資料１－５
１５．７．２

画期的なビジョン
昨年8月30日、厚生労働省は医薬品産業ビジョンを公表し、
今後5年間を「イノベーション促進のための集中期間」と位置付けた

医薬品産業政策の推進に係る懇談会

マーティン・ライト
欧州製薬団体連合会
在日執行委員会 会長
2003年7月2日

まず初めに、欧州製薬団体連合会（以下EFPIA）はこの医薬品産業ビジョンを支持します。

そして昨年、医薬品産業ビジョン（案）について我々の意見を述べる機会を頂戴したこと、また今回その進捗状況について意見を述べる機会を頂戴したことに感謝します。

わずか1年間で既にいくつかの分野で進展が見られることを喜ばしく思います。しかしながら、これは長期的なビジョンであり、アクションプランをすべて遂行するには今後更なる積極的な取り組みが必要です。本日、我々はEFPIAとして、建設的な意見をお示しできればと思います。またその後の意見交換を楽しみにしております。

An Exciting Vision

On 30 August 2002, the MHLW published its vision for the Japanese pharmaceutical industry and designated the next five years as a "Period of intensive promotion of innovation".

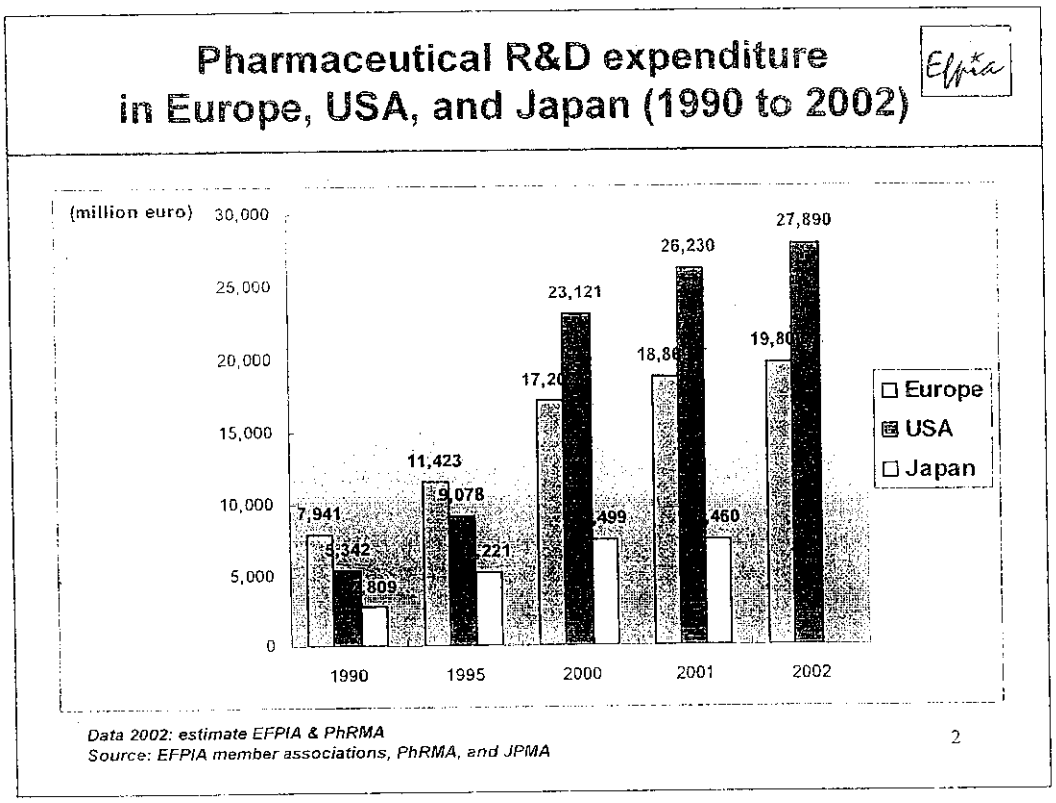
Discussion on policies for improving the pharma industry competitiveness

Wright Martin
Chairman
EFPIA Japan Executive Committee
2 July 2003

EFPIA supports this vision for the pharmaceutical industry in Japan.

