



VICH OUTREACH FORUM
9th meeting
14 & 15 November 2017
Tokyo, Japan

SUMMARY REPORT

Session 1: Reports and Group Discussions

1. Opening of the meeting and chairperson's introduction

The meeting was jointly chaired by Dr Kenji Ohara, Director General of the National Veterinary Assay Laboratory, Ministry of Agriculture, Forestry and Fisheries, Japan and Dr Jean-Pierre Orand, Director of the French agency for veterinary medicinal products - OIE collaborating centre, on behalf of the OIE.

Dr Ohara opened the meeting by welcoming the participants to the 9th VICH Outreach Forum (VOF) meeting in Tokyo.

The OIE welcomed the participants by pointing out that this meeting is being held at exactly the same location as the first contact meeting in October 2011, which was then followed by the launch of the VOF the following year.

The OIE considers these meetings as very important and supports the global harmonisation leading to improvements in the animal medicines' quality to maintain and improve the health of animals. The objective of the VOF meeting is to exchange information and experiences and to create a global network of collaboration.

2. Report by the SC on issues raised by Outreach Forum members during the 8th VICH Outreach Forum meeting in Buenos Aires in February 2017

The VICH Secretariat reported ([link](#)) on the outcome of the discussions that took place at the 34th VICH Steering Committee (SC) meeting in Buenos Aires on the issues raised by the participants in the 8th VOF meeting. In line with the comments received, the 9th VOF agenda will cover in particular:

- VICH SC and observers experience, description of the EU regional collaboration in the authorisation of VMPs
- Discussions on how to develop Regional organisation and collaborating systems
- Pharmacovigilance
 - o Needs of the VOF members
 - o Global electronic systems
 - o Sharing of the Pharmacovigilance data
- AMR and how VICH GL 27 is used in Japan - surveillance connected to efficacy
- Alternatives to Antimicrobials: processes for regulation to control autogenous vaccine in Thailand

- Vaccines stability and Immunogenicity studies
- Review of the VICH GLs on Biologicals
- Feed-back of the training workshop for ASEAN countries held in Brunei
- New VOF members Registration systems (Nigeria & Zimbabwe)

The Secretariat also highlighted the active role of VOF members' experts in different EWGs' activities.

The VOF participants took note that the interval between VOF (and VICH SC) meetings may change from a 9 month to a 12-month cycle, but after 2020 only.

3. Report by OIE on their activities concerning Veterinary Medicinal Products (VMPs) since the last Forum

The OIE confirmed ([link](#)) its ongoing support to the VOF activities by liaising with the Specialist Biologicals standards committee. Information on VOF activities is also provided after each meeting to the 181 OIE Member Countries and invitation letters sent to the VOF delegates are copied to the national Focal Points for Veterinary Products.

The OIE also promotes the VICH activities in the successive OIE Focal Points for Veterinary Products training seminars.

The OIE highlighted several resolutions that were adopted by the World Assembly of OIE Delegates during their 85th General Session on 21-26 May 2017.

Finally, the OIE mentioned some meetings with the OIE involvement, that are of potential interest to the VOF.

4. 1st Discussion of individual VICH Outreach Forum member questions - Regional organisation and collaborating systems:

CAMEVET explained ([link](#)) that VICH & CAMEVET have similar objectives (Harmonisation of regulatory requirements, elimination of minor differences between members, balance of the demands to facilitate trade of veterinary products) although the starting realities and development baseline have been different.

CAMEVET described the results of a survey on the implementation status of CAMEVET guidelines in the CAMEVET countries.

In conclusion it was noted that there are different levels of VICH Guidelines implementation among the countries in CAMEVET; this year a working group for the revision of harmonised documents and guidelines has been formed, which will use VICH GL as references for revising existing documents.

ASEAN described ([link](#)) the ministerial statement on Animal Health and gave an overview of the ASEAN Cooperation on Animal Health and the ASEAN Cooperation on Veterinary Products through the ASEAN National Focal Points for Veterinary Products (ANFPVP).

The participants took note of the mechanism that has been developed for the ASEAN Registration of Animal Vaccines. If a batch has been tested in 1 country by an OIE accredited lab, it will be accepted in all ASEAN countries.

