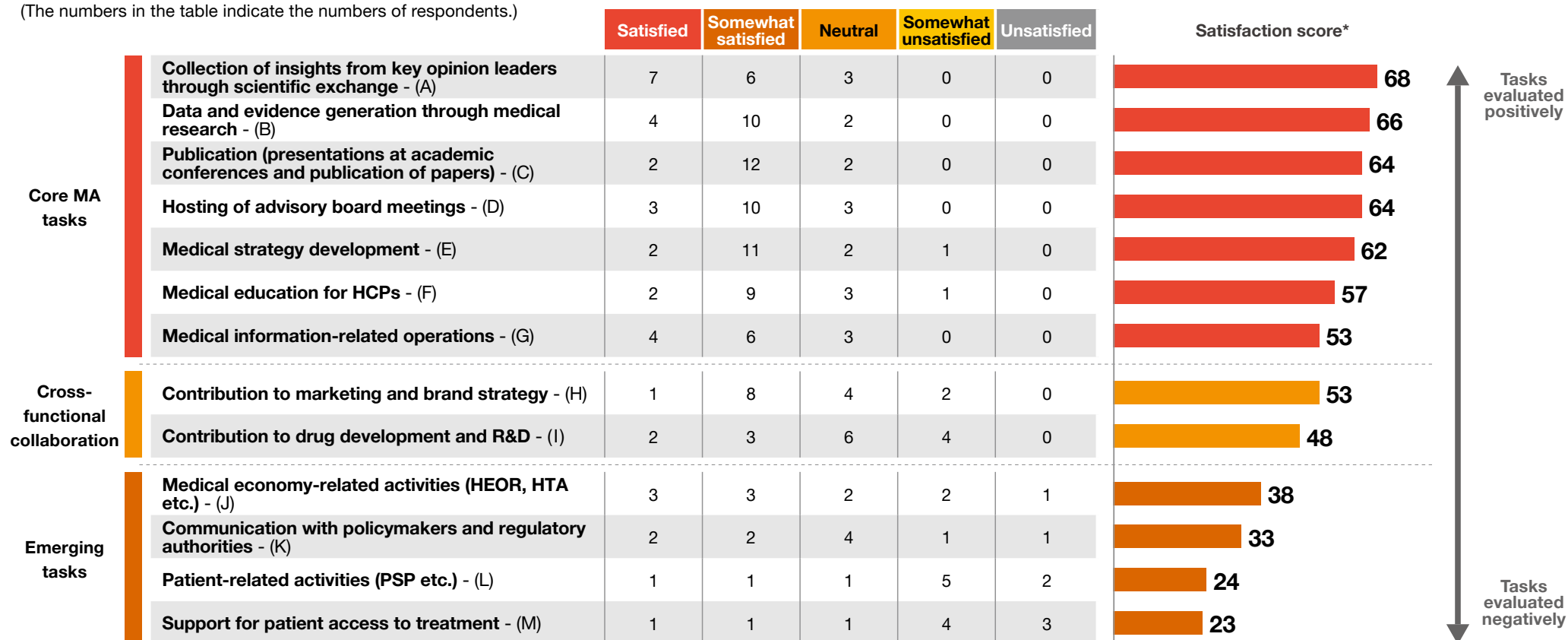
MA organisations generally evaluate their performance of core tasks highly

- Respondents evaluated their own companies' performance of the common core MA tasks positively, with almost all respondents selecting 'satisfied' or 'somewhat satisfied' (Fig. 6. A-G).
- On the other hand, the evaluation of tasks other than those core MA tasks varied among respondents. Particularly in emerging areas that involve patients or policy makers and regulators, many responses tended toward the 'unsatisfied' end of the scale, even at companies where such tasks fell within the responsibilities of the MA organisation (J-M).

Figure 6. Self-evaluation of tasks performed by MA organisation

Degree of satisfaction with each task

(The numbers in the table indicate the numbers of respondents.)



* Satisfaction score: Calculated as the total of the scores (where 'satisfied' represents a score of 5 and 'unsatisfied' represents a score of 1) multiplied by the number of respondents who selected each score. For example, the score for task A would be calculated as: 5 points × 7 + 4 points × 6 + 3 points × 3 = 68

Issues within MA organisations (1) - Issues with scope of responsibility and authority

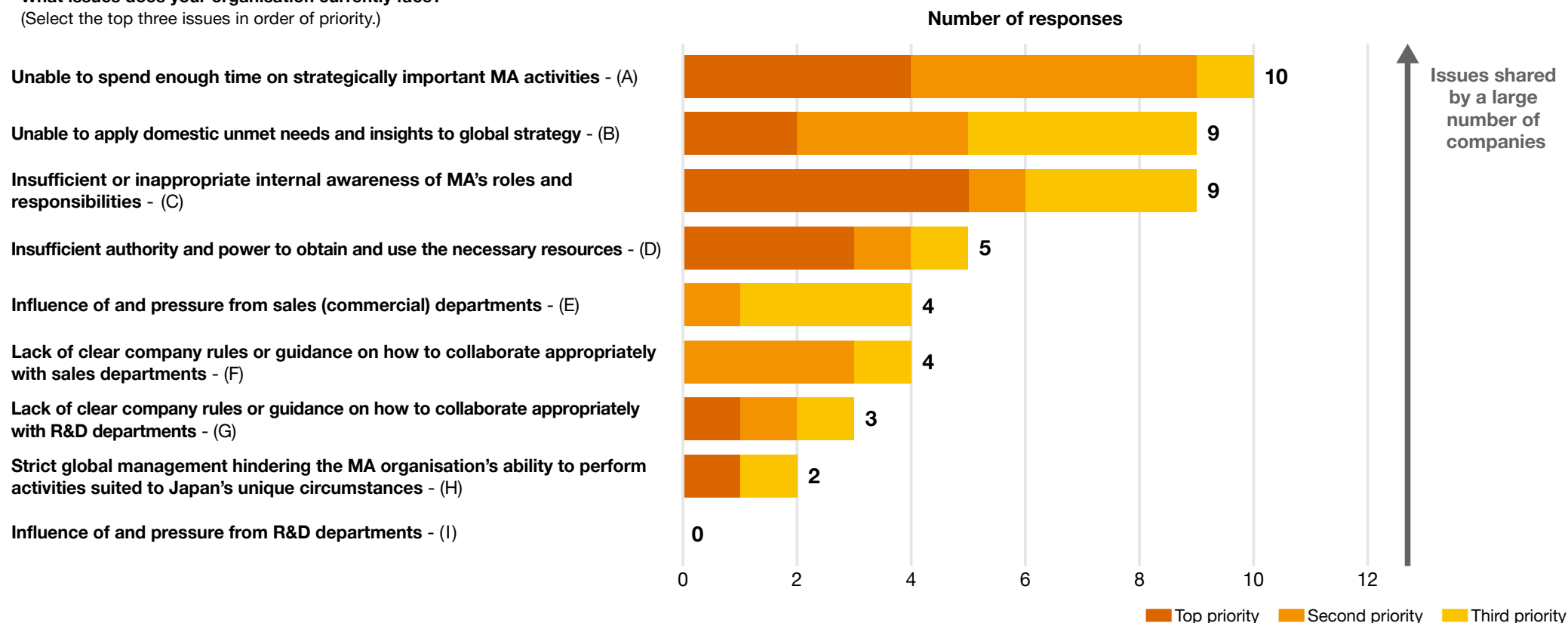
Major issues include an inability to focus on strategic work, insufficient organisational resources, and a lack of internal understanding of the role of MA