We appreciated the opportunity to input into the draft vision a year ago, and we are equally pleased with the opportunity today to give our feedback on progress so far.

We would like to congratulate the MHLW for the progress that has already been made in some areas in just one year. It is, however, a long term vision and much still needs to be done to implement all actions in full. We aim to give constructive feedback to you today, and look forward to our discussions.



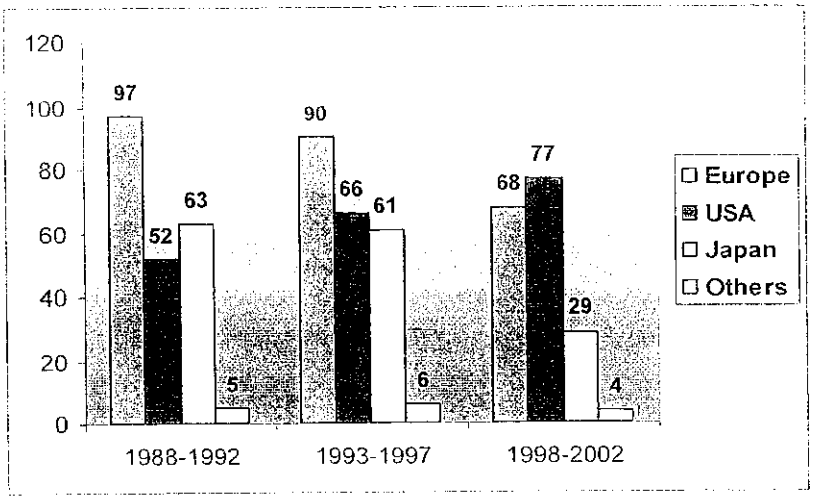
First, I would like to share with you 3 slides that have been used by EFPIA in Europe at their annual meeting last month. I am sure you agree that the message for Europe is equally valid for Japan.

This first slide shows how that over the past 12 years there has been a significant shift of R&D to the USA from both Europe and Japan. In 1990, R&D expenditure in the USA was about half that in Europe and Japan combined. By 2001, the expenditure in the USA equaled that in Europe and Japan combined.

This shift in expenditure makes the vision for the pharmaceutical industry in Japan and the G10* initiative in Europe highly relevant and important for both markets.

* G10 Medicines Group, composed of Health and Industry Ministers form Member States, representation from different sectors of the industry, mutual health funds and a specialist in patient issues, was created to explore ways of improving industry competitiveness in Europe while encouraging high levels of health protection.

Country of origin of new molecular entities 1988 to 2002



Source: SCRIP Publications - EFPIA calculations (according to nationality of mother company)

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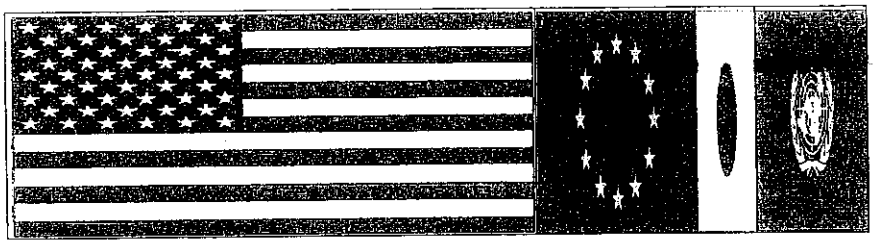
The change in pattern of R&D expenditure shown in the previous slide is flowing through to the proportion of new molecular entities discovered in the 3 regions. This slide supports the notion that the increased R&D expenditure in the USA seems to be driving an increase in new molecular entities from that country, once again at the expense of Europe and Japan.

