



Report of the Third Meeting of the PharmaSea Work Package 6 Advisory Panel of Policy and Legal Experts



Planktonic organisms. Image credit: Woods Hole Oceanographic Institution.

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TABLE OF CONTENTS

EXECUTIVE SUMMARY	4
1. INTRODUCTION	6
1.1 THE PHARMASEA PROJECT	6
1.2 THE PHARMASEA WORK PACKAGE 6 ADVISORY PANEL OF POLICY AND LEGAL EXPERTS (APPLE)	6
2. THE THIRD MEETING OF THE PHARMASEA WP6 ADVISORY PANEL OF POLICY AND LEGAL EXPERTS	8
3. SUMMARY OF PRESENTATIONS AND DISCUSSIONS	8
3.1 WELCOME AND UPDATE ON THE PHARMASEA PROJECT	8
3.2 OVERVIEW OF PHARMASEA WP6 ACTIVITIES AND PROGRESS TO DATE	9
3.3 CASE STUDIES – PRESENTATION OF PROPOSALS AND DISCUSSION	11
3.4 WP6 SECOND WORKSHOP, DISCUSSION ON POSSIBLE TOPICS AND TIMING	13
3.5 UN GENERAL ASSEMBLY PROCESS TOWARDS AN INTERNATIONAL LEGALLY BINDING INSTRUMENT ON MARINE BIODIVERSITY OF ABNJ	14
3.6 BUILDING BLOCKS AND DIFFERENT OPTIONS FOR AN UNCLOS IMPLEMENTING AGREEMENT	16
3.7 HOW CAN PHARMASEA BE INVOLVED WITH THE NEGOTIATIONS AT UNCLOS?	17
3.8 PHARMASEA USER TOOLKIT, WAY FORWARD	18
3.9 CLOSURE OF THE MEETING:	18
ANNEX 1 - LIST OF ABBREVIATIONS	19
ANNEX 2 - AGENDA OF THE ADVISORY PANEL OF POLICY AND LEGAL EXPERTS (APPLE)	20
ANNEX 3 LIST OF PARTICIPANTS WHO ATTENDED THE 3RD PHARMASEA APPLE MEETING	21
ANNEX 4 PHARMASEA WP6 ADVISORY PANEL OF POLICY AND LEGAL EXPERTS - TERMS OF REFERENCE	22
1. SCIENTIFIC BACKGROUND AND RATIONALE	22
2. AIMS AND OBJECTIVES OF THE APPLE	23
3. COMPOSITION AND OPERATION OF THE APPLE	24
4. TRAVEL COSTS	24

EXECUTIVE SUMMARY

The PharmaSea project, funded by the European Union Framework Programme 7 (FP7), represents a model marine biodiscovery pipeline within which existing challenges hampering marine biodiscovery research and development (R&D) are addressed.

Within the PharmaSea project, one work package (WP6) aims to clarify the legal and policy obligations relevant to users of Marine Genetic Resources (MGR) and provide guidance to ensure that marine genetic resources (MGR) used in marine biodiscovery are sourced and utilized legally. PharmaSea WP6 also aims to contribute the experience of the MGR practitioners to policy discussions concerning regulations which may impact on their R&D activities.

To oversee and advise on the progress of WP6, an advisory panel has been convened. The panel consists of PharmaSea scientific partners (MGR users) and invited legal and policy experts from governmental and non-governmental bodies. In addition to its advisory role, this panel will also act as a *de facto* science-policy interface, addressing policy and legal bottlenecks in the marine biodiscovery process.

The third APPLE meeting was convened in Glasgow on the 3rd September 2015. It was aimed at presenting the outputs already produced by the Project and to discuss tasks ahead, such as: the development of ABS Case Studies; the second stakeholders' workshop; the drafting of Best Practices for marine bioprospecting under EU Regulation 511/2014; and the development of the ABS Users Toolkit. The meeting was moreover finalized to discuss with high level experts how the PharmaSea consortium can be involved in the negotiation of the Implementing Agreement to the United Nations Convention on the Law of the Sea (UNCLOS) to ensure that scientific research remains open and innovation supported.

It was stressed that the Project has already produced significant outcomes in terms of scientific results. The main goal of the project was to have two compounds in small animal trials, and so far one has been identified and tested.

WP6 has carried out several research activities to identify the main legal barriers, as well as awareness-raising activities. A stakeholders' consultation was conducted for these two purposes, complete with interviews. The results of the consultation showed two main barriers: the lack of awareness on Access and Benefit-Sharing (ABS) and the difficulties in undertaking marine biodiscovery. Costs represent another important issue. Taking into consideration that scientists are sensitive to the requirements to obtain research funding, and the extent to which they can publish their research results, WP6 proposes that editors of scientific journals make compliance with ABS a mandatory requirement to publish papers on genetic resources (GRs).

For the activities ahead, before presenting the 11 possible case studies to the experts for their consideration, it was decided to stimulate discussion in order to get ideas from the experts on other possible ABS issues that need attention. The group came up with several interesting issues to analyse. It was then decided to circulate an email later on for a final decision on the 6 Case Studies for WP6 to work on.

Even though the drafting of Best Practice for marine bioprospecting under the EU Regulation 511/2015 raised significant interests, the meeting decided to dedicate the second stakeholders workshop to the analysis of the ABS Case Studies, as stated in the Description of Work.

For the Toolkit for Users of MGR, Thomas Vanagt recalled that the original objective was the development of a global interactive map where, by clicking on the location of

sampling activities, all the necessary ABS information would appear. This original plan proved to be very ambitious, demanding, and overlapping with the ABS Clearing House of the CBD Secretariat. Simpler options will be considered.

