

Survey on AMDD's Contributions to COVID-19

Survey Results

(Implemented in July 2021)

American Medical Devices and Diagnostics
Manufacturers' Association (AMDD)

Survey design:

- Period surveyed: March 2020 to July 2021
- Survey target AMDD member companies
- Survey Format Online survey
- Number surveyed 75 companies (regular members: 62, supporting members: 13)
- Number of respondents 39 companies*

*All respondents were regular members.

Survey results:

Q1: What measures has your company taken to ensure the stable supply of your products? Multiple choices are possible.

n=39

Answer	Number of responses	percentage
Staff infection prevention measures (checking temperature, keeping hand sanitizer on hand, etc.)	38	97.4%
Social distancing measures for offices, factories, distribution centers, etc., and measures for facilities such as air conditioning	33	84.6%
Negotiations with the U.S. head office and other parties on product supply to Japan	28	71.8%
Switching to a mode of transportation that prioritizes delivery over cost (e.g., switching to aircraft transport)	21	53.8%
Increase in production of COVID-19 related products	14	35.9%
Implementation of PCR testing for sales staff, etc.	14	35.9%
None in particular	1	2.6%

Q2-1: Is there any product or technology development that your company has started in relation to COVID-19?

n=39

Answer	Number of responses	percentage
Yes	18	46.2%
No	21	53.8%

Q2-2: If you answered "Yes" in Q2-1, would you please provide an outline.

Free description (n=18):

- **Reagents and equipment for testing**

- Development of products that meet the needs of the medical field and clinical research, including genetic, antigen, and antibody tests
- Development of products using the TMA method, which can produce test results in less time than the PCR method
- Development of a wide range of products from rapid testing products for clinics and POC (point of care) to products for high-volume processing in central laboratories of testing centers and hospitals
- Development of containers and consumables for transport and storage of specimens

- **Infection control in hospitals and for healthcare workers**

- Face shield, surgical gown by OEM
- CT IN BOX (a simple container-type CT room)
- Monitors that reduce the frequency of medical personnel's contact with patients
- Robots equipped with a germicidal lamp
- Joint development with a university hospital of infection control products for health care workers in surgeries and procedures for patients infected with COVID-19, patients with an unspecified infection, and patients transported to emergency rooms
- **Vaccines and vaccination equipment**
 - vaccine
 - Syringe for vaccination
- **Contribution to the treatment of COVID-19 patients**
 - COVID-19 patient monitoring using in-house products (glucose meters, etc.)
 - Increased production of ventilators and release of design specifications. Hitachi, Ltd. created 3D work procedures based on the design specifications and provided them free of charge.
 - Development of an emergency bed

Q3-1: Did your company donate items such as PPE (personal protective equipment)?

n=39

Answer	Number of responses	percentage
Yes	17	43.6%
No	22	56.4%

Q3-2: If "Yes" in Q3-1, is it your own product?

n=17

Answer	Number of responses	percentage
In-house products	8	47.1%
Not an in-house product	9	52.9%

Q4: Has your company made any monetary donations?

n=39

Answer	Number of responses	percentage
Yes	4	10.3%
No	35	89.7%

Note: AMDD donated a total of 10 million yen to the Center Hospital of the National Center for Global Health and Medicine and the Disaster Medical Assistance Team (DMAT) in 2020.

Q5: Did your company provide labor or other human support? (e.g., dispatch of vaccination workers, etc.)

n=39

Answer	Number of responses	percentage
Yes	10	25.6%
No	29	74.4%

Q6: What measures has your company taken for your employees in terms of COVID-19 infection prevention? Multiple choices are possible.

n=39

Answer	Number of responses	percentage
Internal infection control	39	100.0%
Implementation or enhancement of telework opportunities	39	100.0%
Distribution of masks, etc.	36	92.3%
Financial and material support for development of telework, etc.	33	84.6%
None in particular	0	0.0%

Q7-1: Has your company implemented a workplace vaccination program?

n=39

Answer	Number of responses	percentage
Implemented.	21	53.8%
Not implemented or could not be implemented.	18	46.2%

Q7-2: If you selected "Implemented" in Q7-1, did you face any challenges in implementation?

n=39

Answer	Number of responses	percentage
None in particular / No answer	21	53.8%
There was a challenge (free description)	18	46.2%

Summary: Challenges in implementing vaccine occupational immunization

- Difficulty in obtaining vaccines/insufficient supply
- Difficulty in internal communication and scheduling due to uncertainty of vaccine availability/uncertain supply until the last minute
- Cost burden due to the need to rely on outsourcing for scheduling, etc.
- Large administrative burden in case of joint occupational vaccination without meeting the 1,000-person scale
- Difficulties in joint inoculation for non-metropolitan employees