US patients getting earlier access to new medicines

Sales of new chemical entities launched first time (1998 to 2002)



70%	18%	4%	8%
USA	Europe	Japan	RoW

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Not only is there an increasing level of R&D in the USA, but new products are also launched earlier in that country. The slide above shows that patients in the USA are clearly benefiting from earlier access to new products compared to all other regions in the world, and totally out of proportion to the size of their market. This trend has been increasing, and for example in the 5 years, 1995-1999, the proportion of new drugs sold in the USA was 57%. So you can see there has been a significant shift in just 3 years.

EFPIA feedback

1. **World-class regulatory system**
   - Commitment to global harmonisation is vital to be internationally competitive – absent from the progress report.
   - EFPIA accepts the need for increased fees, but in return wants a commitment for clear performance criteria for drug approvals.
   - EFPIA appreciates the plan to decrease the GCP-required documents for regulatory trials.

2. **Fast access by patients to new medicines**
   - High expectations from the merger of Kiko and the Evaluation Centre. EFPIA requests elimination of any redundancies and more streamlined drug evaluation and approval process.
   - EFPIA appreciates the support for clinical trials, including the tax incentives for R&D, but we see some imbalance in the budget allocation between basic research and clinical trials.
   - EFPIA requests that education on conducting clinical trials be extended also to practicing clinicians.

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1. **World-class regulatory system**

EFPIA looks forward to the development of a world-class regulatory system in Japan as a key corner stone for the development of an internationally competitive pharmaceutical industry. In today's modern world, harmonisation between regulatory authorities is ever more critical. EFPIA believes that a commitment in global harmonisation is vital to be internationally competitive. This issue is absent from the progress report.

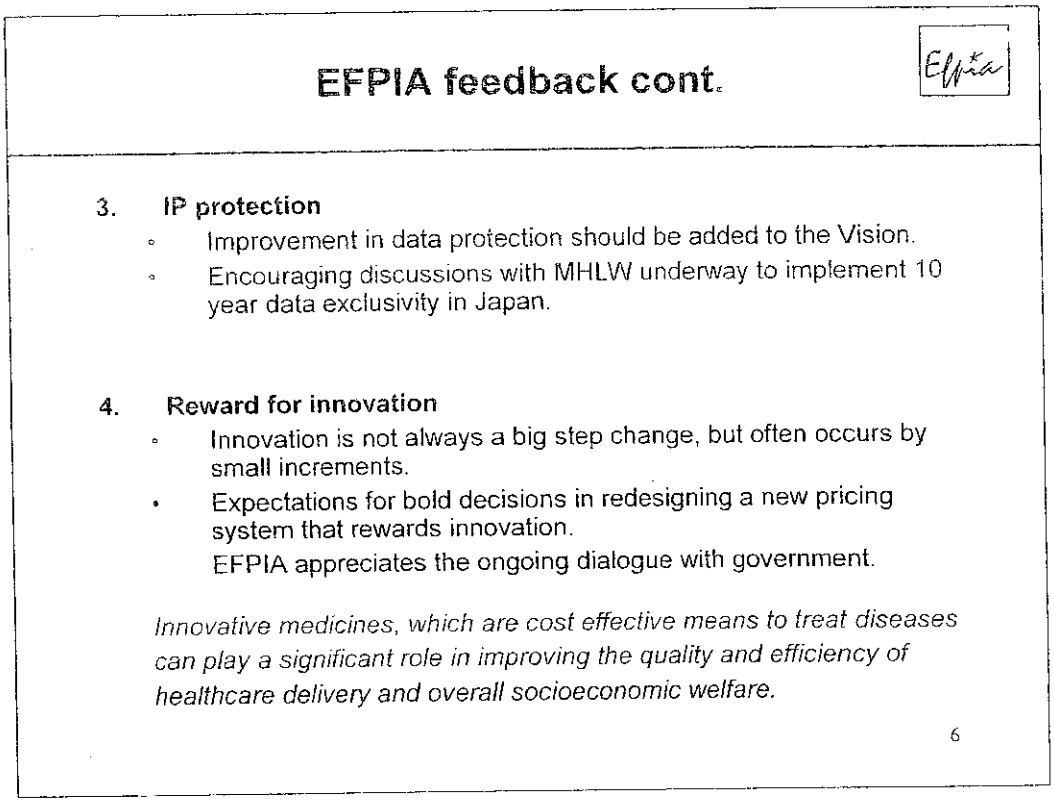
EFPIA supports the increasing fees to ensure that the new independent agency is able to do higher quality reviews, and is better able to manage peaks in workload. But in return, the industry does need from the agency clear performance criteria with long term goals and mile stones in place to meet these targets.