- When asked about the most important issues facing MA organisations, many respondents named an inability to sufficiently prioritise strategically important MA activities, as well as difficulties in securing the talent and budget they need. Furthermore, many MA organisations also cited a lack of understanding within the company of the role and value of MA. (Figure 7, A, C, D).
- On the other hand, only a small number of participants named building good relationships and collaborating with other functions such as R&D and sales (commercial) departments as critical issues. (Figure 7, D, E, F, G)

Figure 7. Priority issues facing MA organisations (related to scope of responsibilities and authority)

What issues does your organisation currently face?

(Select the top three issues in order of priority.)



Issues within MA organisations (2) - Issues related to talent

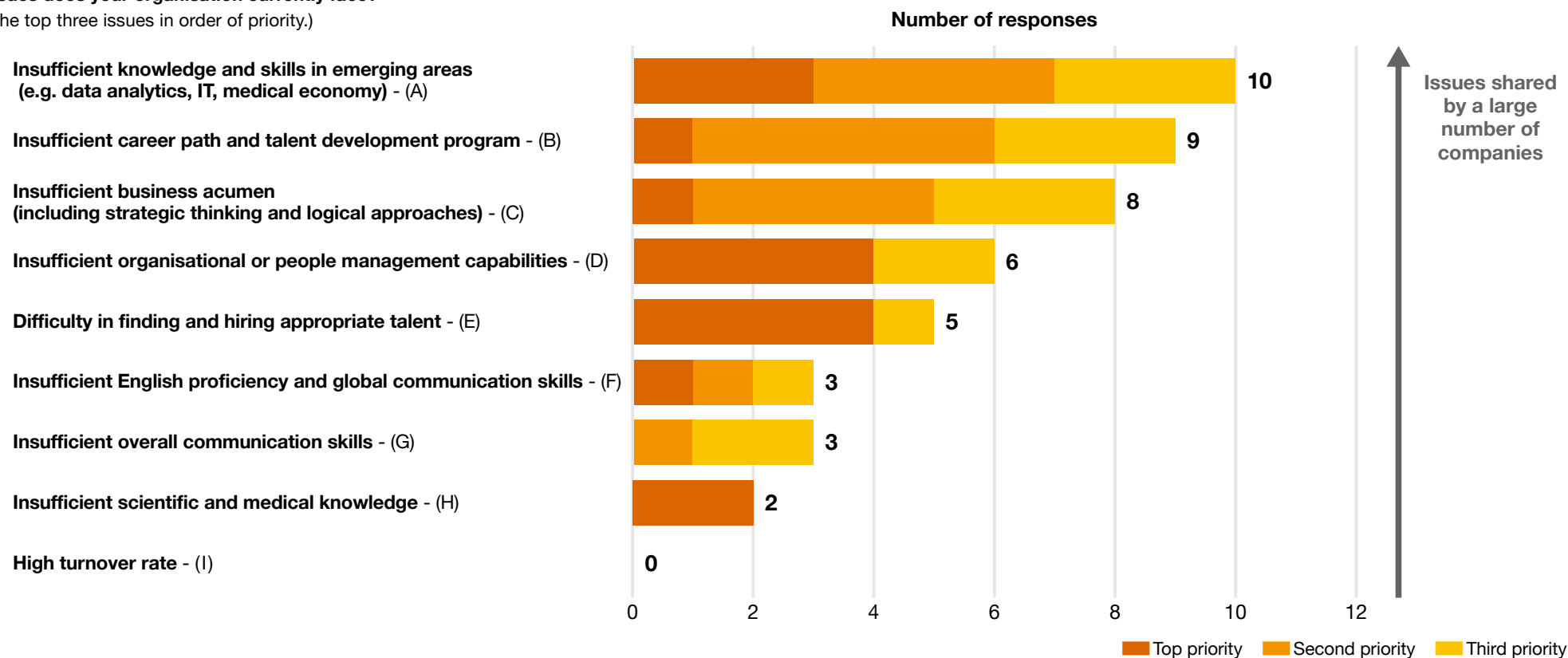
Major issues include the handling of diverse and emerging issues and the challenge of securing and developing the necessary talent

- The most common issues were related to insufficient capabilities, knowledge and experience in emerging areas of MA, such as the utilisation of digital technologies, data analysis, patient-related activities and the medical economy. (Fig. 8. A)
- Many MA organisations also cited HR-related issues such as providing career paths and development opportunities to MA personnel, and identifying and hiring the appropriate talent. (B, E)
- Lack of sufficient management capabilities in MA (D) was named the top priority issue by the highest number of respondents, along with difficulty in recruitment (E).

Figure 8. Priority issues facing MA organisations (related to talent)

What issues does your organisation currently face?

(Select the top three issues in order of priority.)