Free text: Issues in implementing vaccine occupational vaccination

- **Vaccine supply, government policy**
 - Difficulty in obtaining vaccines
 - Government policies were not finalized early.
 - Vaccine supply for occupational vaccination
 - Uncertainty of the availability of vaccines
- **Implementation plan/issues and initiatives related to implementation**
 - Preparation of detailed implementation plan, etc.
 - Because of the small size of our company, we are taking advantage of the efforts of the Chamber of Commerce and Industry to which we belong.
 - The number of vaccine recipients will not reach 1,000 on its own, but it's possible through joint implementation. There is a high administrative burden in terms of determining the number of inoculated persons and managing medical questionnaires.
 - Securing place, dates, physicians, nurses and medical staff, Cost, Scheduling for those who wish vaccination, Significant burden on coordinators in our organization, Significant burden on coordinators in our organization.
 - Recruitment of vaccine recipients in line with vaccine supply

- Difficulties in employee communication as actual vaccine supply was not known until the last minute

● **Inoculation for employees outside the Tokyo metropolitan area**

- Delay in vaccination schedule for employees living outside the Tokyo metropolitan area
- Vaccination of employees in the Tokyo suburbs proceeded without problems, but because we were unable to apply for a large group of employees to be vaccinated at their workplaces, we were unable to ensure vaccination opportunities for employees living in rural areas.
- I understand that this is unavoidable since there is a nationwide shortage of supply, but the vaccine was not supplied in some areas.
- Since it was not possible to conduct the vaccination independently, we participated in a joint job site vaccination with several companies. However, it was not possible to conduct vaccinations at local offices.

● **Cost**

- A large portion of the work is outsourced, resulting in substantial out-of-pocket expenses.

● **Other**

- Securing anaphylaxis response drugs

Q8: As of July 2021, by what percentage has telework reduced the number of employees coming to work compared to before the epidemic?

n=39

Answer	Number of responses	percentage
It's back to normal.	0	0.0%
10-20% reduction	2	5.1%
30-40% reduction	2	5.1%
50-60% reduction	6	15.4%
70-80% reduction	27	69.2%
More than 90% reduction	2	5.1%

Q9: Does your company plan to continue teleworking after the pandemic is over?

n=39

Answer	Number of responses	percentage
Yes	33	84.6%
No	6	15.4%

Q10-1: Please tell us about your experience of holding online meetings with government agencies.

Multiple choices are possible.

n=32 (excluding 7 companies that did not hold the meeting)

Answer	Number of responses	percentage
It almost went entirely online.	23	71.9%
We did about half in-person and half online.	7	21.9%
Mostly face-to-face, but occasionally conducted online.	2	6.3%
All meetings continued to be held face-to-face.	0	0.0%

Q10-2: What were your impressions of the online implementation and the challenges you faced?

Summary: Issues and requests for online meetings with the government

- Online meetings have their advantages and disadvantages depending on the nature of the meeting, so it is important to be able to **choose face-to-face or online** depending on the purpose. It is also requested that the **cameras of the parties involved should be turned on** regardless of the meeting.
- Request for **infrastructure improvements in the communication environment**, including securing space for online meetings

Advantages Efficiency and flexibility	Disadvantages Quality and quantity of communication, communication environment
<ul style="list-style-type: none"> · Easy to adjust schedule · In particular, it would be beneficial to invite outside experts and development staff from overseas manufacturers to participate. · No limit on the number of participants. 	<ul style="list-style-type: none"> · PMDA consultation meeting is conducted off-camera, which reduced the quality and quantity of communication during the meeting, as well as lost opportunities for additional communication after the meeting (majority opinion). · It became difficult for the applicant to show the actual product and explain the principle and usage of the applied product, and for the reviewers to actually hold the product in their hands to deepen their understanding. · The MHLW has no space for online meetings and ambient noise makes it difficult to hold meetings. · There are many infrastructure restrictions (number of meeting rooms available for web conferencing, remote work environment) on the PMDA side.

Free text: Opinions on online meetings with the government

- **Positive feedback**
 - It is efficient and should be continued.
 - Since the brief consultation was only 30 minutes, we felt that holding it online was particularly more efficient than in-person.
 - The reading of simple consultations now comes by email (no more reading/writing).
 - Smoothly set the time and no problem with communication.
 - The online PMDA consultation meeting was effective. In particular, it facilitated the participation of advisors' doctors and others who could attend from distant locations.
 - Not only from the perspective of infection prevention, but also because of the flexibility of the schedule, we were able to secure dates quickly.
 - The PMDA's consultation meeting has the advantage of efficiency, such as reduced travel time, as well as the ability for overseas manufacturers and development staff to participate if necessary (they could participate in the past, but without the need to travel, which allows for more flexible participation). Although each of these has its own merits and demerits, we hope that this operation

will continue (including maintaining it as an option) for after COVID-19.