Charlotte Salpin from the United Nations Office of Legal Affairs, Division for Ocean Affairs and the Law of the Sea (UNDOALOS), illustrated the outcome of the UN Working Group on marine biodiversity beyond national jurisdiction and the work ahead of the Preparatory Committee that will prepare elements of the draft text in the upcoming two years. By the end of 2018, the UN General Assembly will decide whether to convene an intergovernmental conference. Charlotte Salpin underlined that the engagement of the scientific and business communities has been fairly limited during the BBNJ process. During the discussion, it was underlined that stakeholders need to lobby in their own countries, as intervening in the UN meetings is already too late to actually influence the debate. Another tool for stakeholders to influence the process is to make their publications and scientific findings more visible to negotiators. Charlotte Salpin recalled that there is a dedicated webpage on the DOALOS website for publicly accessible publications and information papers that they receive.

Charline Gaudin from the International Union for the Conservation of Nature (IUCN), illustrated the IUCN matrix addressing the elements of the BBNJ package deal, which is the result of independent experts. She concentrated on the issues related to marine genetic resources (MGR) in areas beyond national jurisdiction (ABNJ): access, benefit-sharing and compliance.

A final discussion focused on the important legacies left by EU funded projects on marine biotechnology: how to deal with issue of legacy of samples and data, after the end of the project? What will happen after the project closes? This should be looked at: it would provide interesting inputs for the discussions within the BBNJ process. All these projects are or have been facing the issues of ownership of materials, access within and beyond the consortium. Open access should be advocated.

1. INTRODUCTION

1.1 The PharmaSea Project

PharmaSea is a Framework Programme 7¹ project that focuses on the obstacles which impede marine biodiscovery research, development and commercialization in Europe. PharmaSea brings together a multi-disciplinary team of academic and industry researchers and specialists to identify and characterize blockages in the marine biotechnology innovation chain and to develop solutions to overcome them. The partners are ideally placed to demonstrate how to widen the bottlenecks and increase the flow of ideas and products derived specifically from the marine microbiome towards a greater number of successes in a larger number of application areas.

PharmaSea will establish a robust pipeline to process microbial samples drawn from very different origins, including marine microbial strain collections held by partners and new strains taken from extreme environments (deep, cold and hot vent habitats). By screening such a broad genetic diversity, the project partners concentrate their combined expertise and resources on the key objective of producing new products with desirable characteristics for development by the SME partners in three accessible market sectors: health, personal care and nutrition. The research focuses predominantly on developing biotechnological agents for use in treating human microbial infection, diseases of the central nervous system and inflammation. The latter is also relevant for nutritional and personal care/cosmetic uses.

1.2 The PharmaSea Work Package 6 Advisory Panel of Policy and Legal Experts (APPLE)

Within the PharmaSea project, one work package (WP6) focuses on analysing the legal and policy barriers which hamper the sustainable exploitation of marine bioresources for European biotechnological research, development and commercialisation. Ultimately WP6 aims to clarify the legal and policy obligations which are relevant to the MGR practitioner and to provide guidance which supports the use of legally sourced MGR in their research and development activities.

To oversee and advise on the progress of WP6 an advisory panel consisting of PharmaSea partner MGR practitioners and invited legal and policy experts from governmental and non-governmental bodies has been convened. In addition to its advisory role, this panel also acts as a *de facto* science-policy interface focusing on the policy and legal bottlenecks in the marine biodiscovery process. The profile of the advisory panel also ensures that the work of PharmaSea WP6 is relevant and of high impact to PharmaSea and the wider marine biodiscovery community.

The First Meeting of the PharmaSea WP6 Advisory Panel of Policy and Legal Experts took place in September 2013 in Vigo, Spain. Participants were invited to advise on specific tasks within PharmaSea WP6 and also to help identify significant legal / policy bottlenecks which may hamper marine biodiscovery R&D in the EU. The meeting

¹ Framework Programme 7 (FP7) is the EU programme for research and technology development for the period 2007 to 2014.

provided context for participants on the scientific progress in marine biodiscovery and the new and existing governance frameworks which are relevant to the sustainable exploitation of MGR from within or beyond national jurisdictions, sourced either *in-situ* or from *ex-situ* collections. The APPLE meeting demonstrated the need for a science-policy forum focusing on the sustainable advancement of marine biodiscovery.

The Second Meeting of the APPLE Panel convened in Leuven on the 8th of May 2014, back to back to the Pharmasea Stakeholders Workshop to consider ‘Options for an Access and Benefit-Sharing (ABS) regime for Marine Genetic Resources (MGR) from Areas Beyond National Jurisdiction (ABNJ)’. The participants comprised legal experts in the fields of law of the sea, ABS and intellectual property rights, policy makers, representatives from scientific bodies relevant to marine scientific research along with experts from science and industry engaged in R&D on MGR. The workshop was organised with the objective to present and discuss a potential future regime for ABS of MGR from ABNJ before submitting a paper to the UNGA. It was considered too early in the BBNJ process for such a detailed regime to be submitted at this stage however the workshop raised some important issues. The discussions focused in three sessions on aspects of non-monetary benefit sharing, monetary benefit sharing and issues related to compliance and monitoring.

2. THE THIRD MEETING OF THE PHARMASEA WP6 ADVISORY PANEL OF POLICY AND LEGAL EXPERTS

The primary objective of the third APPLE meeting was to present the outputs already produced by the Project and to discuss WP6's tasks ahead, such as: the development of ABS Case Studies; the second stakeholders' workshop; the drafting of Best Practices for marine bioprospecting under EU Regulation 511/2014; and the development of the ABS Users Toolkit. The meeting finished with a discussion between high level experts on how the PharmaSea consortium can be involved in the negotiation of the Implementing Agreement to the United Nations Convention on the Law of the Sea (UNCLOS) to ensure that scientific research remains open and innovation supported.

The meeting comprised a combination of formal presentations from APPLE participants and open discussion facilitated by the APPLE Chair and PharmaSea Project Leader, Professor Marcel Jaspars. Representatives from the UN Office of Legal Affairs (Division for Ocean Affairs and the Law of the Sea - DOALOS), the CBD Secretariat and the European Commission were invited to present and comment on relevant provisions under UNCLOS, the CBD and the Nagoya Protocol. PharmaSea partners provided background to the PharmaSea project, WP6 and relevant aspects of marine biodiscovery.