As for the registration procedure, if the 1st national product approval has been granted, a product can go to the ASEAN procedure.

ASEAN does not yet accept the concept of Bioequivalence studies.

The EU detailed ([link](#)) the EU approach for a multinational collaboration in the authorisation of VMPs and summarised the 4 procedures in place: the Centralised Procedure (CP), the Mutual Recognition Procedure (MRP), the Decentralised Procedure (DCP) and the purely national

procedure.

The EU pointed out that a multinational collaboration should begin by collectively setting the rules; for large regional organisations, some flexibility may be necessary by enabling market authorisations to be granted in several ways, whilst the Member States must have opportunities to discuss their concerns for example in a scientific or a coordination committee; an arbitration mechanism should be in place as well with clear procedures on the ways to address issues.

Each EU country has its own fee structure.

It was reminded that the centralised procedure is restricted to innovative/bio products (typically 10 to 12 products per year) and their generics, whereas around 200 products are evaluated yearly through the decentralised or mutual recognition procedures.

The EU stressed that there is not only a need to develop trust between the countries, but that these countries must also have the necessary solid legal basis. The 28 national agencies in the EU have a benchmarking system in place and come also together to improve procedures, at the political as well as the technical levels. This collaboration enhances the trust-building effort and facilitates knowledge transfer and common understanding.

The EU countries also have a common set of standards very much based on the VICH GLs.

5. Group Discussion on how to develop Regional organisation and collaborating systems

Two breakout groups were organised comprising both VOF members and SC members. Each team designated a rapporteur and a moderator. These groups were composed of the following VOF members:

Group 1: Argentina, Saudi Arabia, Taiwan, Uganda

Group 2: Brazil, China, Korea, Nigeria, Thailand, Zimbabwe,

6. Reporting back to plenary on outcome of 1st group discussions

Each of the 2 groups focused their discussions on the differences with VICH member countries and the acceptance of studies conducted according to VICH GLs.

Group 1

The participants in Group 1 listed ([link](#)) the needs for a regional cooperation i.e. political will, trust, strong leadership and resources, but also harmonised guidelines, common dossier structures, experienced assessors – training capacities and ways to solve language issues.

Group 2

The participants in Group 2 explained ([link](#)) the steps to be taken for regional collaboration such as political agreement to work together, similarity in technical standards, flexibility in choice of reference state, training of regional authorities, the need for a resource with common guidelines and a proper balance between the level of requirements and the cost of development and availability of products.

Trust building was of course considered as a key element of success.

7. 2nd Discussion of individual VICH Outreach Forum member questions

- Pharmacovigilance (PhV)

The topic for discussion, pharmacovigilance ([link](#)), was introduced by the chair of the PhV EWG, Dr Linda Walter-Grimm. She gave an overview of the current situation of global harmonisation and provided an insight into future developments.

8. Tour de table

The questions to be addressed by the VOF members were the following:

- How does your region handle Adverse Drug Events (ADEs) reporting from industry and consumers? Is an adverse drug event database for individually reported cases maintained by regulatory authorities in your region? Do you utilise periodic safety update reports or some form of periodic analysis/aggregate reporting?
- What additional pharmacovigilance resources/data are you currently using to support analysis?
- What are your additional needs for developing pharmacovigilance programs in your region? (e.g. regulations, access to ADE data, education/training?)

Saudi Arabia: has no real PhV report yet, but gathers complaints from farmers; an investigation is then made to determine if the report relates to an ADE or a drug quality related problem.

Saudi Arabia intends in the next 5 years to implement a PhV database and if possible would like to access a worldwide database. The main issue is to encourage reporting by companies. AnimalhealthEurope recommended to encourage reporting by making a form readily available and providing feedback so that veterinarians know their report has been used.

Zimbabwe: reports have started on the human medicines side and training of vet practitioners for reporting has been initiated. The authorities do not receive many reports because mainly generic products are used, with very few innovative products. Zimbabwe asked who is reporting in the USA and if trainings for the practitioners are in place. FDA replied that most reports are done by farmers or vets to manufacturers which then send these reports to FDA. FDA has done some outreach to vets and technicians, however there may still be underreporting because they do not have the time or the desire to report. The FDA electronic platform used is a reporting portal compliant with GL 24. Some companies have developed their own mobile apps.