Issues within MA organisations (3) - Issues related to technology

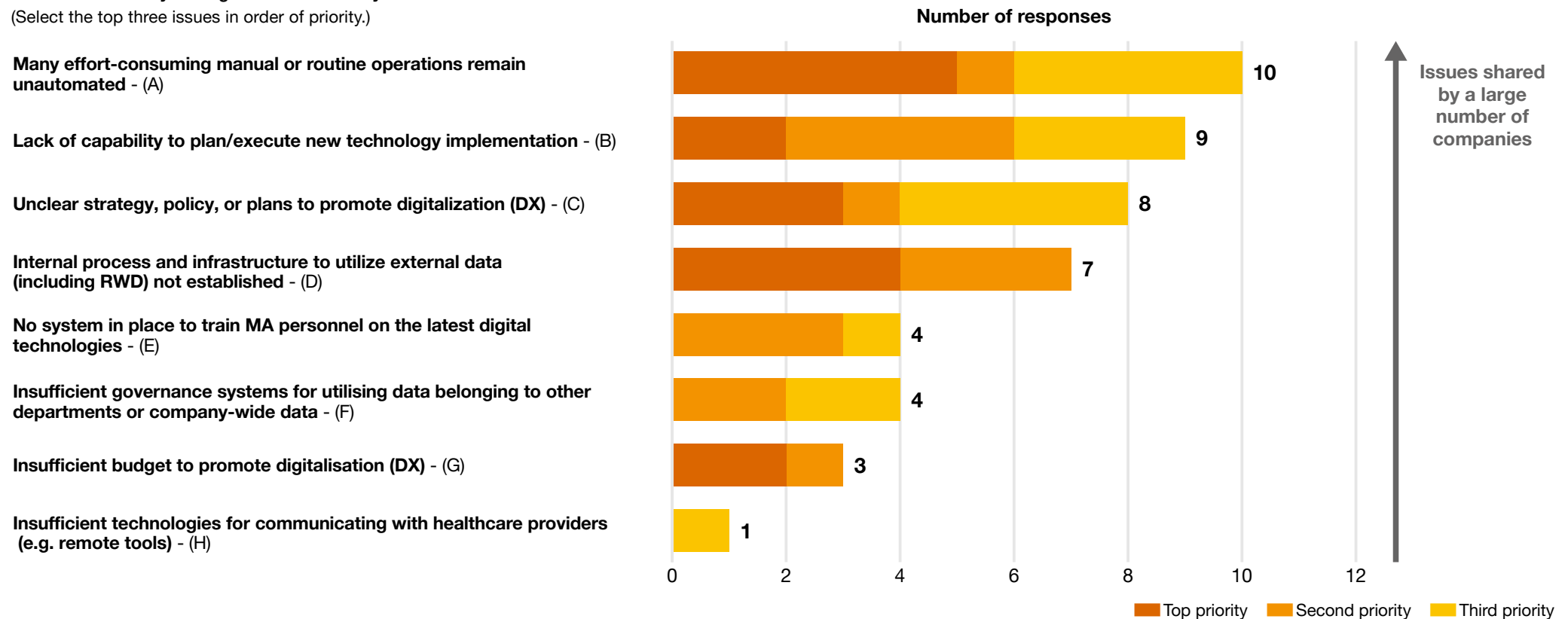
DX (digital transformation) efforts tend to be sluggish or insufficient, failing to resolve inefficiencies in routine work and problems with effective data utilisation

- The most common 'top priority' issue among respondents was the fact that many tasks have yet to be automated, and remain inefficient as a result. (Fig. 9. A)
- Similarly, a lack of established organizational governance or infrastructure for effective data utilisation and data analytics was also raised as a priority issue by many respondents. (D)
- These issues coincide with other wide-reaching problems such as insufficient DX strategy and planning (C) and insufficient talent, expertise and budget in the field (B, G).

Figure 9. Priority issues of MA organisations (related to technology)

What issues does your organisation currently face?

(Select the top three issues in order of priority.)



Issues within MA organisations (4) - Issues related to organizational culture

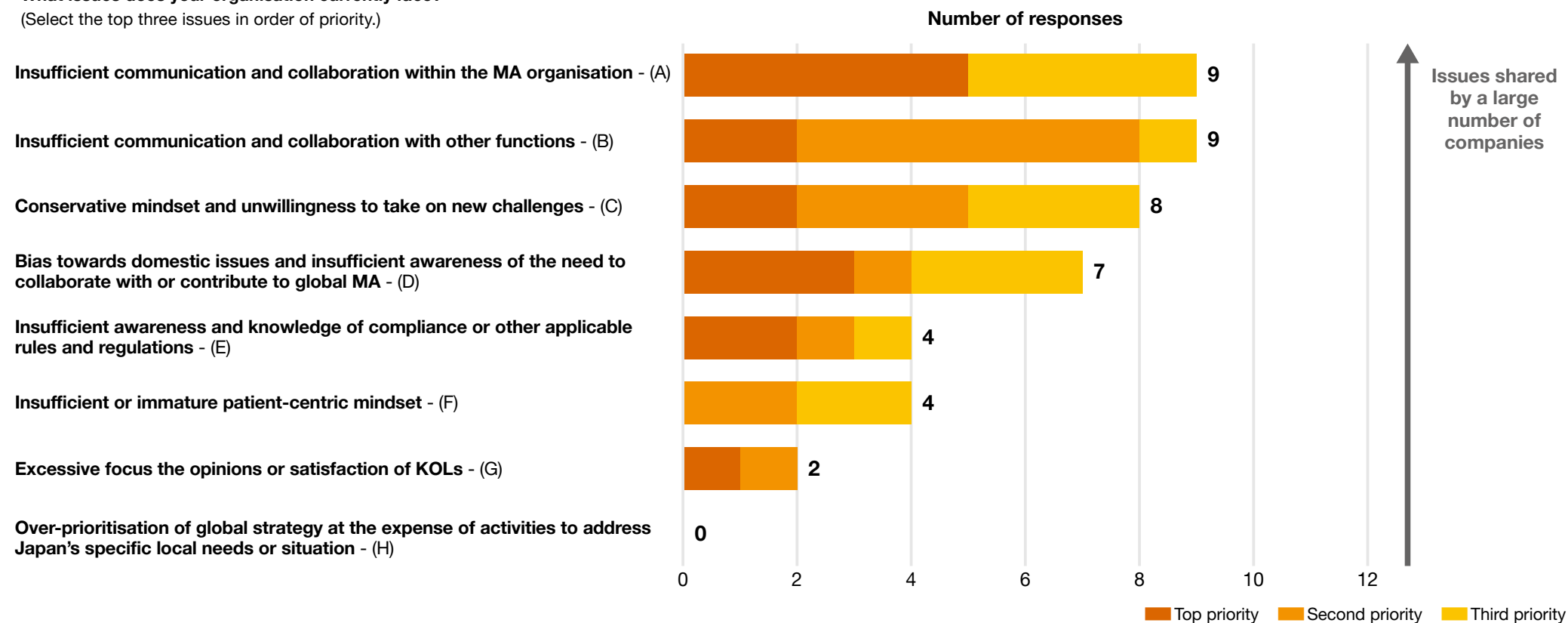
Major issues include insufficient communication skills and a conservative mindset

- Many respondents listed insufficient communication and collaboration both within the MA organisation and with external parties (Fig. 10. A, B), with the highest number of respondents selecting insufficient communication, information sharing, collaboration and cooperation within the MA organisation as their top priority issue (A).
- Many respondents also selected issues related to the mindset of their MA organisations, such as a conservative mindset and unwillingness to take on new challenges (C) and insufficient awareness of the need to collaborate with the global MA organisation (D).

Figure 10. Priority issues facing MA organisations (related to organizational culture)

What issues does your organisation currently face?

(Select the top three issues in order of priority.)



