



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



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## 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 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 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 Convention on Biological Diversity (CBD) is an international treaty that recognises the sovereign rights of states over their natural resources and includes the authority to determine access to genetic resources within national jurisdiction (including *marine* genetic resources).

The Nagoya Protocol of the CBD provides a legal framework for implementing the third objective of the CBD, i.e. access to genetic resources and the sharing of benefits arising from the use of genetic resources. The Protocol is expected to enter into force by October of 2014. All Parties to the Protocol will be obliged to monitor the use of genetic resources within their jurisdiction. Under the Protocol, access to genetic resources is subject to the prior informed consent of the Party providing the resources, unless that Party determines otherwise.

A regulation to implement the Nagoya Protocol in the EU is expected to enter into force in 2014. Subsequent to this, the utilization of genetic resources within the Union will be monitored to ensure that only legally acquired resources are used in research and development and that the 'utilization' corresponds with any applicable access and benefit-sharing (ABS) regimes.

There is general agreement that the Nagoya Protocol is a positive outcome for biodiversity-based R&D. It should facilitate access to genetic resources, provide the R&D sector with legal certainty and encourage the use of benefits for the conservation and sustainable use of biodiversity.

The United Nations Convention on the Law of the Sea (UNCLOS) sets out the global legal framework within which all activities in the oceans and seas must be carried out, including marine scientific research (MSR). In particular, UNCLOS defines the limits of the various maritime zones as well as the respective rights and obligations of coastal States and flag States within those zones.

In relation to sampling MGR within national jurisdiction, the provisions of UNCLOS and the Nagoya Protocol overlap. Researchers must: i) contact the CBD National Focal Point of that coastal state to establish what regimes are in place in relation to genetic resources and; ii) ensure they have received the necessary clearance under UNCLOS (through the appropriate official channels of the researching and coastal States) well in advance of any proposed sampling expedition. It is important to note that compliance with the CBD and its Nagoya Protocol does not ensure compliance with UNCLOS and *vice-versa*.

Under UNCLOS, the areas beyond national jurisdiction (ABNJ) are all parts of the sea that are not included in the exclusive economic zone, in the territorial sea or in the internal waters of a State, or in the archipelagic waters of an archipelagic State (the high seas) and the seabed and ocean floor and subsoil thereof, beyond the limits of national jurisdiction (the Area).

Whilst there are no specific references to MGR in UNCLOS, a number of its provisions apply to activities related to MGRs, in particular its Part XIII on marine scientific research.

Issues related to MGR of ABNJ, including questions on the sharing of benefits, are one of a package of issues currently under discussion at the UN General Assembly, in the context of its Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction. In that context, a process was established in order to prepare for the decision to be taken before the end of the sixty-ninth session of the General Assembly in 2015 on the development of an international instrument under UNCLOS. This process will include consideration of issues related to MGR, including questions on the sharing of benefits.

Although activity related to sampling MGR in ABNJ is currently considered to be low level, this activity can be expected to increase in the future. Any future regulation should take this expected increase in activity into account.

Few countries have the capacity to sample MGR in ABNJ. Many more countries have the biotechnological capacity to exploit these resources if they had access to them. R&D on MGR from ABNJ needs an enabling environment, legal certainty, clarity and fairness.

The first of two stakeholder workshops to be organized by PharmaSea WP6 will develop a model for how MGR from ABNJ, and related data, can be made more widely available to interested parties who lack the capacity to sample in ABNJ and consider how benefit-



sharing could be facilitated. This also represents an opportunity for the scientific community to provide input towards a potential future regulation which may impact their R&D activities on MGR from ABNJ.

PharmaSea WP6 will produce an MGR User toolkit which will provide information to assist MGR practitioners to access and utilize MGR legally. It will help clarify, for the User, the applicable regimes in respect of sampling and / or utilization of MGR sourced from within or beyond national jurisdiction. The toolkit will provide practical guidelines explaining, in simple terms, how to source MGR lawfully.

Awareness-raising of these issues within the marine scientific community is necessary. Whilst international organisations such as CIESM have made considerable contributions in this regard, large consortia such as PharmaSea and funding agencies can play a significant role.

The APPLE meeting provided a first opportunity to collect the views of an expert community to guide the tasks of PharmaSea WP6. It also demonstrated the need for a science-policy forum focusing on the sustainable advancement of marine biodiscovery.



## INTRODUCTION

### 1.1 The PharmaSea Project

PharmaSea is a Framework Programme 7<sup>1</sup> 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.

### 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 only 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 will act also as a *de facto* science-policy interface focusing on the policy and legal bottlenecks

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

in the marine biodiscovery process. The profile of the advisory panel will also ensure that the work of PharmaSea WP6 is relevant and of high impact to PharmaSea and the wider marine biodiscovery community.

### **Regulatory Frameworks Governing Access to, and Utilization of, MGR.**

The United Nations Convention on the Law of the Sea<sup>2</sup> sets out the global legal framework within which all activities in the oceans and seas must be carried out, including marine scientific research (MSR). In particular, UNCLOS defines the limits of the various maritime zones as well as the respective rights and obligations of coastal States and flag States within those zones.

The Convention on Biological Diversity (CBD)<sup>3</sup>, adopted in 1992, is an international treaty that recognises the sovereign rights of states over their natural resources and includes the authority to determine access to genetic resources (including marine genetic resources). The CBD, in its article 22, provides that its Parties shall implement it with respect to the marine environment consistently with the rights and obligations of States under the law of the sea.

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization<sup>4</sup> (ABS) was adopted in October 2010 as a Protocol to the CBD. The Protocol is intended to provide a legal framework for implementing the third objective of the CBD, ‘the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those technologies and resources.’