3. SUMMARY OF PRESENTATIONS AND DISCUSSIONS

3.1 Welcome and update on the PharmaSea project

Marcel Jaspars (PharmaSea Coordinator and APPLE Chair), University of Aberdeen, Scotland, U.K.

Introducing the PharmaSea project as one of three consortia² funded under the EU framework programme 7 KBBE.2012.3.2-01 call³, Professor Marcel Jaspars PharmaSea Project Leader and Director of Marine Biodiscovery Centre, University of Aberdeen explained the PharmaSea mission statement is to 'increase value and flow in the marine biodiscovery pipeline.'

Marcel Jaspars presented the updates from the research activities of the PharmaSea project.

He recalled that the project's idea originated from the need for new medicines considering the decline in antibiotics and increase in infections. The project aimed at going to extreme marine environments, in order to analyse extremophiles.

Through the project, samples are gathered either from existing collections of the partners (45%) or from new sampling at sea (55%). The analysis consists in the use of a series of filters to see whether the molecules are interesting. The original goal was to isolate 2.500 strains but at the 30th month of the project, 13.000 strains have already been isolated and more than 14.000 extracts have been tested. Over 110.000 screening events have been carried out, and 700 active de-replicated extracts have been identified.

² BlueGenics www.bluegenics.eu/cms/, Micro B3 www.microb3.eu/ and SeaBioTech <http://spider.science.strath.ac.uk/seabiotech>; are marine biodiscovery projects funded under the KBBE.2013.3.2-01 call. Together with PharmaSea, they have agreed to interact on legal/policy issues of ABS where relevant.

³ This project arose from the FP7 KBBE.2012.3.2-01 call 'Innovative marine biodiscovery pipelines for novel industrial products'

Extreme environments can reveal undiscovered biology and chemistry, and thus novel activity that can potentially lead to a new product. However two issues are critical with working in extreme environments: legal and the physical access.

So far, samples with the following origins have been gathered from existing collections: the Arctic, the Antarctic, the Republic of Ireland, South Africa and Argentina. Other samples have been directly collected in Antarctic and South Africa. The next scheduled sampling will take place in South Shetland Trench (-5000 m), where samples will be collected both from the seafloor and the water column, and in Atacama Trench (-8000 m).

One objective of the project at this point was to have identified 8 novel compound families and so far it has already produced 5, with new structural features.

Marcel Jaspars underlined that PharmaSea will make marine bioprospecting more attractive for industry, and that the project is widening the bottlenecks for marine biodiscovery.

The project is also aimed at providing mechanisms to transfer the findings to ‘end users’, whilst acknowledging:

- The need for legal certainty to sample marine biodiversity.
- The regulatory stress that uncertainty puts on companies, in particular SMEs.
- The lack of risk taken by companies due to shareholder pressure.

Discussion:

The issue of the small percentage of cultivable microorganisms was raised. Marcel Jaspars clarified that metagenomic techniques have also been used for the analysis.

3.2 Overview of PharmaSea WP6 activities and progress to date

Thomas Vanagt, eCOAST, Belgium (PharmaSea WP6 Leader)

Thomas Vanagt underlined that so far, PharmaSea WP6 has not only been successful in streaming information from policy to science, but also the other way around: policy-makers improved their understanding of the scientific world throughout the activities of the project.

He then reviewed the progress for each of the WP’s five tasks:

- Setting up the Advisory Panel of Policy and Legal Experts (APPLE) and organizing 4 meetings

The first two APPLE meetings were successful in building up the science-policy interface. The 4th meeting will probably not be held, unless the project is granted an extension of 6 months without extra budget (as it will be requested at the General Assembly).⁴ The extension will be requested in order to have time to study the Chilean samples before the end of the project. Indeed, the Chilean sampling expedition has been delayed due to technical difficulties encountered. However, the campaign in Chile remains important to the PharmaSea project’s objective of overcoming the monetary barrier of sampling in extreme environments: the deep ocean trench targeted is close enough to the shore to lower the vessel transit costs⁵.

⁴ The six months extension was granted in principle.

⁵ Update May 2016: due to logistic difficulties and problems with the development of the deep sampling device, the Chile sampling campaign has been cancelled. However, deep sediment samples are being sourced elsewhere.

The extension has been recommended by the external reviewer of the project. If it is granted it might be possible to organise the 4th meeting of APPLE.

- Identify legal and policy barriers for marine biodiscovery

WP6 has carried out several research activities to identify the main legal barriers, as well as awareness-raising activities. A stakeholders' consultation was conducted for these two purposes, complete with interviews. The results of the consultation showed two main barriers: the lack of awareness of Access and Benefit-Sharing (ABS) and the difficulties in undertaking marine biodiscovery. Costs represent another important issue. Moreover, small *ex situ* collections do not have PIC nor MAT archives for the items they store (e.g. PhD students in small university laboratories). In an effort to raise awareness, a paper was published by WP6 experts on the Nagoya Protocol (NP) and marine scientific research (MSR) provisions of the United Nations Convention on the Law of the Sea (UNCLOS). Scientists are sensitive to the two following issues: requirements to obtain research funding, and the extent to which they can publish their research results. Taking these into consideration, WP6's paper suggested that editors of scientific journals make compliance with ABS a mandatory requirement to publish papers on genetic resources (GRs). Would the 6 months extension be granted, a new stakeholders consultation is planned to monitor progress in awareness within the consortium considering the undertaken efforts.

For the near future, awareness-raising activities are planned and organized closely with the European Commission (DG ENV). Five training workshops on ABS will take place in London, Brussels, Paris, Berlin and Florence, targeting non-experts in order to inform them on the implementation of the Nagoya Protocol and the EU ABS Regulation and the administrative consequences for their research projects. More information can be found here:

<http://www.euconf.eu/abs/en/registration/index.html>

Other awareness raising activities are planned: a paper on the state of the art of marine bioprospecting is in progress⁶, as well as a chapter on policy and regulatory issues in a scientific book on marine microbial research.⁷ The latter is financed by the MaCumBa project.

