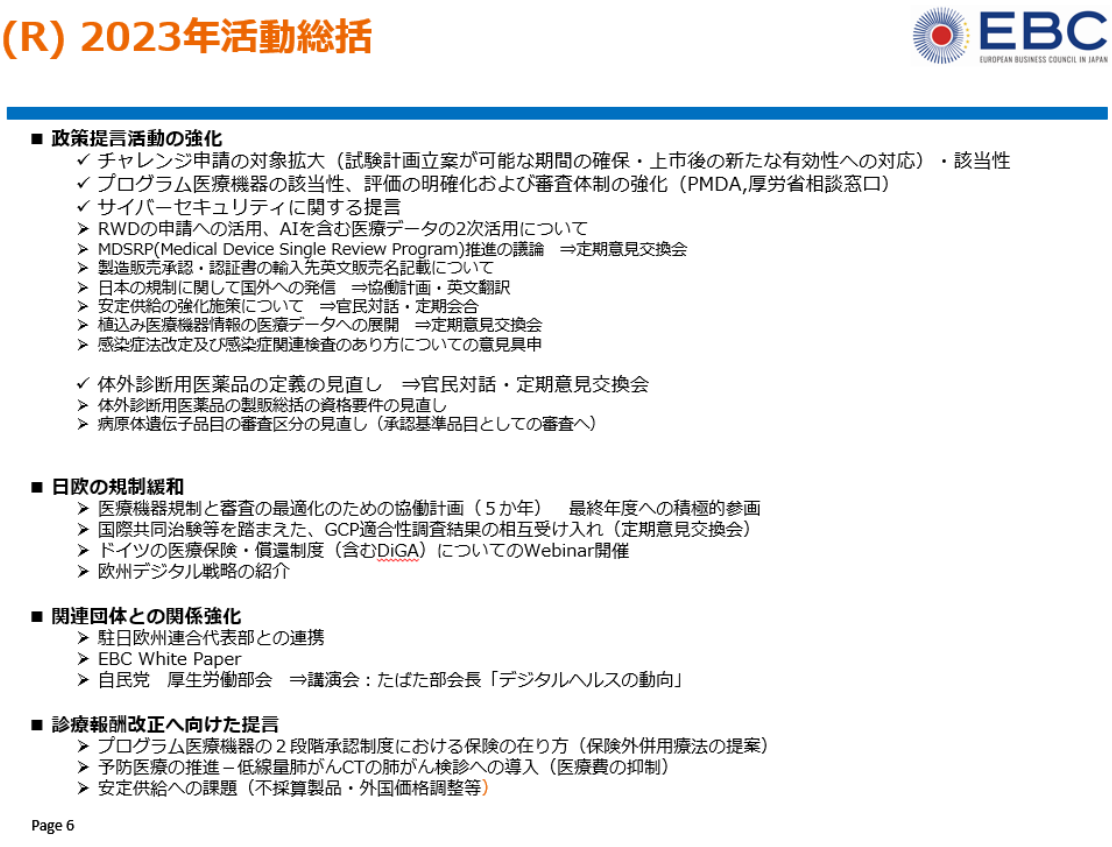
Activity report (2023) and activity policy (2024) by committee chairperson



(R) 2023年活動総括

EBC EUROPEAN BUSINESS COUNCIL IN JAPAN

■ **政策提言活動の強化**
- ✓ チャレンジ申請の対象拡大（試験計画立案が可能な期間の確保・上市後の新たな有効性への対応）・該当性
- ✓ プログラム医療機器の該当性、評価の明確化および審査体制の強化（PMDA,厚労省相談窓口）
- ✓ サイバーセキュリティに関する提言
- ➢ RWDの申請への活用、AIを含む医療データの2次活用について
- ➢ MDSRP(Medical Device Single Review Program)推進の議論　⇒定期意見交換会
- ➢ 製造販売承認・認証書の輸入先英文販売名記載について
- ➢ 日本の規制に関して国外への発信　⇒協働計画・英文翻訳
- ➢ 安定供給の強化施策について　⇒官民対話・定期会合
- ➢ 植込み医療機器情報の医療データへの展開　⇒定期意見交換会
- ➢ 感染症法改定及び感染症関連検査のあり方についての意見具申

- ✓ 体外診断用医薬品の定義の見直し　⇒官民対話・定期意見交換会
- ➢ 体外診断用医薬品の製販総括の資格要件の見直し
- ➢ 病原体遺伝子品目の審査区分の見直し（承認基準品目としての審査へ）