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<sup>2</sup> United Nations Convention on the Law of the Sea, Montego Bay, 10th Dec. 1982. Entered into force 16th Nov. 1994, 166 parties on 20.09.13. [www.un.org/Depts/los/index.htm](http://www.un.org/Depts/los/index.htm)

<sup>3</sup> Convention on Biological Diversity, Rio de Janeiro, 22nd May 1992. Entered into force 29th Dec. 1993, 193 parties on 3.10.13. [www.cbd.int/convention/text/](http://www.cbd.int/convention/text/)

<sup>4</sup> Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising of their Utilization, Nagoya, 29th Oct. 2010. Yet to enter into force, expected 2014: [www.cbd.int/abs/text/](http://www.cbd.int/abs/text/)

## THE FIRST MEETING OF THE PHARMASEA WP6 ADVISORY PANEL OF POLICY AND LEGAL EXPERTS

The primary objective of the first APPLE meeting was to introduce all panel members to the PharmaSea project and its specific aims towards assisting MGR Users to access and utilize only legally sourced MGR in marine biodiscovery research and development (R&D). 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. Due to the multidisciplinary nature of the APPLE, presentations were chosen to provide context for participants on the scientific progress in marine biodiscovery and the new and existing legal and governance frameworks which impact on these activities. 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 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, including biorepositories. The APPLE members were invited to advise on specific tasks of WP6 and also to consider the most significant non-technical barriers for both science and/or industry in accessing MGRs from within and beyond national jurisdiction.



PharmaSea Project Leader Marcel Jaspars addressing the first meeting of the PharmaSea Advisory Panel of Policy and Legal Experts. Participants pictured clockwise: Laura Lallier eCOAST, Camilla Esguerra KU Leuven, Isabelle Huys KU Leuven, Alan Dobson UCC, Juan Asenjo University of Chile, Kathryn Garforth CBD Secretariat, Thomas Greiber IUCN, Jan-Bart Calewaert EMODnet Secretariat, Laura Giuliano CIESM, Kjersti Lie Gabrielsen MarBank, Giselle Tamayo INBio, Meredith Lloyd-Evans BioBridge, Oonagh McMeel eCOAST. Also present but not visible: Vassilis Koutsouris EC DG ENV, RuAngelie Edrada-Ebel SeaBioTech project, Charlotte Salpin Office of Legal Affairs, UN Division for Ocean Affairs and the Law of the Sea. Remote participants (via web connections): Lyle Glowka Secretariat of the Convention on Migratory Species, Arianna Broggiato MicroB3 project, Michael Lodge International Sea Bed Authority.

## SUMMARY OF PRESENTATIONS

### 2.1 Introduction to the PharmaSea Project and the Marine Biodiscovery Pipeline

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

Introducing the PharmaSea project as one of three consortia<sup>5</sup> funded under the EU framework programme 7 KBBE.2012.3.2-01 call<sup>6</sup>, 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.’ The PharmaSea project represents a model marine biodiscovery pipeline within which existing challenges would be addressed. Identifying these challenges as; access to bioresources (physical and legal), quality of bioresources, technical aspects of elucidating novel compounds and extracts, scale-up of novel compounds and extracts and the dissemination of effectively mined and annotated data, Professor Jaspars went onto explain how each of these challenges would be addressed by PharmaSea.

Introducing PharmaSea’s ‘guiding philosophy’ whereby unique environments give rise to novel biology which in turn produces novel chemistry and ultimately novel products, Marcel Jaspars identified the unique environments to be targeted by PharmaSea sampling as; the deep seas, cold oceans and thermal vents. With the inclusion of project partners from Norway, Costa Rica, Chile, South Africa, China and New Zealand, PharmaSea had access to both poles, the world’s deepest trenches and thermal vents. Through new *in-situ* sampling and from existing *ex-situ* partner collections, PharmaSea would select 2,500 microbial strains to be subjected to successive selective screening assays with the ultimate aim of producing two leads showing interesting antimicrobial or central nervous system activity. Marcel Jaspars further described how PharmaSea outputs and data would be primarily used to advance PharmaSea goals. However, he also pointed out that, having extracted value in the first instance, there would likely be a range of project outputs which could be made more widely available in line with the pharmaceutical practice of exploiting intellectual property (IP) for the common good. Marcel Jaspars concluded by saying that PharmaSea was an industry-driven project the ultimate aim of which is to reduce the obstacles which hamper the interest and active participation of industry in marine biodiscovery.

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<sup>5</sup> BlueGenics [www.bluegenics.eu/cms/](http://www.bluegenics.eu/cms/), Micro B3 [www.microb3.eu/](http://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.

<sup>6</sup> This project arose from the FP7 KBBE.2012.3.2-01 call ‘Innovative marine biodiscovery pipelines for novel industrial products’

## 2.2 Introduction to PharmaSea Work Package 6

Oonagh McMeel, eCOAST Marine Research Centre, Ostend, Belgium (PharmaSea WP6 Leader)

Oonagh McMeel gave an overview of PharmaSea work package 6 which examines the ethical, legal and policy aspects of accessing and utilizing MGR. Detailing the high level aims and specific objectives of the work package, she noted that, in line with the overall PharmaSea aim to make marine biodiversity more attractive to industry, WP6 aims to provide information and tools to assist scientists to sample and / or utilize MGR which had been sourced legally, in respect of the provisions of UNCLOS, the CBD and its Nagoya Protocol. Drawing expert input from forums such as the APPLE and stakeholder workshops, WP6 also aims to contribute the voice of the MGR practitioner to policy discussions concerning regulations which may impact on their R&D activities. WP6 will consider the new and existing legal and governance frameworks which are relevant to the sustainable exploitation of MGR sourced from within or beyond national jurisdictions, either *in-situ* or from *ex-situ* collections. Through stakeholder consultations, workshops and case studies, WP6 will identify the most significant challenges which these frameworks present to marine biodiscovery R&D and propose pragmatic solutions to address these.