AHI suggested that authorities should provide additional data to the veterinarians to stimulate their interest to report. Vets are usually encouraged to report by the reps and are inclined to report only serious events. They may report either to the companies or the agencies. Zimbabwe is considering developing apps for reporting, which would be the easiest for the local vets.

People's Republic of China: has not established a PhV system yet although a regulation was proposed several years ago, but not yet implemented. The focus will be on the safety of the animal and the person using the drugs.

Some vaccines can have serious adverse events on animals, such as TB or brucellosis, because of the adjuvants that are used, but PhV is a challenge for the vet services because of the lack of knowledge of products and systems.

The People's Republic of China is striving to progress on a PhV system.

Taiwan: has a pharmaceutical regulation requiring that companies report ADEs to authorities, but most reports are related to failure of drugs. Most drugs are imported so the authorities are very dependent on international knowledge. No database is in place yet.

Uganda: has an active national PhV center for human medicines, but the vet side is still using the written form for reporting. Most vets have not been trained and are reporting effectiveness issues rather than AERs. Farmers do not report unless the animal has much value. The effectiveness of the vaccines may be questioned when a vaccinated animal dies. There is no online reporting yet although Uganda is moving fast towards electronic systems. There is no mandatory reporting for the companies. Uganda asked if the PhV is mandatory for both human and vet products in the USA? FDA confirmed that it is indeed mandatory for both, as both regulations have the same concepts and principles. It is the same situation in the EU.

Nigeria: a national PhV center and database are being developed but mainly for human products. Manufacturers have to report any AER, but vets do not report, except for pets. Reports on poultry may be done in case of failures of mass vaccination. In this case, farmers or consumers may circulate messages on social media, but not directly to the authorities. The vet side will be trying to build on the human PhV systems.

South Korea: is trying to tie to the human PhV system, focused on post marketing reporting. A vet PhV system will start next year. It is planned to select which products will be under scrutiny. No database is in place yet. South Korea is learning from this meeting what is happening in other countries.

Argentina: companies are not obliged to report although when the authorities audit the GMPs in companies, they audit the reporting system of the company as well. A system of voluntary reporting by vets to the authorities exists, but it is difficult because the vets have not been properly trained to report. All countries in the region are concerned by PhV which is on the agendas of all CAMEVET meetings and CAMEVET is developing GLs based on the VICH GLs. PhV is however very much dependent on local needs and local legislation, so there may be different reporting systems and different requirements in the countries. A training on PhV would be really necessary.

Brazil: has developed a regulation on PhV that was in public consultation, but the conclusion was that the PhV would not be efficient without an electronic based system. This is now being set up, then a new regulation based on this system will be developed. The authorities are meanwhile inquiring which systems companies have in place to receive the AERs.

Thailand: a mandatory electronic and manual PhV system, was implemented this year but only for human medicinal products. The MAH must report to the authorities.

The OIE asked the VOF members which training would be requested, for vets, for authorities? Uganda had concentrated first on training the vets in the field, but then realised that the farmers would be the ones reporting first, either to the authorities, or to the vets. The authorities have therefore involved the farmers in the training because they are always in the field with their animals.

The vets have however the proper knowledge to differentiate between a minor event and a serious ADE; often events are caused by extra-label use or false manipulation of the product so it is important to train the farmers.

It was recommended that training on PhV should be part of the curriculum of the vet schools and that the OIE should support this request.

The EU concluded that awareness of PhV issues is very important for the success of a reporting system so it is essential to create awareness with the vets. The reporting must be

made easy through different means of reporting, and the persons who report must get feedback to be encouraged to report.

There is also potential for regional collaboration on PhV, which would increase the pool of reporting and share the workload.

In regions however, the language may be an issue so countries need to use the same definitions and terminologies. Regional organisations should therefore support the use of international standards rather than creating new ones.

When setting up a system, countries should not immediately start developing a big database but progress in small steps at a time, by creating a vet specific easy to use system, which does not have to be established within a complicated existing human system.