- Organize 2 stakeholders workshops

The first stakeholder workshop was held in 2014 in Leuven on the topic of marine genetic resources (MGR) in areas beyond national jurisdiction (ABNJ), focusing mainly on monetary and non-monetary benefit-sharing (BS) and compliance. The results of the workshop were presented to the UN working group on marine biodiversity beyond national jurisdiction (BBNJ WG) to inform the delegates on good practice in the marine scientific community on data, storing, and biorepositing. The second workshop's topic was discussed later on. It will be organized in spring 2016.⁸

- Set up the MGR User Toolkit.

The project's description of work for the User Toolkit is very ambitious and probably overlapping with the work of the ABS Clearing House. A discussion on this specific issue followed later on during the meeting (see below).

⁶ Deliverable of the EU Horizon 2020 funded project MarIBE

⁷ Laura E. Lallier, Arianna Broggiato, Dominic Muyldermans, Thomas Vanagt. "Marine Genetic Resources and the Access and Benefit-Sharing Legal Framework". In *The Marine Microbiome An Untapped Source of Biodiversity and Biotechnological Potential*. Editors: Stal, Lucas J., Cretoiu, Mariana Silvia (Eds.) (Springer, 2016)

⁸ Given that the six months extension was granted the stakeholders' workshop will be organized in early 2017.

- Develop six ABS case studies.

A discussion on this issue followed later on during the meeting (see below).

Discussion

It was underlined by one of the participants that if PharmaSea should demonstrate to developing countries that the costs of sampling are becoming more affordable. It would therefore be very useful if this can be presented at the United Nations process on BBNJ. There is still a lack of knowledge about the costs.

Marcel Jaspars clarified that for a 10 day trip through Eurofleet that includes 8 days of sampling, the cost is half a million euros for the ship alone. The equipment is becoming cheaper, but the cruise is not. The costs are 40.000 € per day for ship time, without counting the costs of scientific activities and equipment.

3.3 Case studies – presentation of proposals and discussion

Meredith Lloyd-Evans, BioBridge UK

Meredith Lloyd-Evans introduced the case studies to be developed by the WP6 partners. The case studies are especially meant to explore emerging ‘hot topics’ in ABS of MGR, and to enhance PharmaSea’s deliverables relating to both Best Practice in bioprospecting and the User Toolkit.

Before presenting the list of possible case studies proposed by WP6, he asked for suggestions from the APPLE participants on emerging hot topics.

Discussion:

The participants proposed the following case studies:

- a) Analyse the discrepancy in expectations between what is feasible for stakeholders regarding monetary benefit-sharing (BS). What would a pharmaceutical company be able to provide? What are the expectations of provider countries?

It was reported that in New Zealand, effective educational programmes have been carried out on the reality of marine biodiversity and marine natural products in order to make the indigenous people well aware of what a realistic expectation is. This has been done by going through case studies showing the reality of the pipeline from the original discovery to the development of a natural product later. In Australia, things are different and the indigenous communities are not as aware.

The discussion pointed out that the trends of royalties in mutually agreed terms (MAT) should be examined (1% of the net revenue for example), and that it could be useful to analyse the cases where large pharmaceutical companies have refused BS terms and why. This could however be difficult in terms of confidentiality. Another participant stressed that pharmaceutical companies make tremendous amount of money, therefore the origin of where the material is found is important.

- b) Study the ethical issue in the absence of MAT: what would a company’s attitude be?

c) Analyse the value of non-monetary BS, which could be more valuable than the monetary ones. What are the options for non-monetary BS? Considering MGR in ABNJ, is there a possibility for countries that cannot afford to take part in an expedition and subsequent research to be effectively compensated with non-monetary BS?

The discussion underlined that most of the developing countries at the UN process on BBNJ are still mainly interested in monetary BS. It is a political issue of willingness to accept that the non-monetary one could be the only viable one and is interesting.

The IUCN matrix document on options for the UNCLOS Implementing Agreement (presented further down) illustrates feasible options of both BS.

It was pointed out that the probability of getting to the development of a product from MGR is 3 out of 12.000.

It needs to be considered that the non-monetary BS are at the early stage of research while the monetary BS are at the later stage, and that researchers usually negotiates BS at the beginning of the pipeline. Besides, scientists' mind-sets are largely non-monetary.

d) In the context of MGR in ABNJ, the notion of fair and equitable access to sample and data as a non-monetary BS should be looked at. The concept of open access raised by Marcel Jaspars at the European Conference on Marine Natural Product should be analysed closely. The Consortium Agreements of the EU funded projects on MGR research should be looked into: do they include clear policies for sharing samples and data with third parties and to promote open access? Where would the firewall between open access and product development be?

Meredith Lloyd-Evans then presented the list of proposed case studies for consideration:

- The impact of the Nagoya Protocol on access to MGR for research and development (R&D) purposes, and the role of biorepositories
- Antarctic Treaty System: pioneer of scientific benefit-sharing in areas beyond national jurisdiction
- Review of the different types of existing agreements for bioprospecting and related experience to date (e.g. Australia, Brazil or India)
- “Piggy-backing”: using samples from other marine activities for bioprospecting, including samples coming from seabed mineral exploration
- ABS in complex inter-connected consortium projects
- ABS and traceability of MGR down the genomics-biotechnology chain
- Industry-academia collaborations
- Challenges of contiguous Exclusive Economic Zones (EEZs) and dynamic MGRs
- Existing ABS frameworks and industrial experience

Discussion:

On the topic of the samples collected within seabed mining exploration, the issue of how the biological samples are collected and stored has been raised. Is it compatible with the research on MGR? It appears that even if the collected organisms are not viable, metagenomic techniques allow the analysis of the sample anyway. This topic should be looked at as a case study considering that when the exploitation phase of seabed mining in ABNJ will start, thousands of samples will be collected for monitoring purposes.