A key output of the work package would be the production of the PharmaSea MGR User toolkit. Aimed at the European User of MGR, it would provide a web-based portal with up-to-date information and practical guidelines explaining, in simple terms, how to source MGR lawfully. The toolkit will also direct the user to ‘MGR Resources’ such as model agreements, data collections, biorepositories and resource sharing networks. Oonagh McMeel explained that two MGR stakeholder workshops would be organised during the PharmaSea project. The first of these will be coordinated by IUCN and will focus on how access to data and samples from Areas Beyond National Jurisdiction (ABNJ) could be made available to practitioners from countries lacking the capacity to sample in ABNJ with and considering also how benefit-sharing could be facilitated. In concluding, she highlighted that this APPLE meeting would provide a first opportunity to receive expert scientific and legal input on ways to maximize the effectiveness and impact of WP6 activities towards providing pragmatic solutions to the most significant legal and policy barriers in marine biodiscovery R&D.

## 2.3 Access to Genetic Resources and Benefit-Sharing – The Nagoya Protocol

Kathryn Garforth, Nagoya Protocol Unit, Secretariat of the Convention on Biological Diversity, Montreal, Canada. In attendance as an observer.

Introducing the Nagoya Protocol and discussing the status of its ratification, Kathryn Garforth said it was fully expected that the Protocol will come into force in time to hold a first meeting of the Parties of the Protocol simultaneously with the next Conference of the

Parties to the CBD in October 2014. Explaining that the Nagoya Protocol builds on and supports the further implementation of the third objective of the CBD, i.e. access to genetic resources and the sharing of benefits arising from the use of genetic resources, Kathryn Garforth detailed some of the specific articles in relation to:

- i) Access which is subject to obtaining the prior informed consent (PIC) of the provider country (Article 6).
- ii) Benefit-sharing through the negotiation of mutually agreed terms (MAT) between the user seeking access and the provider granting access.

It was pointed out that these benefits may be monetary or non-monetary. Further explaining the impact of the Nagoya Protocol, Kathryn Garforth said that all Parties will be obliged to monitor the use of genetic resources within their jurisdiction. To facilitate this, the permit issued by the provider country at the time of access will become an internationally recognized certificate of compliance when it is made available to the ABS Clearing-House. The certificate can then be used at all monitoring checkpoints in user countries. Concerning the ABS Clearing-House mechanism through which parties are required to share information on ABS measures to implement the Nagoya Protocol in their jurisdiction, she stressed that the information will be provided by national authorities, as designated users of the Clearing-House, on the understanding that the information is authoritative and reliable. For marine genetic resources, the Nagoya Protocol applies in relation to Article 15 of the CBD which recognizes the sovereign rights of states over their natural resources. Implementation of the CBD with respect to the marine environment is to be done consistently with the rights and obligations of States under the law of the sea. However Kathryn Garforth also pointed out that some parties to the CBD wished to see MGR in ABNJ being subject to ABS requirements partly for reasons of equity and fairness but also to create a level playing field vis-à-vis MGR from within national jurisdiction.

Kathryn Garforth explained that under the Nagoya Protocol *ex-situ* collections could act as both users and providers of genetic resources. As users, *ex-situ* collections would need to obtain the PIC of the provider and establish MAT with the provider. As a provider, *ex-situ* collections would grant PIC and establish MAT with the user; collections would also need to ensure compliance with any requirements regarding third party transfer arising from the initial collection of the genetic resources. In addition, Articles 19 and 20 encourage all Parties to develop and use model contractual clauses for mutually agreed terms, codes of conduct, guidelines, best practices and standards in relation to ABS. The CBD Secretariat had already received a model agreement from the MicroB3 project on ‘access to marine microorganisms and benefit-sharing’. Recognising the need to raise awareness in this sector, Kathryn Garforth welcomed information on relevant work and said the PharmaSea toolkit could be relevant in this regard.



## 2.4 State of Play of the EU Commission's Legislative Proposal on Implementing the Nagoya Protocol in the Union.

Vassilis Koutsouris, European Commission, Directorate General Environment (DG ENV)

**Vassilis Koutsouris** explained why it had been decided to implement the Nagoya Protocol in the European Union. He described the extensive preparatory work<sup>7</sup> carried out by DG ENV, which included stakeholder consultations, sectoral studies and the establishment of an EU baseline to assess the impact of a proposed regulation. He also noted that there was a general understanding amongst EU stakeholders that the Nagoya Protocol is a positive outcome for biodiversity-based R&D. It is expected to facilitate access to valuable genetic resources in biodiversity-rich countries in return for a fair share of benefits from their use. Furthermore, it provides the R&D sector with legal certainty and encourages the use of benefits for the conservation and sustainable use of biodiversity.

Describing how genetic resources were accessed and utilized within the EU, Vassilis Koutsouris pointed out that it was not simply a bi-lateral arrangement of providers and users but in fact involved the participation of a wide range of actors intervening at different stages of the value chain. He further defined four main stages in the value chain as; *in-situ* collection (sampling), *ex-situ* collection (samples and data), non-commercial uses and commercial uses. Although future interest in R&D on genetic resources in the EU could be considered to be stable or increasing, the demand for *in-situ* access was declining in most sectors. *In-situ* access / sampling is generally performed by university-based researchers and scientists affiliated to *ex-situ* collections with commercial users only rarely collecting in the wild. This highlighted the fundamental role *ex-situ* collections play in the EU genetic resources value chain for both non-commercial and commercial users and had led the Commission to propose a registered list of Union trusted collections containing only legally sourced genetic resources.