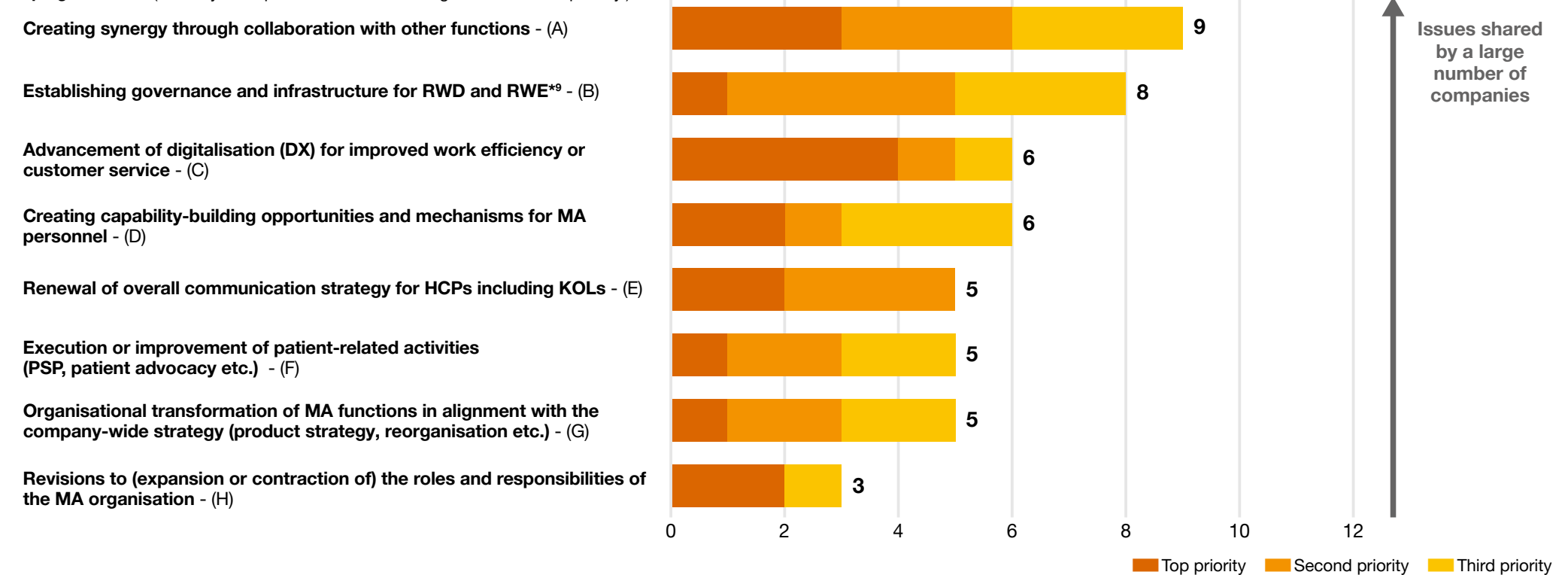
The need for MA organisations to transform

While all organisations face the need to overcome their current issues, specific areas of focus vary

- Top priority focus areas vary amongst MA organisations, with responses dispersed among all options from A to H
- Many respondents expressed a desire to resolve issues related to insufficient communication and collaboration, which was raised as a major issue in the previous section, to create synergy through collaboration with other functions (Fig. 11. A) and to implement new customer communication strategies (E).
- The results also revealed a need to improve insufficiencies in the progress of DX and data analytics, which was also identified as a major issue in the previous questions (B, C).

Figure 11. Transformations MA organisations are making or hope to make

Which of the following full-scale transformations are you currently making or hoping to make? (Select your top three transformation goals in order of priority.)



*9: Real world evidence

Future focus activities of MA organisations

While most organisation will continue to focus on their current core tasks, other priority focus areas vary from company to company

- A significant majority responded that they will continue to prioritise core MA tasks such as evidence generation and collection going forward (Fig. 12. A, B).
- The priority of activities involving other functions, such as R&D strategy development or product value optimisation, varied greatly from company to company (C, D).
- The greatest division of opinion can be seen in the area of patient-related activities, which some MA organisations named as their top priority, but over one third of MA organisations gave them the lowest priority (E).

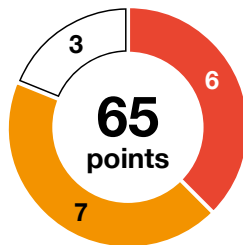
Figure 12. Future priority activities for MA organisations

Which of these activities does your MA organisation plan to focus on going forward?

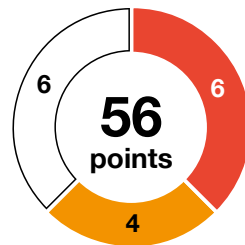
(Rank each of the following six activity areas in order of priority.)



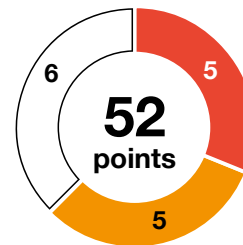
Data analytics and evidence generation (A)



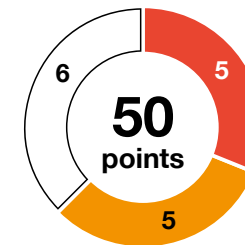
KOL insight generation (B)



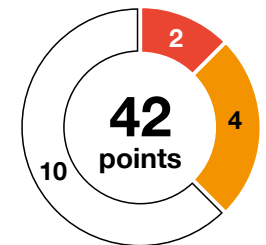
Scientific optimisation of product value and brand strategy (C)



Leading R&D and product strategy development (D)



Patient centricity and patient support (E)



Information dissemination and education of HCPs including KOLs (F)

← Areas of stronger focus

Number of responses: ■ Top priority ■ Moderate priority □ Low priority

Note: The scores (point totals) in the centre of each doughnut chart were calculated as follows: A score was assigned to each degree of priority (6 for the highest priority, and 1 for the lowest priority) and multiplied by the number of respondents. (Please note that this report does not provide the specific results of the six-point scale survey used for scoring.)

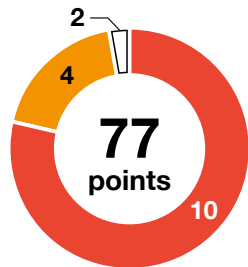
Capabilities sought by MA organisations for the future

The capabilities most sought-after by MA organisations are flexibility and adaptivity to enable new initiatives

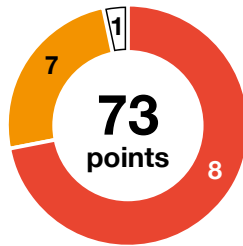
- A majority of respondents chose agile project management as their most sought-after capability. Agile project management will enable MA organisations to take on new initiatives while also adapting to the current situation and transforming themselves in an agile manner (Fig. 13. A).
- The second most highly sought-after capabilities were data analysis capabilities to enable the generation of insights and evidence (B). Many respondents also named data analysis as a current issue facing the MA organisation for which current personnel lack sufficient capabilities to handle.
- For digital capabilities, on the other hand, which were also named as a current insufficiency, the respondents' opinions were divided over whether MA organisations themselves need to have those capabilities (D).

Figure 13. Capabilities sought by MA organisations for the future

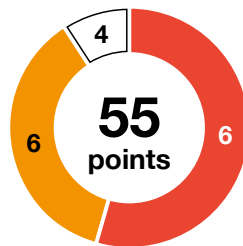
What capabilities will become more important to your organisation in the future? (Rank each of the following six capabilities in order of priority.)