■ **日欧の規制緩和**
- ➢ 医療機器規制と審査の最適化のための協働計画（５か年）　最終年度への積極的参画
- ➢ 国際共同治験等を踏まえた、GCP適合性調査結果の相互受け入れ（定期意見交換会）
- ➢ ドイツの医療保険・償還制度（含むDiGA）についてのWebinar開催
- ➢ 欧州デジタル戦略の紹介

■ **関連団体との関係強化**
- ➢ 駐日欧州連合代表部との連携
- ➢ EBC White Paper
- ➢ 自民党　厚生労働部会　⇒講演会：たばた部会長「デジタルヘルスの動向」

■ **診療報酬改正へ向けた提言**
- ➢ プログラム医療機器の２段階承認制度における保険の在り方（保険外併用療法の提案）
- ➢ 予防医療の推進－低線量肺がんCTの肺がん検診への導入（医療費の抑制）
- ➢ 安定供給への課題（不採算製品・外国価格調整等）

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The chairman、Mr. Mori.
Thank you very much for taking time out of your busy schedule to attend the Medical Devices and IVD Committee Representative Meeting today.
The year 2023 marks the end of the coronavirus pandemic, but it was a very difficult year with various issues remaining. All kinds of costs, including material costs, logistics costs, utility costs, and labor costs, were soaring, and it was also difficult to pass on the costs to the customers, and with the weak yen taking its toll, it was not easy to continue the business.

The 2023 activity summary you are viewing is a list of the EBC's advocacy and activities in various situations over the past year.

Now, medical DX has been a hot topic for the past year or so, and it was thought that it could

be a bright future, but the current situation is that it is not making much progress.

We believe that increasing productivity in the medical field will lead to lower medical costs, and for this purpose, there is value in testing, diagnosis, and treatment, and correct evaluation, such as reducing patient waiting time and assisting doctors in diagnosis and treatment, etc. We are continuing our activities to request evaluations.

As an example of this, we have been introducing the German DiGA program to the Japanese government related over the past few years, and it has now become widely known to all concerned parties, and is used as a reference when considering insurance for programmed medical devices.

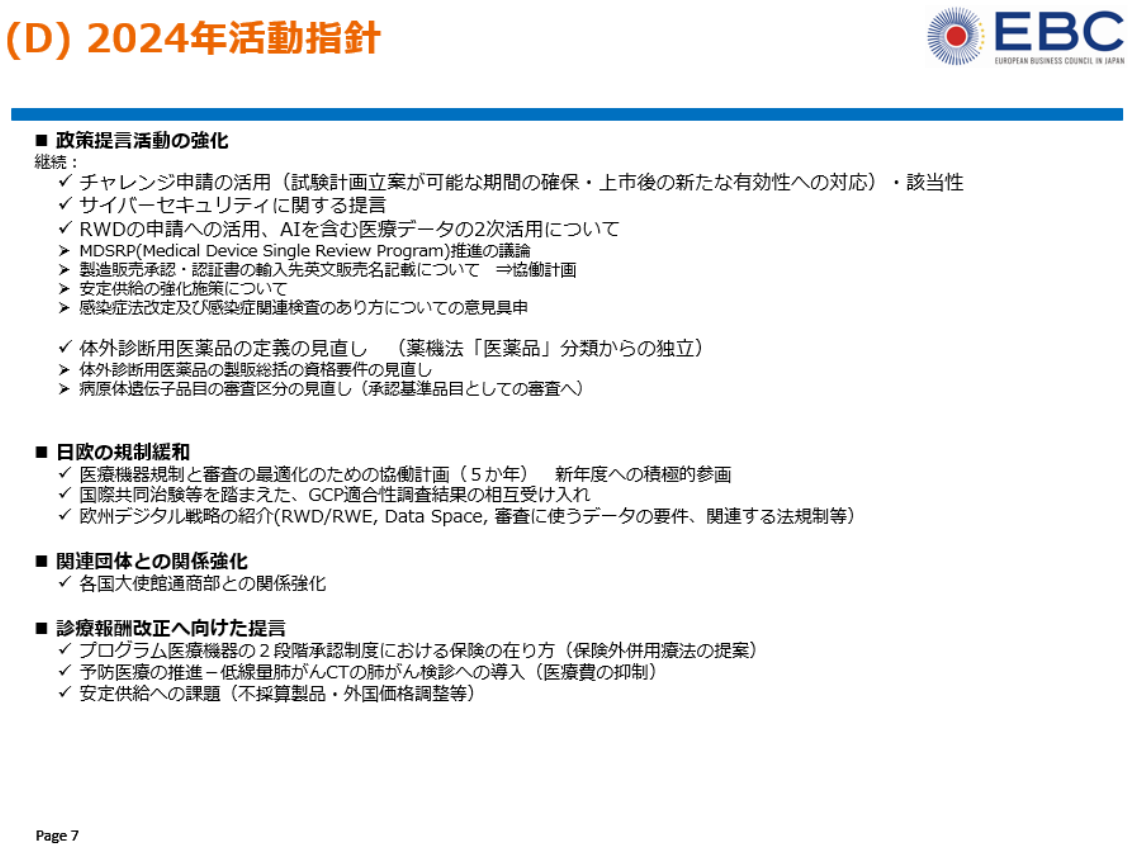
This achievement is the result of the hard work of all members of the Digital Health Task Force. thank you very much.