Vassilis Koutsouris stressed that the EU regulation dealt only with the user-compliance aspect of the Nagoya Protocol and would require all EU users of genetic resources to seek, keep and transfer to subsequent users, information relevant for access and benefit-sharing. In the future, EU users will not be able to accept material input to their R&D activities unless it comes with relevant information on ABS. Taking into account the practical concerns of stakeholders, the Commission has proposed a due diligence approach coupled to the register of trusted collections. Users of these collections would be considered to have exercised due diligence. Similarly there would be a recognition of best practice which will reduce the number of compulsory compliance checks. Summing up with the next steps in the legislative procedure Vassilis Koutsouris said there was a commitment to ratify before October 2014 and that work on the required implementing acts would begin after the regulation had been adopted.

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<sup>7</sup> All documentation relevant to the legislative work of the European Commission DG Environment, including the text of the current draft regulation can be found at: [http://ec.europa.eu/environment/biodiversity/international/abs/index\\_en.htm](http://ec.europa.eu/environment/biodiversity/international/abs/index_en.htm)

## 2.5 Marine Genetic Resources and the United Nations Convention on the Law of the Sea (UNCLOS)

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 provided an overview of the relevant provisions of UNCLOS and current discussions at the UN General Assembly on issues related to marine biodiversity beyond areas of national jurisdiction. She noted that UNCLOS represented a delicate balance between the rights and obligations of coastal States and those of other States (e.g. researching States) in the various maritime zones. She provided an overview of the specific maritime zones under UNCLOS, both within and beyond national jurisdiction, highlighting the rights and obligations of States within those zones, in particular with respect to marine scientific research (MSR). In that context, she drew attention to the general provisions of UNCLOS on MSR, which applied to MSR undertaken both within and beyond areas of national jurisdiction, including that MSR should be conducted exclusively for peaceful purposes, that it should not unjustifiably interfere with other legitimate uses of the sea and that it did not provide any legal basis for claims to any part of the marine environment or its resources. She also highlighted the requirements of UNCLOS regarding international cooperation in MSR, including the creation of favourable conditions for the conduct of MSR and the publication and dissemination of information and knowledge resulting from MSR.

With regard to MSR within national jurisdiction, Charlotte Salpin explained that MSR within the internal waters and the territorial sea could not be undertaken without the express consent of the coastal State and under the conditions set out by the coastal State. In the exclusive economic zone and on the continental shelf, she noted that the coastal State had the right to regulate, authorize and conduct MSR, and provided an overview of the procedure to seek the consent of the coastal State, drawing attention to the fact that, although the consent was expected to be granted for projects to increase scientific knowledge of the marine environment, such consent may be withheld in a number of cases, including if the research project was of direct significance for the exploration and exploitation of natural resources. She also highlighted the duties of States and competent international organizations wishing to undertake or undertaking MSR in the EEZ and the continental shelf, including regarding the provision of information to the coastal State on the project as well as participation of the coastal State in the project and sharing of data, samples and research results with the coastal State. She drew attention to the “Marine Scientific Research: A Revised Guide to the Implementation of the Relevant Provisions of the United Nations Convention on the Law of the Sea”, which includes practical guidance, including standard forms for vessel clearance requests.<sup>8</sup> With regard to areas beyond national jurisdiction, namely the high seas, where the freedom of the high seas applies, and the Area, which is the common heritage of mankind, she noted that States and competent

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<sup>8</sup> “Marine Scientific Research: A Revised Guide to the Implementation of the Relevant Provisions of the United Nations Convention on the Law of the Sea”: is available at: [www.un.org/depts/los/doalos\\_publications/publicationtexts/msr\\_guide%202010\\_final.pdf](http://www.un.org/depts/los/doalos_publications/publicationtexts/msr_guide%202010_final.pdf).

international organizations had the right to conduct MSR in conformity with the relevant provisions of UNCLOS on the high seas and the Area.

Charlotte Salpin then provided an overview of the current discussions at the UN General Assembly in the context of its Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction.<sup>9</sup> She noted that MGR, including questions on the sharing of benefits, were one of a package of issues being considered as a decision on the development of an international instrument under UNCLOS was expected before the end of the sixty-ninth session of the General Assembly in 2015. She explained that different views continued to be held on MGR of ABNJ, some States, particularly developing countries, advocating for the application of the common heritage of mankind, including benefit-sharing, whereas other States considered that they were freely accessible and exploitable without the need for benefit-sharing.

In concluding, Charlotte Salpin stressed several points relevant to marine scientists, including that:

- UNCLOS has a defined consent procedure for MSR in the EEZ and on the continental shelf which operates through official channels (usually a State's ministry of foreign affairs) and within a specific timeframe (request to be submitted no less than 6 months before a research project begins). These official channels may be distinct from those in charge of implementing the Nagoya Protocol;
- There may be issues related to resources found both within and beyond areas of national jurisdiction, as well as in regards of activities undertaken on the continental shelf beyond 200 nautical miles; and the ongoing discussions at the General Assembly provide a unique opportunity to strengthen the science-policy and industry-policy interface.