It was stressed that academia needs to be involved now, while the legal framework for BBNJ is under development, and that more attention should be devoted to the

protection of the marine environment. It was underlined that the IUCN matrix document on Options for a UNCLOS Implementing Agreement (presented below) provides opportunities for stakeholders's involvement in the section dedicated to global and regional cooperation.

The ABS – Capacity Development Initiative, a multi-donors capacity building initiative, produced studies on ABS experiences in India, South Africa and Brazil that might be useful for developing the case studies on ABS regimes. It was underlined that the virtual library of the Clearing House is open to everybody to upload documents of interests.

A discussion on the option to boost the sharing of samples and data took place. It was pointed out that the collected samples are being underexplored and that a lot of data has been produced but not yet analysed. There is a need for global coverage to really understand the functioning of the marine environment.

3.4 WP6 second workshop, discussion on possible topics and timing

Arianna Broggiato, eCOAST, Belgium (PharmaSea WP6 Leader)

Two options for the second WP6 stakeholders' workshop to be held in spring 2016⁹ were proposed:

1. Development of ABS Best Practices for marine sampling/bioprospecting within the meaning of article 8 of EU Regulation 511/2014. The development of ABS best practice is already planned in the description of work of WP6. However, such development will be carried out only upon approval of the General Assembly of PharmaSea, as WP6 is advocating a shift of resources to eCOAST and IUCN to undertake such task. A recommendation by the APPLE meeting to support such request was obtained.
2. ABS case studies analysis and comparison as provided in the project description.

Leonhard-Matthias Maier – European Commission (EC) DG Environment illustrated the concept of best practices according to the Nagoya Protocol (article 19) and the EU ABS Regulation (article 8 and 9) as a broad set of things including codes of conduct, guidelines and standards in relation to ABS. The main advantage of having best practices developed by an association of users or other interested parties (including an EU consortium), and recognized by the European Commission, is that the Competent Authorities in the Member States will take them into account when deciding to verify user compliance. This would lead to fewer checks in time and frequency for the users that are implementing such best practices. The EU Regulation does not provide inspiration on what the best practices should be like, and the implementing regulation under draft will only provide for procedural aspects on the recognition of best practices. The recognition will not be granted indefinitely and the best practices will be reviewed and assessed against the level of compliance by the members of the association of users. There will be a specific procedure in case of failure to comply despite the use of recognized best practices. So far only one association of users in the cosmetic sector has consulted the EC to apply for recognition of their best practices. The timeline for the procedure for recognition remains to be set, so it might take some time.

To apply for the recognition of best practices, the association of users must be identifiable with a clear membership, therefore it is not certain whether a project

⁹ Given that the six months extension was granted the stakeholders' workshop will be organized in early 2017

consortium, which has a limited lifetime, can be the promoter of best practices. It is unlikely that the PharmaSea consortium can draft best practices and ask for recognition itself. To do so, it may need the umbrella of a permanent marine association or organization, such as the European Marine Board.

It was underlined that within the EC, the Directorates General for Research and Innovation might also be interested in the development of best practices for marine research, together with DG MARE and DG Environment. The head of the Marine Resources Unit, Gruber Sigi, will be contacted.

Summing up the conclusion of the discussion, the APPLE meeting opted for the ABS case studies workshop. The participants also agreed to recommend that the PharmaSea General Assembly shift the budget to eCOAST and IUCN. This will be necessary to enable a joint effort with the European Marine Board and other interested partners, possibly with support from the European Commission, to organize a workshop addressing the development of ABS best practices for the marine sector. However, the scope of best practices first needs to be defined.

3.5 UN General Assembly process towards an international legally binding instrument on marine biodiversity of ABNJ

Charlotte Salpin, United Nations Office of Legal Affairs, Division for Ocean Affairs and the Law of the Sea, New York, USA. In attendance as an observer.

Charlotte Salpin first introduced the legal framework of the UNCLOS and customary international law. She then recalled the work undertaken by the BBNJ Working Group to study issues relating to the conservation and sustainable use of marine biological diversity in ABNJ from 2006 to 2015. She recalled the two legal regimes applying in ABNJ: the freedom of the high seas and the common heritage of mankind of the Area and its mineral resources, where the International Seabed Authority manages exploration and exploitation of the seabed. The BBNJ process at the UN developed a package in relation to marine biodiversity beyond national jurisdiction made up of 4 components:

- MGR;
- Conservation and management tools: establishment of area-based management tools and environmental impact assessment;
- Capacity building and transfer of marine technology, which has been recognized as lacking implementation;
- Governance.

Resolution 69/292 adopted in June 2015 decided on the drafting of an internationally legally binding instrument under UNCLOS for BBNJ. The UN General Assembly established a Preparatory Committee that will prepare elements of the draft text in the upcoming two years, focusing on the package of issues introduced above. By the end of 2018, the UN General Assembly will decide whether to convene an intergovernmental conference.

Charlotte Salpin recalled that the UN held intersessional workshops in 2013 as an awareness-raising process.

So far, the BBNJ process highlighted the following issues to be addressed in the draft legally binding instrument on ABNJ:

- Need to clearly define MGR;
- Consistency with the terminology of UNCLOS;

- Encourage cooperation with ABS related legal instruments;
- Consider both MGR in the Area and in the high seas;
- Promote scientific collaboration and avoid creating disincentives for innovation;
- Need to consider sustainable use and conservation;
- Need to foster participation of developing countries;
- Adopt a pragmatic approach.

In relation to ABS of MGR in ABNJ, the main issues that emerged in the BBNJ working group and need to be further discussed are:

- Equitable access and benefit-sharing even though equity is not consistently referred to in official documents;
- Need to facilitate access to data;
- Need to decide if conditions for access will be established;
- Non-monetary and monetary BS;
- Definition of commercial and non commercial use;
- Determination of activities that will trigger BS and interaction between actors (Who will be required to share the benefits and with whom?);
- Intellectual property rights issues;
- Draw inspiration from existing international agreements and legal regimes of the UNCLOS (e.g. MSR, flag State jurisdiction), or establish new regimes.