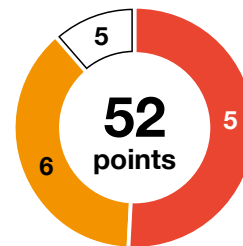
Agile project management skills to enable necessary transformations (A)



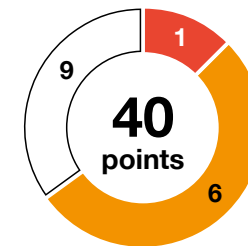
Data analysis skills to enable insight and evidence generation (B)



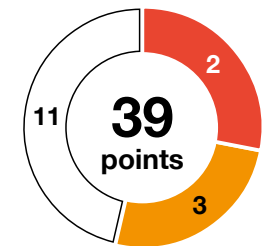
Compliant and business-minded execution capability (C)



IT and digital capability to enable effective DX (D)



Expertise in R&D, Knowledge in drug development including regulatory affairs (E)



Business and commercial knowledge (F)

← Highly sought-after capabilities

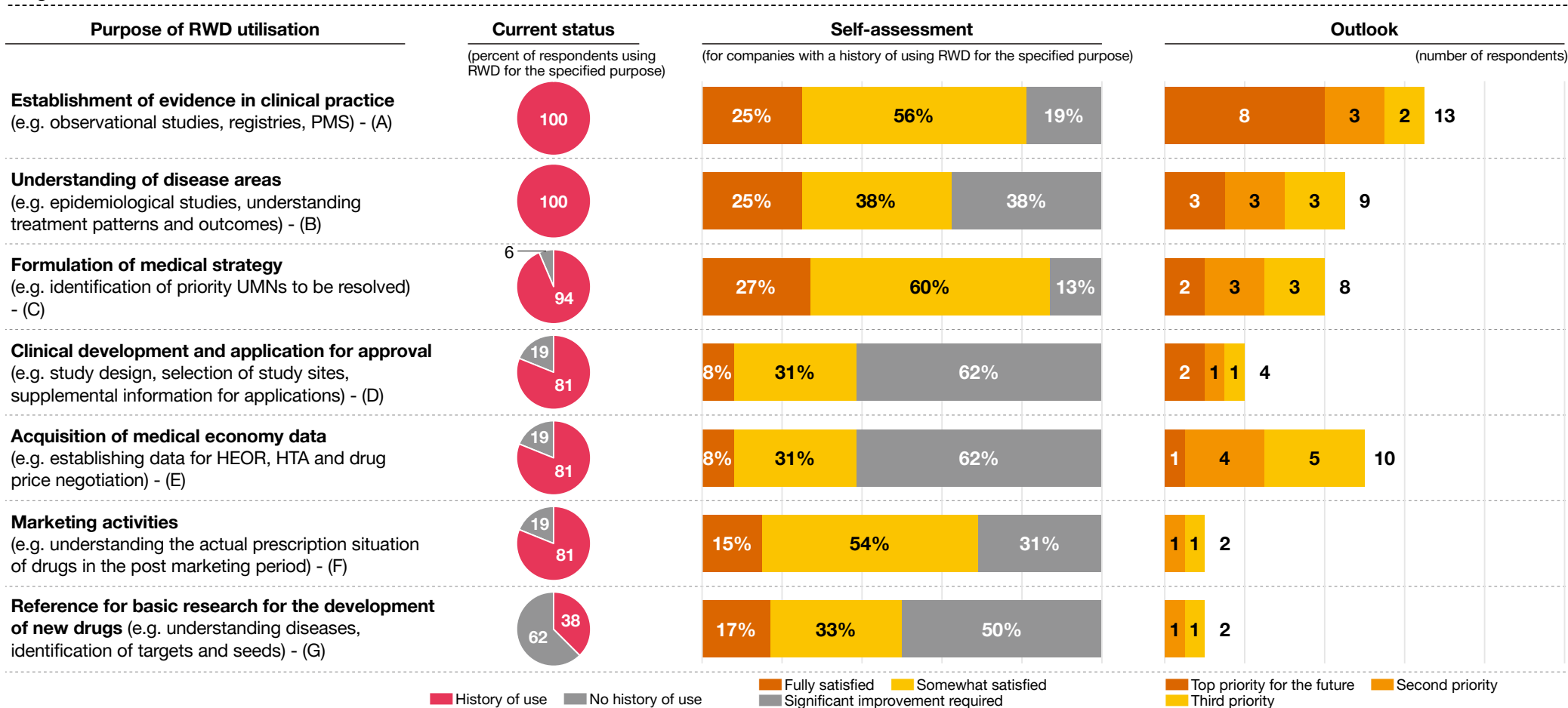
Number of responses: ■ Most highly sought-after ■ Moderately sought-after □ Least sought-after

The scores (point totals) in the centre of each doughnut chart were calculated as follows: A score was assigned to each degree of priority (6 for the highest priority, and 1 for the lowest priority) and multiplied by the number of respondents. (Please note that this report does not provide the specific results of the six-point scale survey used for scoring.)

While the current degree of RWD (real-world data) utilisation varies among respondents, all agreed that the main purpose of RWD utilisation is to establish clinical evidence and medical strategies

- All responding companies reported conducting some kind of RWD collection and analysis.
- A majority of respondents said their companies used RWD to establish clinical evidence for drugs in the post marketing period, promote the understanding of disease areas and formulate medical strategies. Results also indicate that these will continue to be the main objectives of RWD utilisation going forward (Fig. 14. A-C).
- In R&D, RWD is seldom used in basic research for the development of new drugs or for clinical development at present. The number of respondents indicating that they plan to use RWD in these areas in the future is also low (D, G).
- On the other hand, many companies responded that they hoped to make more effective and proactive use of RWD in the area of medical economy related to HTA, HEOR, drug prices etc. (E).