## **2.6 Implications for the MGR User and WP6 MGR Workshop 1 Focusing on ABS of MGR in ABNJ**

Thomas Greiber outlined the contribution of IUCN in the PharmaSea project and specifically its role in the organisation of one of two multi-stakeholder workshops focusing on the sustainable use of MGR in marine biodiscovery activities. He provided a rationale for the decision to focus the first workshop on MGR from ABNJ. He emphasised that R&D on MGR from ABNJ needs an enabling environment, legal certainty, clarity and fairness. Given that the ABS conditions of the CBD and Nagoya Protocol do not apply in ABNJ, the UNCLOS is the only applicable legal framework. Within UNCLOS, there is no specific regime covering MGR, but there are provisions relevant to marine scientific research which, he proposed, could embody a form of non-monetary benefit-sharing, e.g. the sharing of available knowledge is obviously beneficial to the global research community. Although the freedom of the high seas applies, some issues remain such as

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<sup>9</sup> See <https://www.un.org/depts/los/biodiversityworkinggroup/biodiversityworkinggroup.htm>.

sustainable access, sectoral access and transboundary issues. Coming back to discussions at the UN General Assembly about options to regulate access and exploitation of MGR from ABNJ, Thomas Greiber noted that this is an ongoing process to which the research community and the PharmaSea project in particular could make a very useful contribution.

Thomas Greiber stated that the first WP6 workshop would bring together relevant stakeholders and practitioners and enabling entities to discuss the key legal and policy constraints surrounding access and use of MGR from ABNJ. The workshop would be used to identify pragmatic solutions for benefit-sharing and for facilitating and promoting the access to these valuable resources. He noted that the timing will be important, such that ideas and solutions arising from the workshop could be relevant to the state of progress in the ongoing process. He closed by noting that while there was only a low level of sampling activity and associated environmental impact within ABNJ at present; any proposed implementing agreement should consider the long term possibilities, with the real likelihood of increased activity.

## 2.7 Biorepositories as a source of Marine Genetic Resources, the Experience of Marbank, Norway's National Marine Biobank

Kjersti Lie Gabrielsen, Marbank, Norway

Providing the perspective of the biorepository, Kjersti Lie Gabrielsen introduced Marbank, Norway's national marine biobank and forthcoming ABS regulations in Norway. Marbank, she said, was formed in 2009 as an initiative of several Norwegian research institutes. Marbank works to collect, preserve and catalogue marine organisms, mainly from Norwegian jurisdictions, and make them available for research and exploitation purposes to projects such as PharmaSea. She said that the advantage of *ex-situ* collections was that samples may be widely distributed, particular to researchers lacking the capacity to carry out *in-situ* sampling. Discussing quality assurance aspects of their work, Kjersti Lie Gabrielsen described the tracking system used by Marbank which contains comprehensive sample data, including sampling location and taxonomic classifications. Referring to the extensive taxonomic expertise of their Russian collaborators, she pointed out that Marbank had collected samples from Russian jurisdictional waters but had not yet transferred these samples to Norway as they were awaiting clarification as to how this could be carried out legally.

Describing the background to forthcoming ABS regulations in Norway, Kjersti Lie Gabrielsen, said that in 2009 the Government had devised a national strategy on marine bioprospecting which recognised the economic potential of this activity to Norway. As part of the strategy the government committed to regulating and facilitating access to Norwegian genetic resources and to further support marine biodiscovery R&D. In spring of 2013 a public hearing was held to discuss proposed regulations for access and exploitation of Norwegian genetic material, based on the Norwegian Nature Diversity Act, the Marine Resources Act, and international conventions (CBD, NP, and UNCLOS). The

new regulations are expected to come into force in Norway in January 2014 and will make Norway one of the few developed countries to regulate access to its genetic resources. The regulations will allow the government to monitor exploitation of their genetic resources, ensure exploitation is sustainable and consider benefit-sharing arrangements. In relation to Norwegian MGR, access will be granted by the Directorate of Fisheries. Kjersti Lie Gabrielsen noted that in general the response from stakeholders to the proposed regulations was positive. Industrial actors welcomed the legal security they would provide. She also stressed that ultimately the aim was to encourage activity on Norwegian genetic resources so the regulation was designed to be supportive rather than restrictive. Collections such as Marbank will be given a mandate to sign contracts for the exploitation of the genetic material in their own collections thus precluding the need for a researcher to obtain a permit to access/collect genetic resources from habitats within Norwegian jurisdiction.

Finally, Kjersti Lie Gabrielsen said that Marbank is in the process of coordinating the establishment of a national pool of samples from various Norwegian collections. The aim being to secure all marine samples and make them visible and available for research and exploitation. Stressing the importance of the initial contracts with the original owner of the samples, she said that the process would involve the use of material transfer agreements (MTAs) with a possibility of licenses granting exclusive periods of exploitation. All previously generated IPR will follow the samples and 3rd party transfer and reporting of results would be monitored. Discussing possible fee structures, such as up-front payments and royalties she said both the interests of the government and the original owner of the samples would be taken into account. Summing up Kjersti Lie Gabrielsen said Marbank provides access to a wide variety of legally acquired, quality assured marine organisms.

## 2.8 Case Studies on ABS of MGR

Meredith Lloyd-Evans, BioBridge UK

Introducing Task 6.3 of PharmaSea WP6, which involves the development of a selected number of case studies, Meredith Lloyd-Evans said the purpose of this task was to support the production of guidelines and best practice in relation to ABS of MGR. He explained that a draft list of seven potential case studies had been proposed and that the final profile would be made following advice from the APPLE.

Meredith Lloyd-Evans described the first case study to be developed as focusing on the role of biorepositories and the impact of the proposed EU regulation on ABS, using MarBank as a model. Justifying the choice of this case study, he explained the crucial importance of the identity chain in marine biodiscovery for MGR from point of access (origin) to benefit-sharing arising from exploitation. Repositories can play an important role in safeguarding identity and validity of origin and also in establishing IP. In relation to IP, Meredith Lloyd-Evans referred to the composite licenses in the electronics industry in terms of how to apportion effort.