9. Report from SC discussions on proposed new topics from VOF

9.1 AMR – how VICH GL 27 is used in Japan - surveillance connected to efficacy

JMAFF explained ([link](#)) the process and data requirements of approval for VMPs in Japan and gave an overview of VICH GL 27, which is a Guidance on Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food Producing Animals with Respect to Antimicrobial Resistance. JMAFF then described how VICH GL 27 is used in Japan and pointed out that a sensitivity testing before treatment is not compulsory but nevertheless recommended.

Zimbabwe asked how bacteria are collected from animals. JMAFF replied that bacteria are not isolated from food, but from animal faeces etc...

Uganda asked how antimicrobials for aquatic animals are handled. JMAFF replied that veterinary medicinal products (VMPs) for aquatic animals are approved by JMAFF through the same process as VMPs for terrestrial animals, and regulated by JMAFF. However, 3rd generation cephalosporins and fluoroquinolones are not authorised in fish and shellfish in Japan, because VMPs for aquatic animals are used in a water environment, and 3rd generation cephalosporins and fluoroquinolones are not necessary for the moment, based on the prudent use principle. The NVAL website provides the annual reports of sales amount of VMPs in Japan at: <http://www.maff.go.jp/nval/iyakutou/hanbaidaka/index.html>, and the Japanese Veterinary Antimicrobial Resistance Monitoring System (JVARM) reports at: <http://www.maff.go.jp/nval/english/AMR/index.html>.

Uganda asked why fluoroquinolones are used for cattle, swine and chicken in Japan. JMAFF replied that risk assessment on antimicrobial resistant bacteria resulting from the use of fluoroquinolones in cattle, swine and chicken was completed by the Food Safety Commission, and the estimated risk was medium. So JMAFF regulates fluoroquinolones strictly and enhanced AMR monitoring, and continue their approval used for these animals. If the AMR rate will be increasing in the future, the risk assessment will be done again, and the further risk management will be done according to the result of the risk assessment.

Saudi Arabia asked about the regulation regarding residue limits in fish imported from third countries. JMAFF replied that the maximum residue limits (MRLs) for veterinary medicines are determined by the Ministry of Health, Labour and Welfare, in the positive list system which is used to check imported foods as well as for domestic foods. If no MRL for a certain drug exists in Japan, the drug residues in foods must not be above 0.01ppm which is the uniform limit; all MRLs are available on the website of the Ministry of Health, Labour and Welfare.

9.2 Alternatives to Antimicrobial: processes for regulation to control autogenous vaccine in Thailand

Thailand described ([link](#)) the regulation in place to control autogenous vaccines in Thailand and explained that there had been a proposal, not yet adopted, to amend the national Drug Act covering both human and vet products in order to establish specific criteria and conditions for veterinarians to produce vaccines for animals in their charge under the exemption of the Drug Act.

South Africa agreed that vets can make the autogenous vaccines only for the farm from which the strains come, but some vets sometimes sell vaccines to third parties. Thailand recognised the need to control the labs which produce the vaccines, but there are for the moment no criteria for such controls. The ideal rule would be not to authorise autogenous vaccines if efficient commercial vaccines exist for a specific disease.

In the EU, the use is controlled at national level and is different across member states, but recently a document on GMP for autogenous vaccines has been adopted by all member states. All member states will accept inactivated bacterial vaccines, and most accept also inactivated viral vaccines. Live autogenous vaccines are however never authorised in the EU. The focus is on quality control and safety, rather than efficacy. A new regulation will include in GMP for autogenous vaccines to harmonise the production and the quality of such vaccines.

USDA confirmed that in the USA all autogenous vaccines must be inactivated, and utilised for emergency situations only in order to have a product rapidly available. If it is used regularly, the criteria will be more stringent

10. Registration systems in

10.1 Nigeria

Nigeria described ([link](#)) the registration system for veterinary medicines, biologics and vaccines, in particular the registration system for Nigerian made vet drugs and vaccines, the document that is required for the registration of imported vet drugs and vaccines, the cost of these registration's and the labelling requirements on product packages.

10.2 Zimbabwe

Zimbabwe presented ([link](#)) the evolution of the national veterinary medicine legislation and the Veterinary Medicines Governing Bodies, and described the Medicines Control Authority of Zimbabwe's evaluation and registration system for veterinary products.