2. **Fast access by patients to new medicines**

We all agree that in the end, it is the patients who must benefit and EFPIA has high expectations from the merger of KIKO and Evaluation center. During the integration phase, we ask that there be a focus on efficiency and streamlining of the drug evaluation and approval processes, and that any duplications and redundancies be eliminated.

EFPIA appreciates the encouragement of clinical trial activity including the tax incentives for R&D. We do, however, feel that there is imbalance in the budget allocation between basic research and clinical trials. For example, the budget for the Large Scale Clinical Trial Initiative is now just Yen 850m, which seems too small for such an important initiative.

EFPIA applauds the education imitative on how to conduct clinical trials, but asks that this be extended to practicing physicians as post graduate education, and not be limited to the medical education system.



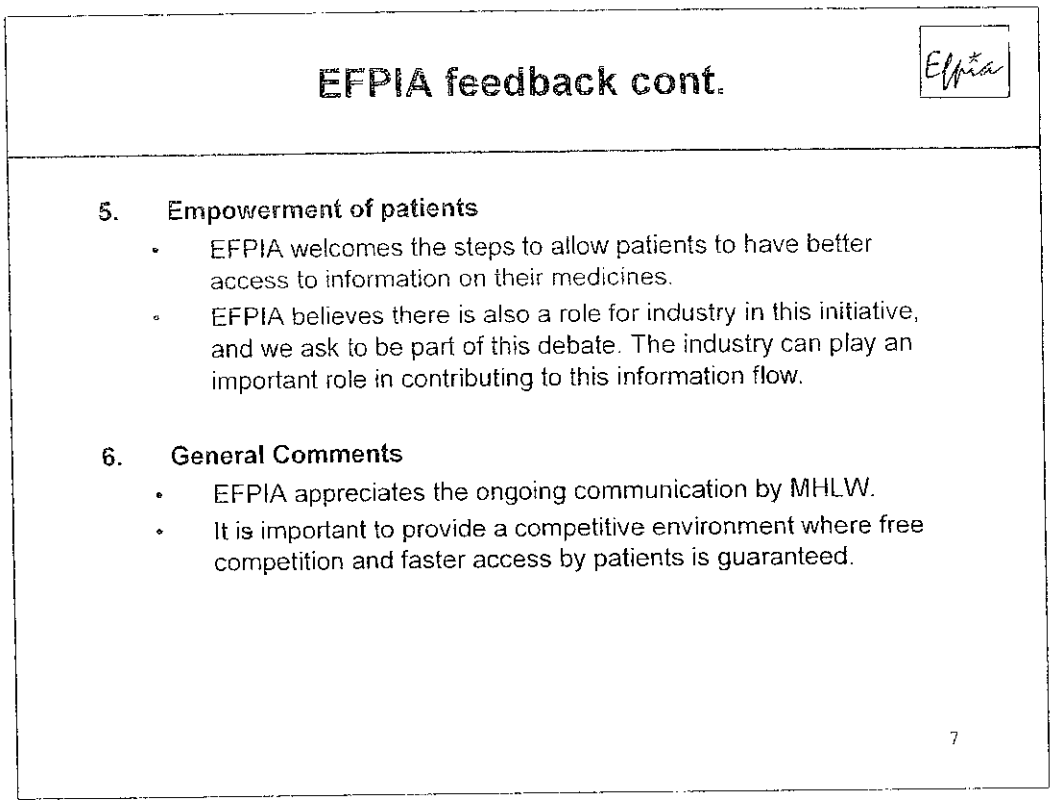
3. **IP protection**

Strong IP protection is important to facilitate a competitive industry. EFPIA asks that an improvement for data protection should be added to the vision for the pharmaceutical industry. In Europe, data protection is being extended to 10 years plus 1 extra year for additional indications with significant therapeutic benefit. We would like to see a similar development in Japan, and the industry is currently having encouraging discussions with the MHLW to implement a 10 year data protection period in this country.