In addition, as a basic activity, we are continually discussing various issues with the Medical Device Review Management Division and PMDA regarding optimization and speeding up reviews.
Programming medical devices was a big challenge. As for the approval system, we were able to achieve great results by issuing notifications for DASH for SaMD2 and establishing a two-step approval system.
Regarding IVD, there are still discrepancies in the review requirements and standards at the PMDA, and we are currently in the process of steady discussions regarding their improvement, including the review of review categories for pathogen genetic testing.

Regarding medical fees, I feel that further discussion is necessary regarding unprofitability related to stable supply and foreign price adjustment, and that challenge applications that can secure time for research planning should also be discussed.
Regarding the state of insurance related to the two-step approval of programmed medical devices, we are proposing the concept of combined treatment not covered by insurance. This is a challenge that must be discussed with the Ministry of Health, Labor and Welfare and insurance unions, which want to maintain universal health insurance at all costs, but it is also true that everyone involved feels that universal health insurance will collapse if things continue as they are.

It may be time to consider the use of Combined treatment not covered by insurance as a

measure to protect universal health insurance.
As I said at the beginning, it was a very difficult year. I would like to express my gratitude to the members of the committee who took time out of their busy schedules to participate in discussions with industry and government to achieve results.
Thank you very much. ⇒ Next page 2024 Activity policy



Now, regarding the issues that we must tackle in fiscal 2024, as you can see, we must continue to address many of them.

The most recent issue is cybersecurity. As reported in the Nikkei Shimbun newspaper last Saturday, there has been a general agreement in Europe to require all products connected to the Internet to have cybersecurity measures. We have also been closely monitoring the coming into force of the Cybersecurity Act in 2019 and the EU Cyber Resilience Act in 2022 (currently excluding medical devices).

As you know, in Japan, "Article 12, Paragraph 3 of the Basic Requirements Standards for

Medical Devices" was newly established in 2023. Requirements for cybersecurity measures are presented to each company and they are required to apply them. It will be applied from April 1, 2024, and I think each company is preparing. However, as confusion is expected after implementation, the committee believes that it is necessary to provide support to member companies.

We would also like to promote the secondary use of RWD (real world data)/RWE (real world evidence), registry data, etc. used in examinations by companies.
Although the handling of personal information has been relaxed in Japan under the Next Generation Medical Infrastructure Act, progress is still slow. In the United States, the number of implementation cases is increasing due to FDA guidance, and in Europe, laws and regulations are being developed with the aim of secondary use by companies by 2025. As long as Japanese data is requested, I would like to work to ensure that it can be utilized domestically as soon as possible.

The most important thing about IVD is that it will be independent from the drug classification in the next revision of the Pharmaceutical Machinery Act. It's a huge challenge, but I hope that this year will serve as a guidepost for moving forward.
We will promote transparency and simplification of the examination process and international harmonization of examination requirements, etc., with the aim of reducing the burden on both government and industry and improving productivity.

Regarding medical fees, future insurance systems may need to be significantly reviewed depending on how we can show the path to combined treatment not covered by insurance. The discussion of universal health insurance and non-insurance coverage can be said to be a major initiative for next year.

Based on the experience of COVID-19, the ``Revision of the Infectious Diseases Law'' that incorporates logistics issues in 2024 has been under discussion since last year. I have heard that it includes quite a few demands for companies.
The committee will also respond appropriately.

We will continue to work on a wide variety of issues in 2024. We appreciate your continued understanding and support.
Once again, thank you very much for taking time out of your busy schedule to join us today. We would also like to thank you for your evaluation of our excellent staff.

This concludes my greetings.