10.3 Feed-back of training Workshops held in Brunei

JMAFF presented a report ([link](#)) on the VICH Training Seminar in Brunei on 26th April, 2017 for ASEAN member states and indicated it was a great honour to provide the very first training in Asia ahead of other regions. The participants seemed very relaxed in their home region with the regular meeting members. The delegates felt this trial was quite valuable for VOF members to complement the lack of information by conveying correct information especially in those countries which do not attend VOF meetings regularly. The delegates found that the trainers had to highlight fundamental understandings such as the fact that the VICH GLs are not legally binding, that an applicant can employ different testing when there is a fair justification based on science or that slight modifications are allowed for VOF/Observer countries according to the regional situation. The trainers addressed the topics of VICH GL 50

(Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use) and VICH GL 27 (Guidance on pre-approval information for registration of new veterinary medicinal products for food producing animals with respect to antimicrobial resistance) with related information on veterinary vaccine and antimicrobials regulation including the Japanese national antimicrobial resistance monitoring strategy.

The delegates strongly recommended continuing with such training events as much as possible in the all VOF member countries/regions to complement the VOF meetings.

No other training session is planned for the moment but VICH will reply to any request, as long as the budget is covered by the requesting country.

Session 2: Issues of interest to Outreach Forum members

11. Specific issues

11.1 Vaccines

USDA described ([link](#)) the vaccines efficacy requirements and stability studies in place in the USA.

Saudi Arabia asked what type of studies was needed if subsequent products are considered in a case where the first product already has an established efficacy and potency. USDA replied that if it is exactly the same product, USDA will accept a reduced testing/some bridging of studies, otherwise the full product development will be requested.

Zimbabwe questioned the duration of the shelf life for a vaccine and the possibility of extrapolation. USDA explained that for an established antigen, 18 months shelf life will be allowed, but for a new antigen it must be shorter.

Zimbabwe mentioned that regarding reference products, it is the original innovative product that is the reference for the generic pharmaceuticals, is it the same situation for vaccines?

USDA confirmed that the reference is the early produced vial and potency of subsequent products are then tested against that one.

In the USA all the data, such as preliminary safety data, must be submitted to the authorities.

AnimalhealthEurope explained that out of stock situations can arise because sometimes suppliers are not able to provide the starting material to the manufacturer anymore.

Moreover, under GMP requirements, cleaning validations are needed to pass the manufacturing line from one product to the other and the outcomes may lead to delays in re-starting production.

Zimbabwe asked what the rules are in case of importation of unknown strains. USDA explained that when this happens, a Risk Assessment is done and the similarity with an antigen already in the country will be part of the assessment. In any case authorities need to prevent the risk of pathogens originating from new live vaccines from being spread throughout the country.

11.2 Review of VICH GLs on Biologicals

JMAFF gave an overview ([link](#)) of the Vaccine Quality Control in Japan and described briefly the 6 VICH Guidelines that have been developed exclusively for vaccines.

11.3 Introduction to VICH 6

The participants received an update ([link](#)) on the draft programme for the VICH 6 Conference and were informed that the dates have been changed: the Conference will now take place on 26-28 February 2019 in Cape Town – South Africa.

The Secretariat encouraged all to attend and to share the information with their colleagues, also in other countries whom they know and will be interested in the Conference.

Session 3: Discussions and conclusions

12. Feedback on the meeting from Outreach Forum members and open discussion

The VOF members unanimously considered the VOF meetings as very important for the improvement of the VMP registration criteria in the VOF countries. They expressed their satisfaction for the quality and the level of information received during the meeting. The current setup of the discussion sessions (1 breakout in small groups + 1 tour de table) was strongly supported as this gives all participants the opportunity to express their opinions and pose questions.