Explaining the choice of MarBank as a model, Meredith Lloyd-Evans referred to Norway's national strategy for bioprospecting and safeguarding its MGR. Marbank had been established as a specific MGR repository with an objective to commercialise resources and support industry. Also, the University of Tromsø, to which MarBank is closely linked, is a partner in the PharmaSea project. In relation to the EC's proposed regulation to implement the Nagoya Protocol in the EU, Meredith Lloyd-Evans highlighted the concept of 'trusted collections' and the role they will play in assisting MGR users to exercise due diligence. He noted that one of the PharmaSea objectives is to develop a Toolkit for users (e.g. researchers and industry) which will simplify ABS and management of MGR in the biodiscovery chain. The concept of 'trusted collections' as sources of validated MGR is very relevant to this.

Summing up, Meredith Lloyd-Evans outlined the remaining proposed list of case studies and said that these will be circulated amongst the APPLE members for input and advice towards producing a final list of relevant case studies to best contribute to the aims of PharmaSea WP6

## KEY MESSAGES OF THE MEETING

### 3.1 The Nagoya Protocol – What (M)GR Users Should Know.

The Nagoya Protocol is expected to enter into force by October 2014. The Protocol should facilitate access to genetic resources by demonstrating to providing countries that users, who are parties to the Protocol, will respect their ABS regulations. It should also provide users with greater legal certainty for future commercial exploitation.

The European Commission regulation to implement the Nagoya Protocol in the EU is expected to enter into force by October 2014. Subsequently, all EU users of genetic resources, including *marine* genetic resources, will be required to hold the necessary documentation proving that those resources were lawfully accessed. If this evidence is not clear and cannot be obtained and made available for monitoring checkpoints, then the user will be advised to discontinue further R&D activity around the (M)GR in question or be subject to sanctions. This obligation extends to non-EU users if they commercialize in the EU a product developed on the basis of a genetic resource.

The EU will recognise a system of trusted collections, users of these collections will have been considered to have exercised due diligence.

Whilst a partnership with a research institution in a providing country is considered to be best practice, this does not preclude the obligation on the user / receiver of the (M)GR to ensure that the adequate prior informed consent (PIC) has been obtained and mutually agreed terms (MAT) have been negotiated, as appropriate, allowing transfer of the resources to the user country.

EU researchers are advised not to leave a providing country in which they have obtained (M)GR without PIC/MAT and the subsequent permit or its equivalent (made available to the CBD's ABS Clearing-House mechanism). This permit should be presented at all monitoring checkpoints within the EU. All samples should be properly documented. If the genetic resources are being utilized within the EU then this activity must be covered by the MAT. If there is any change of intent during the R&D process then the MAT must be renegotiated. All evidence must be retained for at least 20 years and fully transferred to further users of the material. All benefit-sharing obligations must be fully complied with.

### 3.2 Sampling MGR Within National Jurisdiction - the Overlapping Regimes of the UNCLOS and the Nagoya Protocol

The CBD and its Nagoya Protocol recognise the right of a state to regulate access to the genetic resources within its jurisdiction. In parallel, the UNCLOS provides a framework



within which coastal States can regulate marine scientific research carried out within their territorial sea, EEZ and on the continental shelf. As such the access to MGR from areas within national jurisdiction will be subject to regulation under UNCLOS and possibly also the CBD/Nagoya Protocol, depending on the coastal State's national laws in this regard.

Greater clarity on the respective extent of areas within and beyond national jurisdiction is becoming available with the increasing number of EEZ being declared by coastal States around the world and the on-going process of the establishment of the limits of the continental shelf beyond 200 nautical miles.<sup>10</sup> This will result in greater clarity also in the application of the Nagoya Protocol for users of MGR.

Scientists may be aware of the existing marine research regimes in place in some countries (e.g. requirement to include an observer or national representative on board the vessel) but may not be aware that such requirements actually reflect the exercise, by the coastal state, of its rights under UNCLOS to authorize and regulate MSR within its jurisdiction. These MSR provisions are distinct from the requirements by the coastal state regarding access and benefit-sharing pursuant to the Nagoya Protocol.

**As a result, researchers wishing to obtain MGR from the areas under the sovereignty (internal waters, territorial sea, archipelagic waters) or jurisdiction (exclusive economic zone, continental shelf) of a coastal State, must contact both:**

- (i) the CBD national focal point of that coastal State, as detailed in the CBD Clearing-House Mechanism, in order to establish what regimes are in place in the coastal State in relation to genetic resources.**
- (ii) the competent governmental authorities within the State the flag of which the research vessel flies or on behalf of whose the research is carried out, well in advance of any proposed sampling expedition, in order to obtain the necessary consent from the authorities of the coastal State concerned to access the maritime zones of that State through the appropriate channels as set out in UNCLOS.**

**It is important to note that compliance with the CBD and its Nagoya Protocol does not ensure compliance with UNCLOS and vice versa.**

The APPLE discussions also touched upon some questions arising out of some practices of the research community. For example, with regard to sampling within areas under national jurisdiction from vessels of opportunity; i.e. vessels which are not dedicated research vessels and have hence not normally submitted a request to carry out MSR in advance. It seems clear under UNCLOS that where a scientist enters the waters of a coastal state on board a vessel of opportunity for the purposes of carrying out marine scientific research, a request must be submitted in advance to the relevant authority, through the appropriate official channels.