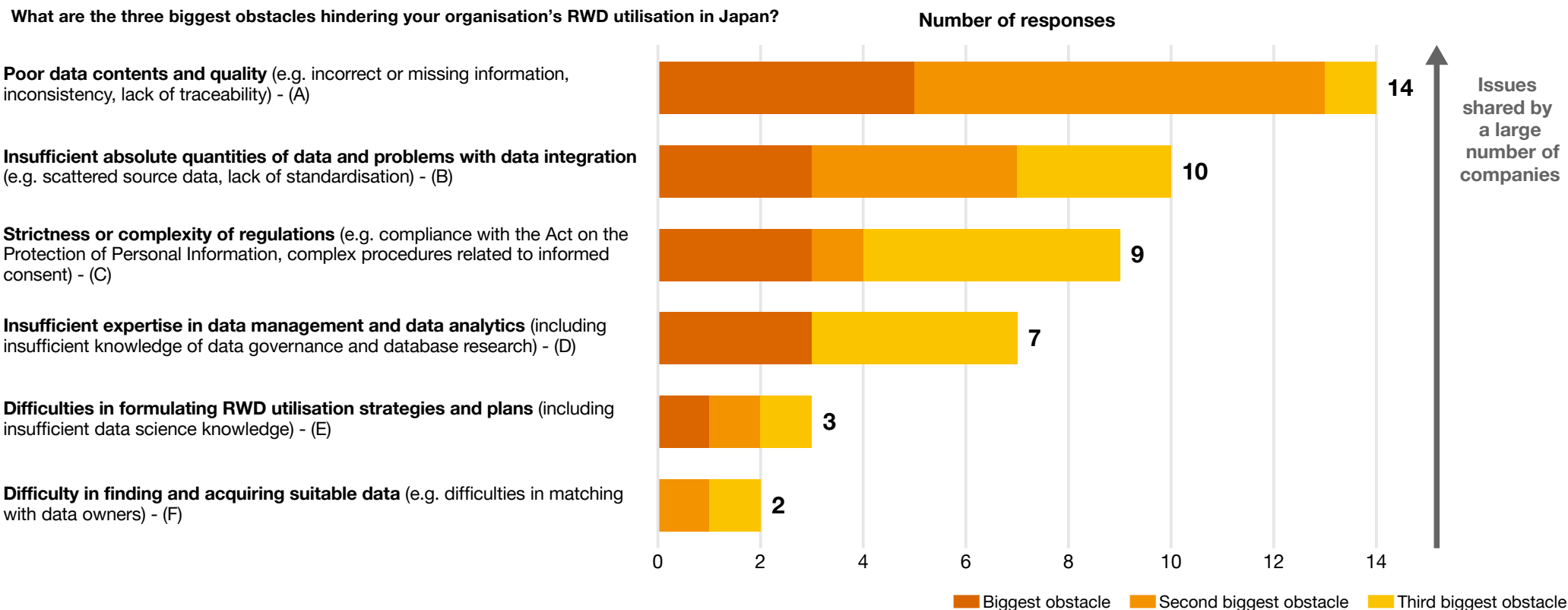
Figure 14. RWD utilisation: Current state and outlook



Insufficient quantity and quality of the source data that companies are able to obtain were named as two of the most significant issues with RWD utilisation

- Almost all respondents named insufficient quantity and quality of currently available RWD in Japan (Fig. 15. A), as well as insufficient sample sizes and inconsistency of sources and origins among data (B) as current issues hindering RWD utilisation in Japan.
- The next most significant obstacle is the complexity of the processes needed to ensure appropriate data governance including the protection of personal information, and the resulting decline in the value of data (C).
- Interestingly, only a few respondents reported concerns about their own data analytics or database research capabilities as an obstacle to RWD utilisation (E, F).

Figure 15. Issues related to RWD utilization



Topic #2 Patient-related activities

How should MA organisations be involved in patient-related activities?

- A majority of respondents said that responsibility for patient-related activities should be shared among the appropriate functions as needed, and that such responsibility should not be limited only to MA. At the same time, smaller numbers of respondents replied that MA should take charge of all patient-related activities in principle or, at the other extreme, that MA organisations should stay out of such activities as much as possible (Fig. 16).
- While most respondents' companies are currently engaged in the provision of information and education for patients, none of the respondents evaluated their current activities as sufficient and appropriate; many also indicated a clear intention to improve these activities with future efforts (Fig. 17. D, E).
- Many respondents also reported collecting patient insights through patient advisory board meetings and engaging in discussion with patient groups as both current activities and future areas of focus (Fig. 17 E, F).
- Although few MA organisations are currently involved in measures aimed at improving patient treatment and outcomes (PSPs), many respondents selected these measures as their highest priority for the future, making them a noteworthy activity of future focus (Fig. 17. H).

Figure 16. MA organisations' stance regarding patient-related activities

What role do you think MA functions should play in patient-related activities?

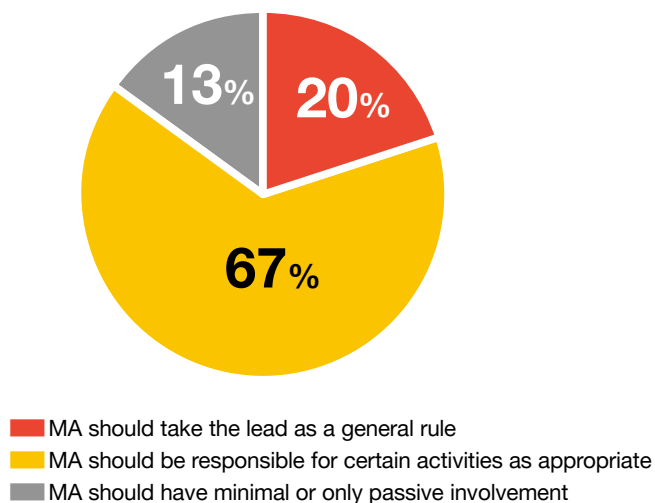
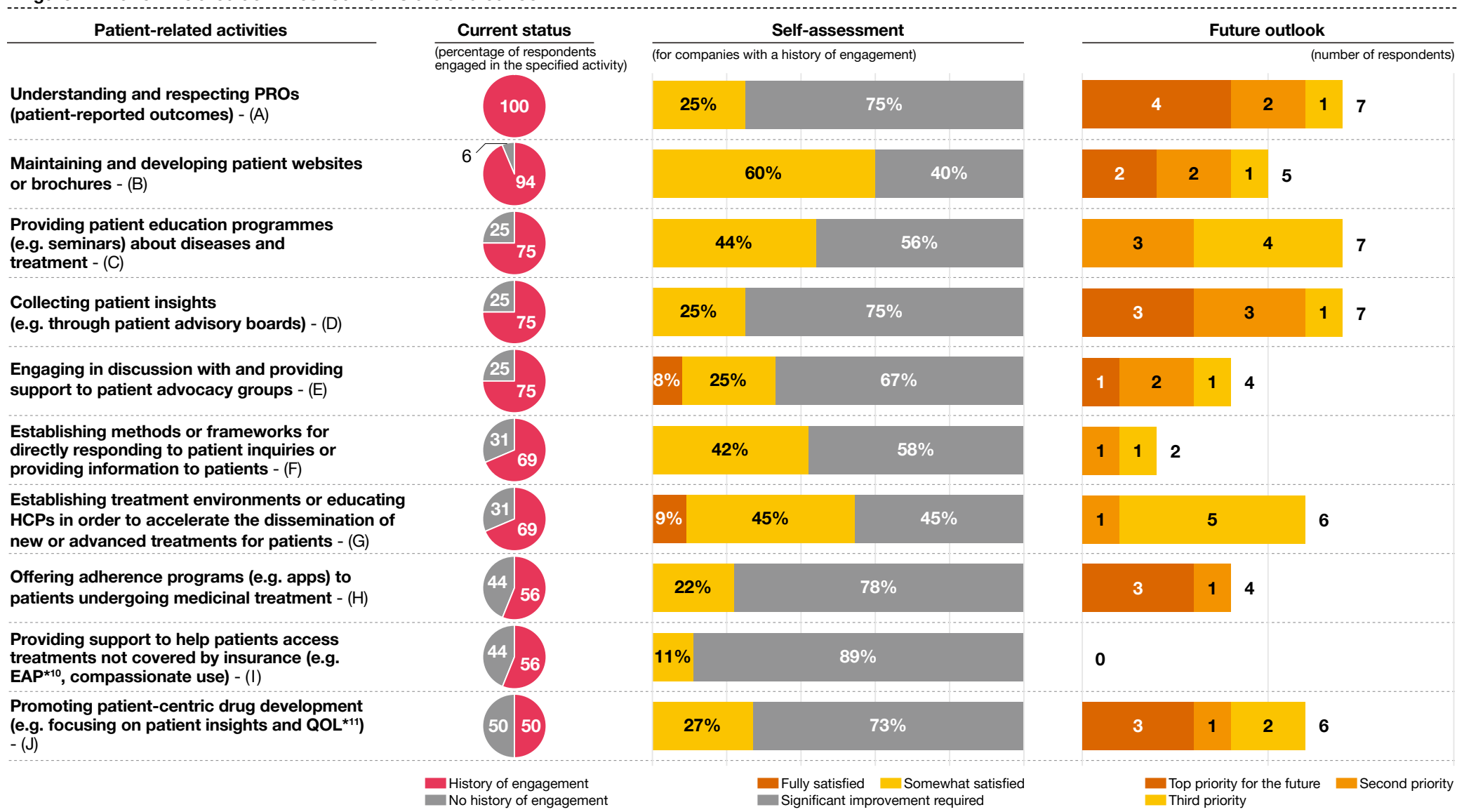