The VOF participants identified the following topics for discussion at the 10th VOF meeting:

Update on the VICH training

AMR

- Monitoring and surveillance plans
- AMR in post approval process
- How to establish human food safety criteria
- Use of the OIE database on AMR in the countries
- Efficacy versus resistance
- Residue monitoring plans

Use of VICH GLs for medicated premixes

MRLs

- Microbiological ADIs and how to establish an MRL
- Extrapolation of MRLs in food producing animals
- Extension of MRLs to other animal species for existing products
- Marker residue depletion studies
- Residues in food

Parasiticides

- Ectoparasiticides

Combination products GLs update

Pharmacovigilance

- Global electronic system (minimum requirements and compatibility allowing exchange of data where needed)
- Pharmacovigilance and post-marketing surveillance

Mutual recognition procedures

Other topics

- Presentation by Saudi Arabia on the new centralised regulatory process for the 6 Gulf Cooperation Council countries (GCC)

13. Conclusions and next steps

The OIE strongly encouraged again all VOF members to provide requests from their countries on specific agenda items to be shared well in advance of the next meeting. A first draft agenda for the 10th VOF meeting will be circulated in early January for all VOF members to review and complete as soon as possible

Action: for All VOF members

Regarding the proposed frequency of the meetings after 2020, all VOF members supported the change to a 12 month cycle, but requested that the meeting timing should be extended to at least to 2,5 or 3 days of meeting each time.

AnimalhealthEurope mentioned that the VICH website, as well as the VOF members only webpage will be updated and modernised in the near future.

14. Confirmation date and venue of 10th and 11th VICH Outreach Forum meetings

- The **10th VICH Outreach Forum** meeting will be held on 26 & 27 June 2018 in Belgium.
- The **11th VICH Outreach Forum** meeting will be held on 25 & 26 February 2019 in Cape Town, South Africa.

<p>9th VICH Outreach Forum meeting Participants</p>
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1/ Forum members

ARGENTINA – CAPROVE	Carlos FRANCIA
BRAZIL – Ministry of Agriculture, Livestock and Food Supply	Pauline MARTINS DA CUNHA
BRAZIL – Ministry of Agriculture, Livestock and Food Supply	Barbara Agate BORGES CORDEIRO
PEOPLE’S REPUBLIC OF CHINA – Institute of Vet. Drug Control	Shixin XU
NIGERIA – NAFDAC	Bukar Ali USMAN
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Ji Ye KIM
SAUDI ARABIA – Saudi Food & Drug Authority	Maher ALJASER
SAUDI ARABIA – Saudi Food & Drug Authority	Taha RAMZI
SAUDI ARABIA – Saudi Food & Drug Authority	Ali ALHOMAIDAN
TAIWAN – Council of Agriculture	Tsung-Fa HSIEH
TAIWAN – Council of Agriculture	Ying-Ping MA
THAILAND – Department of Livestock Development	Sasi JAROENPOJ
THAILAND – Chulalongkorn University	Suphot WATTANAPHANSAK
UGANDA – National Drug Authority	Josephine NANYANZI
UGANDA – Ministry of Agriculture, Animal Industry and Fisheries	Juliet SENTUMBWE
ZIMBABWE - Medicines Control Authority	Zivanai MAKONI

Apologies

ARGENTINA - SENASA	Federico LUNA
MEXICO – SENASICA	Ofelia FLORES
MOROCCO – ONSSA	Benalla HASNAE

2 / VICH Steering Committee

Members and (C) Coordinators

AHI (ZOETIS)	Michael MCGOWAN
AHI	Rachel CUMBERBATCH (C)
EU (EUROPEAN COMMISSION)	Noel JOSEPH

EU (EMA-CVMP)
EU (EMA)
ANIMALHEALTH EUROPE
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JVPA (NISSEIKEN CO.)
JVPA
US (FDA)
US (USDA APHIS)
US (FDA)

OBSERVERS

Australia (APVMA)
Australia (AMA)
Canada (CAHI)
New Zealand (MPI)
New Zealand (AGCARM)
South Africa (SAAHA – BAYER)

INTERESTED PARTY

AVBC

OIE

OIE
OIE

VICH SECRETARIAT

HealthforAnimals

APOLOGIES

AHI (BOEHRINGER INGELHEIM)
Canada (Health Canada)
South Africa (DAFF)
HealthforAnimals

GUESTS

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David MURPHY
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Brigitte BOENISCH
Erik DE RIDDER
Rick CLAYTON (C)
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Ken NODA
Takashi KOZASA (C)
Kenji OHARA (*Chairperson 35th SC*)
Izumi ABE
Kotaro TUCHIYA
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Bettye WALTERS
Byron RIPPKÉ
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Chris PARKER
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Jean SZKOTNICKI
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