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<sup>10</sup> C. Salpin, "The Law of the Sea : A before and an after Nagoya ?". In *The 2010 Nagoya Protocol on Access and Benefit-sharing in Perspective, Implications for International Law and Implementation Challenges*, by E. Morgera, M. Buck and E. Tsiumami, Martinus Nijhoff Publishers 2013, p. 149-183.



Also, questions were raised on the requirements which apply to a foreign scientist sampling in a coastal state's jurisdiction on board a vessel registered in that state (via a partnership with an institution in that same state). Bearing in mind the object and purpose of both UNCLOS and the Nagoya Protocol, it would seem logical that if the MGR sample will eventually be transferred to and utilized in another State, then the same requirements would apply as do to a scientist entering the waters of the coastal State onboard a foreign-flagged vessel. However, this may require further discussion and clarification.

### **3.3 Areas Beyond National Jurisdiction (ABNJ)**

Under UNCLOS, areas beyond national jurisdiction are the high seas (all parts of the sea that are not included in the exclusive economic zone, in the territorial sea or in the internal waters of a State, or in the archipelagic waters of an archipelagic State) and the Area (the seabed and ocean floor and subsoil thereof, beyond the limits of national jurisdiction).

Where confusion can occur is when the continental shelf extends beyond 200nm. In such a situation a sample taken from the water column superjacent to the extent of the continental shelf beyond 200 nautical miles would belong to the high seas regime (ABNJ) and would not be subject to the requirements of the Nagoya Protocol. However benthic organisms sampled from the seabed or subsoil at the same site, given their location within national jurisdiction, would be subject to the requirements of both UNCLOS and the Nagoya Protocol (see 5.2 above).

### **3.4 Facilitating access to MGR from ABNJ and benefit-sharing: PharmaSea WP6 Stakeholder Workshop 1.**

The PharmaSea project is a model marine biodiscovery pipeline, which will process 2,500 organisms (microbial strains) via specific selective screens resulting in the production of two leads. It follows that if the same 2,500 organisms were also subject to different selective screens, then potentially a greater number of leads can be expected to result. Extrapolating this beyond the PharmaSea project, the more sectors which have access to a sample (or associated data), then the greater the potential number of products which may be derived from those samples.

This is particularly relevant to the exploitation of valuable MGR from ABNJ. In light of the on-going discussions towards the scope, parameters and feasibility of an international instrument under UNCLOS, which may regulate access to MGR from ABNJ and the sharing of benefits arising from their utilisation, the following points should be considered:

- Although few countries have the capacity to sample MGR in ABNJ, many more countries may have the biotechnological capacity to exploit these resources if they had access to them.
- It is widely agreed that publicly funded research cruises are the main players currently sampling MGR from ABNJ. There is usually a requirement by public funding bodies to make research results freely available. Increasingly, however, this research may involve an applied or a commercial research aspect.
- Whilst the capability to sample in ABNJ will remain the preserve of wealthier nations, the introduction of the ABS requirements established pursuant to the Nagoya Protocol may make sampling in ABNJ more attractive as a source of MGR.
- Although activity related to sampling MGR in ABNJ is currently considered to be low level, this can be expected to increase in the future. Any future regulation should take this expected increase in activity into account.

The questions remain:

- How could access to MGR from ABNJ and related-data, as well as benefit-sharing be facilitated?
- How can those who do have the capacity to access MGR from ABNJ be encouraged to share their samples, data and research outputs?
- To what extent are MGR from ABNJ being used in commercial R&D?
- How can a proposed open access regime be balanced with options for exclusivity to exploit these resources such as may be required by industrial partners?

The PharmaSea project which encompasses all aspects of the marine biodiscovery pipeline from ‘sampling’ to ‘scale-up,’ provides a pilot-study of the marine biodiscovery R&D process. As such, it can contribute towards answering some of these questions.

The PharmaSea Stakeholder workshop will develop a model, outlined by the European Commission (DG MARE & DG ENV) for how access to data and resources from ABNJ can be facilitated and the benefits arising therefrom can be shared. This represents an opportunity for the scientific community to provide input towards a potential future regulation which may impact on their R&D activities on MGR from ABNJ.

### **3.5 The PharmaSea MGR User Toolkit**

The purpose of the PharmaSea MGR User toolkit is to provide the necessary information and resources to assist users to access and utilize legally acquired MGR.

- It was recommended that the toolkit should contain information relevant to all the various ‘points of access’ to MGR in the value chain and considering the intent of the MGR user, i.e. whether the resource will be used for basic research or commercial purposes.

- Whilst it was considered advisable to wait until after the Nagoya Protocol entered into force before detailing specific information on ABS regulations, it was also important to recognise that PharmaSea is a time-limited project and a high level architecture could be developed containing explanatory information with specific regulatory details to be added as they became available.
- The toolkit should complement the information available via the CBD's Clearing-House mechanism.
- Information on the MSR laws and policies of coastal States should be included in the toolkit. CIESM and MicroB3 are in the process of compiling some of this information. Again, the toolkit should complement this activity.
- How the ABS information can be audited and maintained given the legal and language difficulties involved in accessing and translating the necessary information is to be determined with the assistance of the APPLE.

### **3.6 Dedicated Awareness Raising and Training amongst the Marine Scientific Community**

It was recognised by the APPLE that among the scientific community engaged in marine biodiscovery activities, there are varying levels of awareness of the legal and policy frameworks that govern the access to and utilisation of MGR from different locations. Those actively involved in sampling expeditions generally have a greater understanding of some of the issues than, for example, a third party receiving samples from a biorepository or partner institution. The Nagoya Protocol and forthcoming EU regulations will apply to all users of genetic resources irrespective of where the user enters the value chain. Some users are very aware of UNCLOS provisions in terms of sampling procedures while others are quite well versed in the CBD requirements but less familiar with UNCLOS provisions. MGR users must be aware of both regimes.