Charlotte Salpin underlined that the engagement of the scientific and business communities has been fairly limited during the BBNJ process.

Discussion:

At the beginning of the discussion it was stressed that the pragmatic approach of the EU to avoid legal discussion on the common heritage of mankind and freedom of high sea principles at the BBNJ negotiations has paid off.

On the lack of engagement of the scientific and business community, it was stressed that this should be improved either by consulting with stakeholders at the national level, or by enhancing the participation of stakeholders as observers. The latter option is rather unlikely as it is difficult to obtain an observer status in intergovernmental meetings. Some delegations occasionally include representatives of the sectors concerned. However, it was stressed that stakeholders need to lobby in their own countries, as intervening in the UN meetings is too late to actually influence the debate. Another tool for stakeholders to influence the process is to make their publications and scientific findings more visible to negotiators.

It was underlined that the 2013 intersessional workshops were the only chances for bringing experts into the BBNJ discussion, and mentioned the CBD Secretariat's practice of commissioning experts studies in order to bring information into the discussion and to involve the scientific communities. This is also good practice to inform delegations that do not have the resources for it. Charlotte Salpin clarified that it will be up to the chair of the Preparatory Committee to eventually organize this.

3.6 Building Blocks and Different Options for an UNCLOS Implementing Agreement

Charline Gaudin, IUCN

Charline Gaudin introduced the IUCN work done so far on BBNJ and she stressed that the decision to provide options for the implementing agreements within the matrix was adopted in order to ensure rooms for negotiating to the delegations. The main outputs are:

- A series of 13 briefs on key issues published in 2013
- A matrix of options addressing key issues identified in the BBNJ package deal
- A final product combining the various options (matrix)

The July 2015 workshop focused on the matrix addressing the elements of the BBNJ package deal. The matrix will be finalised before November 2015, when a workshop will be held in New York with supporting countries.

In addition, IUCN developed the following key elements in line with UNCLOS provisions:

- Governance principles
- General obligations
- Global and regional cooperation
- Strategic Environmental Assessment (SEA)
- Institutional aspects
- Compliance and financial mechanisms
- Flag State issues
- Emergency measures

Charline Gaudin explained how to use the matrix where information on the legal basis of the options can be found.

With regards to ABS, the matrix considers the following options:

- Access:
 - ✓ No restrictive procedure: notification, reporting and recording obligations of sampling activities in ABNJ
 - ✓ Information provided at the national and international levels, or directly at the international level
- Benefit-sharing general mechanism:
 - ✓ Option 1: Comprehensive set of BS provisions – fully flagged multilateral system;
 - ✓ Option 2: Basic benefit sharing provisions – “CBD like”
 - ✓ Specific provisions on monetary benefits: Distinction made between non-commercial research (no upfront payment or voluntary) and commercial research (mandatory milestone payments or upfront payment)
- ABS Clearing House:
 - ✓ Build on and use the Clearing House mechanism established under the NP or establish a new Clearing House for ABNJ

Discussion:

The discussion highlighted that there might be an issue with applying the flag state approach because of the different nationalities often involved in a research expedition. It might be difficult to identify the responsible person to report to national authorities, as well as to identify the competent national authorities. In addition to reporting obligations for scientific activities in ABNJ, the IUCN proposal advocates the exchange of such reports within the international scientific community. The question of an institution in charge of managing this exchange of information remains open, as States are reluctant to create new bodies requiring new funding.

It was also underlined that while enabling the participation of scientists from developing countries to research cruises is important, it does not particularly enhance their actual capacity building and further involvement in the research pipeline.

It was pointed out that the definition of commercial and non-commercial research should be avoided, as a lesson learnt from the Nagoya Protocol process where the matter proved to be difficult and unsolvable.

Concerns were expressed on the fact that certain delegations are reluctant to see NGOs being involved and influencing the drafting process. It would be a pity if this would hamper the way the delegations will perceive and eventually use the valuable work undertaken by IUCN. It was pointed out that certain elements of the IUCN matrix, even though based on existing agreements, might be perceived as very controversial by certain delegations. It was suggested that the proposal look as innocent as possible to be more palatable for a larger audience among the delegations. Using the wording “options”, which is coming from the negotiating language, might already be limiting. Eventually, it was also recommended that IUCN be careful with the international agreements referred to in the matrix, considering that some of them are very controversial for many delegations.

3.7 How can PharmaSea be involved with the negotiations at UNCLOS?

Thomas Vanagt, eCOAST, Belgium (PharmaSea WP6 Leader)

The participants considered different vectors to influence the BBNJ process and the UN delegations:

- The publication of scientific papers and the best way to reach the targeted audience: which journals have a wider coverage among decision makers?;
- The efficient distribution of the IUCN Information Papers for the Intersessional Workshop on MGR (2-3 May 2013) was mentioned as a good example;
- The organization of side-events during the session of the BBNJ Working Group and in the upcoming years of the Preparatory Committee, although side-events are organized during lunchtime or overlap which does not allow for the effective reach of delegations;
- Other on-going informative projects, such as the one managed by Pew Charitable Trusts.

Charlotte Salpin recalled that there is a dedicated webpage on the DOALOS website for publicly accessible publications and information papers that they receive.

3.8 PharmaSea User Toolkit, way forward

Thomas Vanagt, eCOAST, Belgium (PharmaSea WP6 Leader)

Thomas Vanagt recalled that the original objective was the development of a global interactive map where, by clicking on the location of sampling activities, all the necessary ABS information would appear. This original plan proved to be very ambitious, demanding, and overlapping with the ABS Clearing House of the CBD Secretariat. He then stressed that the work undertaken to develop best practices might be useful for the Toolkit, as well as the conclusions on the case studies. It was also pointed out that standardised operational procedures (SOPs) for labelling samples should be developed and integrated in the Toolkit. In fact, EU FP7 Micro B3 project has already developed SOPs that can be used for the PharmaSea Toolkit.