- I found it a great advantage that online meetings do not limit the number of people who can participate.
- More people can now participate than when face-to-face.
- It made it easier to coordinate the schedules of participating employees and physicians.
- No particular problem. Rather convenient.
- None in particular. Rather, I felt that the flexibility of the date and time of implementation was a benefit.
- None in particular.
- There was no hindrance.
- Online is possible.
- I was able to do it with no problem.
- There was no particular technical trouble, and it was no different from face-to-face.
- Some of the nuances may not have been conveyed, but we were able to conduct it almost the same way as face-to-face.
- It is efficient and I would like to see it continue, but I would prefer face-to-face depending on the agenda.
- Technical aspects are not a problem. There were also advantages in inviting experts and employees to participate remotely. Since we couldn't see their "faces" online, we couldn't understand their facial expressions and had to judge only from their voices.
- It is difficult to discuss important issues by pointing to the relevant parts of the materials online, and both participants need to work together more for the success of the meeting.
- No need to spend time going back and forth, shortening the setup time. Materials to be shown can be highlighted on the screen.
- It is convenient because it can be done without having to think about the location or meeting room schedule. There was feedback that the depth of the communication seemed to be inferior compared to face-to-face.
- No particular problem. However, considering the human connection, a hybrid approach is preferable.
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- **Negative comments/issues**

- There is still a limit.
- The communication environment at the MHLW is not good, and I strongly hope it can be improved. Also, there is no consideration for the controlling the environment (surrounding voices) during online meetings.
- When there were many participants, I was at a loss at first on how to proceed with the conversation because the microphone would not pick up audio if more than one person started to converse at a time.
- The camera on the PMDA side is turned off. I would like them to have the camera turned on.
- The reviewers' cameras are not turned on. Since this is a "face-to-face" session, we would like to see the cameras used.
- Since we cannot see the other person's facial expression, we cannot gauge their true feelings.
- I was concerned about the time lag in the explanation of the materials. It was difficult to read the response of the administration.
- Since it was held off-screen, I could not see the reviewers' facial expressions and felt that the quality of communication would be inferior to face-to-face.
- It is difficult to understand the mood of the other party. When asked to explain a product, it is difficult to convey the message because the actual product cannot be used for explanation.
- It is better to have face-to-face consultations with PMDA related to approval applications, because PMDA face-to-face consultations are basically off-camera (especially in the review department), and it is difficult to read the expressions and mood of the other party. In addition, it is very useful to talk offline with each reviewer after the consultation, so not being able to do so is quite

- unhelpful and hinders smooth approval and review applications.
- In face-to-face meetings, I was able to have additional communication with the reviewers after the meeting, but this became difficult with online meetings.
- I feel as if I have become a little distant from the government because I cannot communicate face to face.
- PMDA: Since it was conducted almost exclusively by voice, it was difficult to grasp the nuances of facial expressions and other changes that are possible in face-to-face sessions. MHLW: In the early days, there was a problem with the connection, and it was not at a usable level. Recently, it has improved, but I would like to see further improvements such as securing dedicated space for online use. In addition, I think it would be a good idea to consider distributing smartphones or tablets to PMDA and MHLW for use in meetings and communication, in addition to the regular PCs.
- Even though the network environment had been checked beforehand, problems unique to online meetings occurred, such as ending the meeting without being able to ask sufficient questions due to audio problems, or having a speaker leave the meeting midway through and then return due to network problems.
- Depending on communication conditions, it was difficult to hear the other person's voice and I had to listen again several times.
- I felt unfamiliar with the other side.
- There are so many limitations on the PMDA side regarding infrastructure (number of meeting rooms available for web conferencing, remote work environment); I feel that PMDA needs to improve its infrastructure. In addition, it was difficult to explain how to use the product and how it works in order to deepen the understanding of the reviewers about products employing new technology.
- There are numerous restrictions on the PMDA side in terms of infrastructure (number of conference rooms available for web meetings, remote work environment); we feel that PMDA needs to improve its infrastructure. In addition, it was difficult for us to explain how to use the product and how it works in order to deepen the understanding of the reviewers about products that employ new technologies.
- When MHLW conducted online meetings with ministry officials only, the participants joined such meetings from their desk, etc., which somehow improved the audio quality of the meetings. However, when MHLW conducted hearings with the Medical Affairs Division or meetings with outside experts (e.g., Insurance material Committee), they connected two online systems in one conference room using a speaker, etc. This caused problems for some participants; for example, they were asked for their opinions, but they could hardly hear what was being discussed, and the background noise was very loud. We believe that the ministry needs to improve its infrastructure."

Q11-1: Has your company conducted any online training for MHLW and PMDA staff during COVID-19?

n=39

Answer	Number of responses	percentage
Yes	3	7.7%
No	36	92.3%

Q11-2: If you answered "Yes" to Q11-1, how would you like the online training to be held after the pandemic is over?

n=3

Answer	Number of responses	percentage
Efficient and will continue	3	100 %
Plan to return to face-to-face with many issues	0	0%

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