Figure 17. Patient-related activities: Current state and outlook



*10: Expanded/Early access program *11: Quality of life

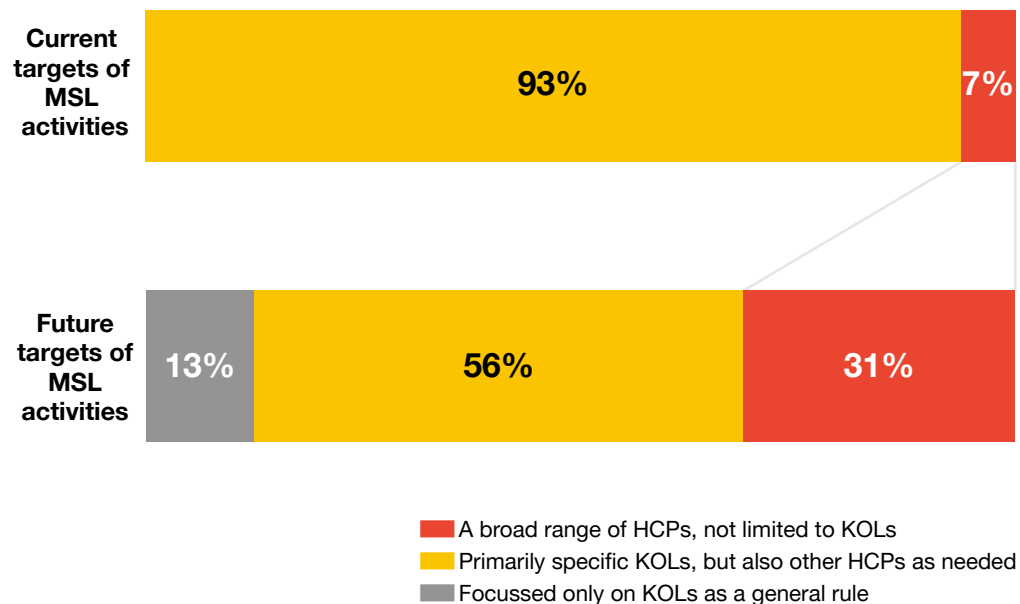
Topic #3 MSL activities

MSL activities are likely to expand their target range in the future

- At present, MSLs usually target specific KOLs and deal with other HCPs only when necessary and appropriate (Fig. 18).
- Over one third of respondents indicated an intent to expand the target of MSL activities to a broader range of HCPs in the future, while a small number of respondents indicated their intent to focus solely on scientific communication with specific top KOLs (Fig. 18).

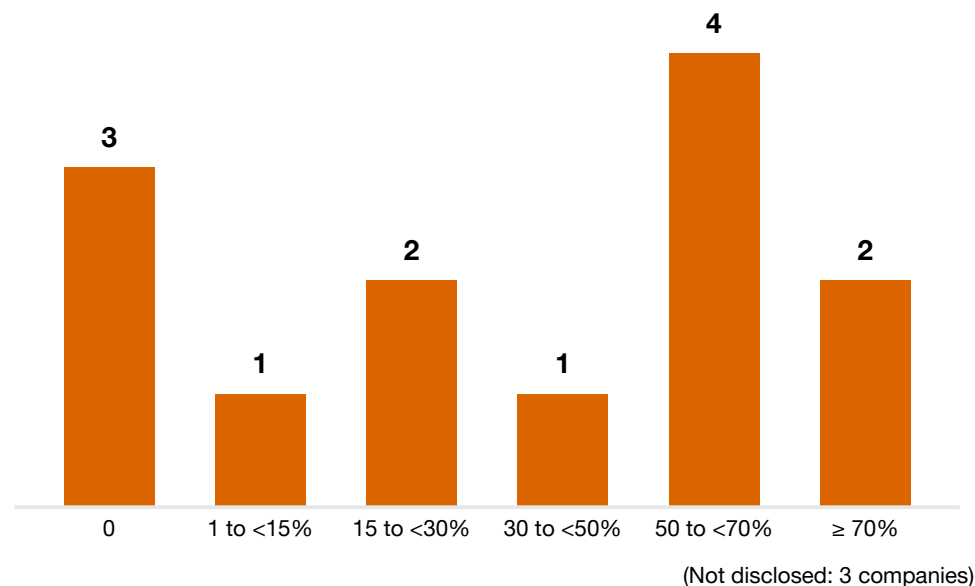
Figure 18. Customers targeted by MSLs in Japan

Which customers do your MSLs handle now, and which do you plan to have them handle in the future?



- The survey results also showed that the academic background of MSLs vary greatly among organisations (Fig. 19).

Figure 19. Percentage of MSLs with an advanced degree (PhD, MD, DVM, PharmD)



In summary

Almost all pharmaceutical companies in Japan have introduced MA functions to date, and many are even expanding the size of their MA organisations. Some of these MA organizations have already experienced several major organisational reforms or started to take on more innovative and proactive work. On the other hand, the survey results revealed that many MA organisations continue to struggle to clearly define their roles and responsibilities and effectively execute their medical plans. On a related note, one of the biggest concerns of many MA organisations is the misunderstanding or lack of understanding of the roles and expectations of MA within the company, which often can make it difficult to focus on strategically important medical tasks or result in a lack of sufficient resources to conduct scientifically meaningful activities in the most effective way. To improve this situation and achieve their true medical goals, each MA

organisation faces the need to reconfirm its mission and objectives, redefine its roles and responsibilities, and promote understanding of the MA function among both internal and external stakeholders. MA organisations also need to carry out more objective- and result-oriented activity planning and execution, and develop their organisation and infrastructure in an innovative way.

In this report, with the aim of providing an objective overview of the facts including the results of interviews with respondents and to accurately share the current views of MA leaders, we have intentionally refrained from commenting on the possible reasons behind these results.