Reference was made to the ASSEMBLE Project¹⁰ that has developed a toolkit considering standardisation and formatting, which will be adopted by the European Marine Biological Resource Center (EMBRC). It was suggested that something similar be produced in the field of IP and ABS. However, other participants expressed concerns in mixing up IP issues with ABS and proposed to stick to legal issues related to ABS.

The issue of maintaining and updating the Toolkit after PharmaSea ends was raised. Three options were identified: either the Marine Biotech ERA-NET or the European Marine Board could take charge of the Toolkit, or a commercial entity that can see the value of it. The best option was identified in the European Marine Board.

The toolkit should focus on *in situ* access, which triggers the most confusion for users, rather than *ex situ* one. The decision tree needs to be integrated with the legal basis, including UNCLOS provisions on marine scientific research.

A discussion focused on the important legacies left by EU funded projects on marine biotechnology: how to deal with issue of legacy of samples and data, after the end of the project? What will happen after the project closes? This could be looked at within a case study also, by asking for an extension of funding for PharmaSea, Micro B3, SeaBioTech, BlueGenics and MaCumBa all together. It would allow pursuing the work on policy and legal issues and to put forward the lessons learnt from these projects. It could also provide interesting inputs for the discussions within the BBNJ process. These projects have been too isolated and nobody has looked into their overlaps enough. All these projects are or have been facing the issues of ownership of materials, access within and beyond the consortium. Open access should be considered but in large projects with SMEs this might not be acceptable.

3.9 Closure of the meeting:

Thomas Vanagt closed the meeting thanking all the experts for their active participation to the meeting.

¹⁰ The Association of European Marine Biological Laboratories (ASSEMBLE) is an EU FP7 research infrastructure initiative comprising a network of marine research stations. <http://www.assemblemarine.org>

ANNEX 1 - LIST OF ABBREVIATIONS

ABS	Access and Benefit-Sharing
ABNJ	Areas Beyond National Jurisdiction
APPLE	Advisory Panel of Policy and Legal Experts
BBNJ	Biodiversity Beyond National Jurisdiction
BS	Benefit-sharing
CBD	Convention on Biological Diversity
SCBD	Secretariat of the CBD
CHM	Clearing-House Mechanism
EC	European Commission
EC COM	European Commission Communication
EEZ	Exclusive Economic Zone
EMBRC	European Marine Biological Resource Center
EU	European Union
FP7	EU 7th Framework Programme
GRs	Genetic Resources
IUCN	International Union for the Conservation of Nature
MAT	Mutually Agreed Terms
MGR	Marine Genetic Resources
MSR	Marine Scientific Research
MTA	Material Transfer Agreement
NP	Nagoya Protocol
PIC	Prior Informed Consent
SOPs	Standardized Operational Procedures
UN	United Nations
UNCLOS	United Nations Convention on the Law of the Sea
UNDOALOS	United Nations Division for Ocean Affairs and the Law of the Sea
WP6	Work Package 6

ANNEX 2 - AGENDA OF THE ADVISORY PANEL OF POLICY AND LEGAL EXPERTS (APPLE)

3rd Meeting

University of Strathclyde, Glasgow, UK

3 September 2015

- 9.30 Welcome and update on the PharmaSea project (Marcel Jaspars, PharmaSea Coordinator and APPLE Chair)
- 10.00 Overview of PharmaSea WP6 activities and progress to date (Thomas Vanagt)
- 10.20 Case studies – presentation of proposals and discussion (Meredith Lloy-Evans)
- 11.20 Coffee break
- 11.40 WP6 second workshop: discussion on possible topics / timing (Arianna Broggiato)
- 12.30 Lunch break
- 13.30 Outlook for an Implementing Agreement for ABS of MGR in ABNJ (Charlotte Salpin)
- 13.50 IUCN proposal for UNCLOS Implementing Agreement for ABS of MGR in ABNJ (Charline Gaudin)
- 14.00 How can PharmaSea be involved with the negotiations at UNCLOS? (Thomas Vanagt)
- 15.00 Coffee break
- 15.20 PharmaSea User Toolkit: way forward
- 16.10 Developing a best practice for marine bioprospecting under EU Regulation 511/2014: is this a valuable and achievable deliverable for PharmaSea?
- 17.00 Closing discussion

ANNEX 3 LIST OF PARTICIPANTS WHO ATTENDED THE 3RD PHARMASEA APPLE MEETING

PharmaSea Project Partners	Affiliation
Arianna Broggiato	eCOAST, Belgium
Charline Gaudin	IUCN - ELP
Chris Battershill	University of Waikato
Juan Asenjo	ICDB, University of Chile
Kjersti Lie Gabrielsen	MarBank, Norway / University of Tromso
Marcel Jaspars	University of Aberdeen (APPLE Chair)
Meredith Lloyd-Evans	BioBridge Ltd UK
Monika Ślęzak	KU Leuven, Belgium
Peter de Witte	KU Leuven, Belgium
Thomas Vanagt	eCOAST, Belgium
External Participants	Affiliation
Ahmed Tawfike	University of Strathclyde - Glasgow
Charlotte Salpin	UN Division for Ocean Affairs and Law of the Sea,
John Brincat	European Commission DG MARE
John Day	SAMS, Scottish Marine Institute
Kathryn Garforth	CBD Secretariat
Lyle Glowka	CMS Secretariat
Matthias Leonhard	EC DG ENV
RuAngelie Edrada-Ebel	SeaBioTech Project (Novamen)

ANNEX 4 PHARMASEA WP6 ADVISORY PANEL OF POLICY AND LEGAL EXPERTS - TERMS OF REFERENCE

1. Scientific Background and Rationale

Increasing Value and Flow in the Marine Biodiscovery Pipeline

PharmaSea is a Framework Programme 7 project that focuses on the obstacles which impede marine biodiscovery research, development and commercialization in Europe. PharmaSea brings together a multi-disciplinary team of academic and industry researchers and specialists to identify and characterize blockages in the marine biotechnology innovation chain and to develop solutions to overcome them. The partners are ideally placed to demonstrate how to widen the bottlenecks and increase the flow of ideas and products derived specifically from the marine microbiome towards a greater number of successes in a larger number of application areas.