4. **Reward for innovation**

In our industry, innovation is not always necessarily a big step change, for example, a drug with the novel therapeutic action. In many cases, innovation occurs in small increments, and there are many examples of this. The first in-class of a therapeutic area is not necessarily the best in-class. This is true, for example, for the penicillins and cephalosporins, beta blockers, the calcium channel blockers, and the statins to name just a few. In all these cases, later molecules have given additional therapeutic and / or safety benefit. This should be recognised in the vision and in particular in the pricing of these products.

EFPIA has high expectations for a new pricing system that truly rewards innovation, and we appreciate the ongoing dialogue that we are having with government on this initiative. Innovative medicines, which are cost effective means to treat diseases can play a significant role in improving the quality and efficiency of healthcare delivery and overall socioeconomic welfare.



5. **Empowerment of patients**

Patients are becoming increasingly involved in selecting their treatment options and EFPIA welcomes the steps proposed to allow patients to have better access to information on their medicines. This will ensure that they can make more informed decisions.

EFPIA believes, however, that there is also a role for industry in this initiative. Industry can play an important role contributing quality information to patients and healthcare professionals. By information we do not necessarily mean advertising and Direct to Consumer activities. We ask to be included in this debate.

6. **General Comments**

Without wanting to be too critical, we feel the most important role of government is to provide a competitive environment where free competition and faster access to medicines by patients is guaranteed. This should be a collaborative project between government, academia and industry, and will ensure integration between basic research, clinical trials, access to new medicine, etc.

G10 Proposals

1. **Price controls and functioning of the single market**
   - Finding alternative ways of controlling national pharmaceutical-related expenditure by letting manufacturers set the prices of new products while negotiating e.g. adjustable yearly rebates in compliance with EU competition rules.

2. **Improved access to innovative medicines**
   - Fast track assessment procedure for medicines of major public health interest (210 to 150 days)
   - Shortening of the decision-making procedure after scientific evaluation.
   - Data exclusivity to be harmonized at 10 years + 1 year.

3. **Incentives for research**
   - Pediatric exclusivity as an incentive to develop better medicines for children.
   - Biotechnology patents – implementation of directive EC/98/44.

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The next 2 slides are provided for information only. They give a brief update on the G10 report in Europe and a summary of current proposals moving forward. As you can see, there are many similarities between this report and the MHLW vision.

Under price control and functioning of the single market, the following proposals are on the table:

1. Member States to allow the immediate launch of all medicines after the grant of a marketing authorisation and before any decision on pricing and reimbursement by the State has been made.

2. Member States to remove price controls on manufacturers that prevent full competition of authorised medicines that are neither purchased nor reimbursed.

3. The Commission to launch a reflection on finding alternative ways of controlling national health care expenditures by letting manufacturers set the prices of new products, while negotiating e.g. adjustable yearly rebates in compliance with EU competition rules.

We have left out a few topics which cover areas such as EU enlargement which are not relevant to the situation in Japan.

G10 Proposals cont.

4. **Strengthening of the EU science base**
   - Establishment of virtual Institutes of Health – European networks of excellence.
   - Implementation of the Biotechnology Strategy Action Plan to harvest the potential of biotechnology in Europe.

5. **Information to patients**
   - To provide a realistic and practical framework for the provisional information on all medicines; the prohibition on advertising prescription medicines to the public will remain.
   - Development of European Health portal to disseminate information on all aspects of public health.

6. **Generics**
   - Introduction of 'Bolar-type' provision.

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