The following is an executive summary of the survey results by category:

Core MA tasks

- All respondents' MA organisations are actively engaged in insight generation, data generation and evidence generation.
- These tasks, together with the provision of information and medical education, make up the 'core MA tasks'.
- These core tasks are also the tasks in which MA organisations currently have the most confidence, and are expected to remain an important area of focus for MA going forward.

Collaboration with other functions

- Although contribution to R&D or to brand and marketing strategy development is within the scope of responsibility of MA at most companies, few MA organisations have thus far been effective in this field
- However, comparatively few MA organisations report facing pressure or expectations from other functions to make these contributions, and only around half of the respondents intend to enhance such contributions in the future.
- In the area of internal communications, insufficient collaboration, alignment, and overall communication with global MA organisations are common issues shared by many MA leaders.

Efforts in emerging areas

- Emerging areas addressed by this survey include the medical economy (e.g. HEOR and HTA), patient centricity (e.g. PSP, access support) and contributions to public health policy.
- Although these areas are within the scope of responsibility of 60–70% of MA organisations, survey respondents reported sluggish activities and actual results in the field, as well as a low degree of satisfaction for all of these emerging areas.
- For patient centricity in particular, the number of MA organisations actively involved in or leading related activities is low, although the importance of this area is widely recognised.

Data and digitalisation

- All respondents' companies make use of RWD in some way. However, they also reported insufficient internal data governance as well as insufficient quantity and quality of the RWD available in Japan as the biggest obstacles hindering RWD analytics.
- While the main objective of RWD utilisation remains the performance of core MA tasks, it should also be noted that MA leaders have a strong desire to utilise RWD for the emerging field of medical economy in the future.
- When it comes to DX, MA organisations currently lack the necessary expertise, strategy and planning capabilities, and budget. The preliminary goal is to use DX to improve the efficiency of work that is currently performed manually.

People and organisation

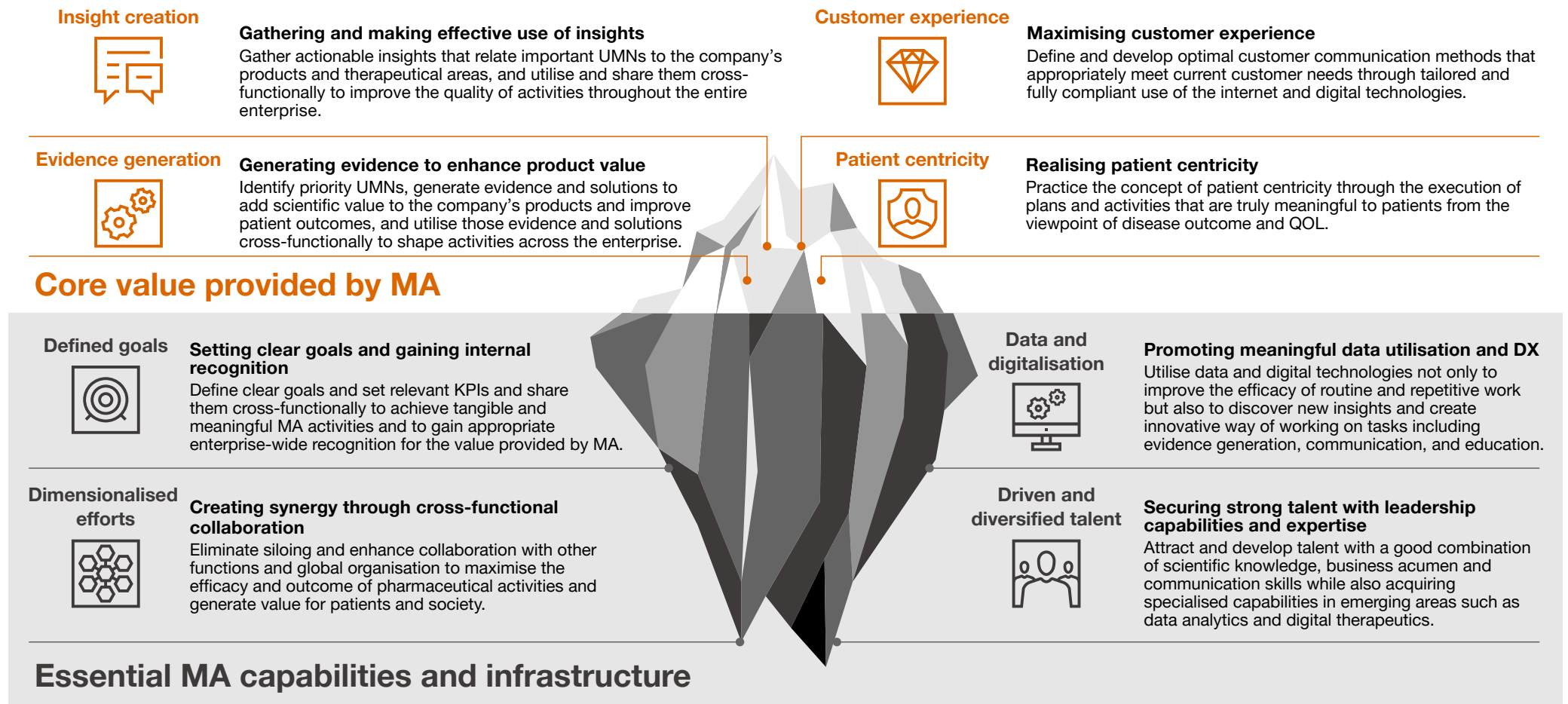
- Before MA functions can improve their external-facing activities, they face the common and serious problem of insufficient transparency, cooperation and collaboration among MA personnel and subfunctions.
- Leadership, organisational management, and agile management skills are among the major capabilities MA organisations want to acquire. Some leaders feel that other capabilities, such as expertise regarding data and digitalisation, can be entrusted to other functions or external vendors.
- In addition to securing and developing talent, the development of attractive career paths for such talent is an issue shared by many companies. The roles, responsibilities and job requirements for MSLs vary greatly among companies

Value proposition and essential elements of MA functions

Finally, based on the survey results, we would like to make a proposal regarding the value that MA functions should provide and the necessary elements for achieving that value. The primary value that we propose MA functions should provide can be summed up as follows: (1) gathering insights and taking appropriate action in response; (2) generating evidence that adds scientific value to the company's products; (3) maximising customer experience; and (4) realising the concept of patient centricity. To effectively deliver this value, MA functions must have the following capabilities: (1) define clear goals and KPIs

and have them recognised internally; (2) create diverse value through cross-functional collaboration, (3) promote data utilisation and DX; and (4) secure and develop skilled talent while promoting diversity and inclusion. Establishing these essential capabilities and infrastructure should enable the development of strong MA organisations that deliver true meaningful value to their companies' medical products, business entities, clinical practice, and patients' prognoses.

Figure 20. MA value proposition and its essential elements and capabilities



Acknowledgements

We would like to thank each of the MA leaders in Japan who participated in this survey.



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