PharmaSea will establish a robust pipeline to process microbial samples drawn from very different origins, including marine microbial strain collections held by partners and new strains taken from extreme environments (deep, cold and hot vent habitats). By screening such a broad genetic diversity, the project partners will concentrate their combined expertise and resources on the key objective of producing new products with desirable characteristics for development by the SME partners in three accessible market sectors: health, personal care and nutrition. The research will focus predominantly on developing biotechnological agents for use in treating human microbial infection, diseases of the central nervous system and inflammation. The latter is also relevant for nutritional and personal care/cosmetic uses.

The ocean environment harbours a multitude of ecological niches and is home to more living organisms, especially microorganisms, than any other environment on Earth. This drives the concept of “blue biotechnology,” where unique and novel biological compounds or principles from the marine environment are harvested and exploited for the benefit of humankind. Despite the tremendous potential, exploitation, particularly at a commercial scale, has been hampered by a number of practical and scientific constraints. These include gaining access to, and sampling from, remote ocean environments, compound isolation, structure elucidation, early reliable validation of biological activity and best mechanisms of flow-through into exploitation.

Policy and Legal Aspects of Access to, and Use of, Marine Genetic Resources

Within the PharmaSea project, one work package (WP6) focuses on another potential impediment to the biodiscovery pipeline; namely the complex and rapidly evolving legal and policy environment surrounding the exploitation of marine genetic resources (MGR).

The access to, and use of, MGR is subject to a complex framework of national regulations and international conventions which were generally not designed to cater for the harvesting of material for biodiscovery purposes. The high-level aim of this work package is to provide clear recommendations and practical solutions to address critical policy and legal barriers which impede the access and sustainable use of marine bioresources for European biotechnological research, development and commercialisation. Ultimately, a web-based, fully interactive, toolkit will be developed to assist MGR practitioners in navigating the different legal and policy regimes involved in access to MGR and associated benefit sharing. This will be embedded into the website of

an international organisation to ensure its longevity beyond the lifetime of the project itself.

The specific objectives of PharmaSea work package 6 are:

- To create a platform that will bring together marine biodiscovery practitioners with legal experts, policy makers and other relevant stakeholders to identify and provide solutions to the key policy issues and legal barriers in the marine biodiscovery pipeline.
- To assess and report on the existing ABS landscape relevant to the sustainable use of MGRs for academic and industrial research, focusing on current efforts towards harmonizing European legislation on ABS, options for an ABS system for MGR in areas beyond national jurisdiction (ABNJs) and the disparity between the United Nations Convention on the Law of the Sea (UNCLOS) and the need to protect research investments by securing intellectual property rights.
- To provide information services, model agreements and best practice guidelines to address identified legal and policy barriers, based on investigations of a limited number of selected case studies.
- To develop a dynamic, web-based, PharmaSea “toolkit” for marine biodiscovery practitioners, containing comprehensive and practical information to assist users in navigating the legal frameworks surrounding access to MGR.

To help achieve these objectives, Work Package 6 of PharmaSea will convene an advisory panel of policy and legal experts (APPLE). Essentially, the APPLE will be an advisory board for Work Package 6 but will have relevance to the full PharmaSea project. It will bring together the breadth of experience necessary to focus the direction of WP6 activities towards addressing the critical policy and legal barriers which currently hinder progress in innovative marine biotechnology in Europe.

2. Aims and Objectives of the APPLE

The overarching aim of the APPLE will be to underpin the key role of Work Package 6 in addressing policy and legal barriers to sustainable exploitation of marine genetic resources for biodiscovery applications. In bringing together MGR practitioners from science and industry with legal experts, the APPLE will also be an expert forum, capable of delivering insight and recommendations which can help to drive WP6 activities towards effectively addressing these barriers.

Specifically the APPLE will:

- Act as a platform for marine scientists and SMEs to contribute to the current discussion on ABS as it applies to MGRs in Europe and beyond;
- Contribute to identifying the main stakeholders to be involved in the targeted stakeholder survey and the two planned MGR workshops currently targeted at identifying policy/legal barriers in ABS of MGR in Europe and in areas beyond national jurisdiction (ABNJs);
- Comment on recommendations arising from the workshops and the targeted stakeholder survey.

- Advise on the development and conclusions of specific case studies examining access and benefits sharing (ABS) of MGR in different regimes to identify best practice with regard to the protection of IP, appropriate governance options and the environmental impact of bioprospecting;
- Provide critical comments on the proposed design, and the final draft, of the PharmaSea MGR User Toolkit.

3. Composition and Operation of the APPLE

The APPLE will include key scientific project partners from academia and industry, who have direct experience of the marine biodiscovery pipeline and the associated challenges both from a European and non-European perspective (the PharmaSea consortium includes members from several non-EU countries including China, Costa Rica, New Zealand and South Africa). In addition to project partners, the APPLE will include invited external IP and legal experts and representatives of relevant authoritative bodies. Representatives from three other FP7 projects exploring aspects of marine biodiscovery - namely; SeaBioTech, BlueGenics and MicroB3 - have also been invited to participate.

The APPLE will be chaired by Professor Marcel Jaspars and its operations facilitated by eCOAST. A list of APPLE members is provided on page 5.

4. Travel Costs

Travel and accommodation costs for invited APPLE members in relation to their attendance at the yearly APPLE meetings will be reimbursed by the PharmaSea project through eCOAST BVBA. Costs will be compensated upon receipt of an invoice on condition that it is in accordance with applicable EU regulations on the spending of the grant (e.g. excessive restaurant bills will not be refunded). All tickets and restaurant receipts, preferably originals, should be attached to the invoice and cover the costs of the person concerned. The APPLE member is not entitled to reimbursement through eCOAST if he/she is representing a PharmaSea partner institution or representing another project financed by the European Commission under the Seventh Framework Programme.