Awareness raising amongst the scientific community that obligations exist, that new regulations are coming into force, and what the implications of these regulations will be is necessary. PharmaSea and collaborating projects, namely MicroB3, SeaBioTech and MaCuMBA, can have considerable impact in this regard, as can codes of conducts such as has been developed in the CIESM charter on ABS<sup>11</sup>. In addition, funding bodies which support marine biodiscovery / biotechnology research can also play an important role in dedicated awareness raising and future training initiatives could focus on this improving knowledge in this area.

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<sup>11</sup> The CIESM charter on ABS addresses the collection and exploitation of MGR and is available at <http://www.ciesm.org/forums/index.php?post/2013/03/14/CIESM-Charter-on-ABS>

### 3.7 Terminology in Marine Biodiscovery

It was suggested that terms such as ‘bioprospecting’ and ‘biopiracy’ are not useful in these discussions. Such terms can be defined differently in different countries and institutes. For example ‘bioprospecting’ is defined by some as simply looking for new materials, for others it assumes the intention to exploit the resource for applied or commercial purposes. It was advised that simple terms relevant to the specific research activity should be used e.g. ‘sampling.’<sup>12</sup>

Other useful terms include ‘misappropriation’ of genetic resources, i.e. obtaining genetic resources in violation of the ABS legal framework in place in the provider countries and ‘misuse’ of genetic resources, where the utilization of the genetic resources contravenes the original permit and the mutually agreed terms.

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<sup>12</sup> Marcel Jaspar’s Information Paper, ‘The Marine Biodiscovery Pipeline,’ (in prep) defines the stages in the marine biodiscovery pipeline.

## CONCLUSIONS

The APPLE meeting provided a first opportunity to collect the views of an expert community to guide the tasks of PharmaSea WP6.

The meeting highlighted the need for communication between the marine biodiscovery / biotechnology sector and the legal experts and policy makers with responsibility for developing regulations governing access to, and exploitation of, MGR. A science-policy forum such as the APPLE could play a significant role in promoting the sustainable advancement of marine biodiscovery.

It was also apparent that the scientific community engaged in R&D on MGR is lacking awareness of the regulatory developments and legal frameworks which govern ABS of MGR. The resulting uncertainty over the legality of both sampling MGR, and using collected samples in marine biotechnology research, could inhibit the development of the marine biotechnology sector in the medium-term.

PharmaSea WP6, through its work in making the relevant information available and accessible, can contribute towards raising awareness within the marine biodiscovery and biotechnology sector. It can also help to reassure the sector that these legal frameworks are ultimately beneficial to their work through facilitating access to MGR and providing the legal certainty which industry requires to secure its commitment to marine biodiscovery R&D.

The discussions and conclusions of the 1<sup>st</sup> APPLE meeting will be taken forward to guide the development of PharmaSea WP6 and to inform the internal PharmaSea planning. They will also be used as a basis for the PharmaSea partners to contribute to the ongoing evolution of the legal and policy framework which underpins the sustainable exploitation of MGR. The 2<sup>nd</sup> APPLE meeting, due to be held in 2014, will provide a beneficial opportunity to review progress in these areas and ensure that PharmaSea work and outputs are relevant and up-to-date.



## **ACTIONS**

Discuss the EC model for facilitating access to MGR from ABNJ for testing at the PharmaSea stakeholder workshop (IUCN). eCOAST to include supplementary questions in their stakeholder consultation process.

[Responsible: PharmaSea - Thomas Greiber IUCN & Oonagh McMeel eCOAST and European Commission Vassilis Koutsouris and John Brincat. Ongoing].

Any further comments on Marcel Jaspars' information paper on 'The Marine Biodiscovery Pipeline' to be sent to Marcel by mid-December. Marcel will have a final draft for circulation for the next APPLE meeting.

[Responsible: All APPLE members. Deadline: December 15th].

WP6 workshop organisers to discuss dates for the 2<sup>nd</sup> APPLE meeting to potentially coincide with the WP6 (IUCN) stakeholder workshop. Disseminate a doodle poll to APPLE.

[Responsible: Oonagh McMeel, eCOAST and Thomas Greiber, IUCN. Deadline: December 30th 2013].

Circulate the proposed shortlist of case studies amongst the APPLE for their comments.

[Responsible: eCOAST. Deadline: February 1st 2014].

Circulate presentations amongst the APPLE

[Responsible: eCOAST. With this report].





## ANNEX 1 LIST OF ABBREVIATIONS

ABS	Access and Benefit-Sharing
ABNJ	Areas Beyond National Jurisdiction
APPLE	Advisory Panel of Policy and Legal Experts
CBD	Convention on Biological Diversity
SCBD	Secretariat of the CBD
CHM	Clearing-House Mechanism
EC	European Commission
EC COM	European Commission Communication
EU	European Union
FP7	EU 7th Framework Programme
MAT	Mutually Agreed Terms
MGR	Marine Genetic Resources
MSR	Marine Scientific Research
MTA	Material Transfer Agreement
PIC	Prior Informed Consent
NP	Nagoya Protocol
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 FOR THE 1ST PHARMASEA APPLE MEETING**

- 9.00** Welcome and introduction to the PharmaSea project and APPLE (**Marcel Jaspars**, University of Aberdeen, PharmaSea Coordinator and APPLE Chair)
- 9.30** Overview of PharmaSea WP6 (**Oonagh McMeel**, eCOAST)
- 9.50** General Discussion and feedback on WP6 activities:  
ABS Case studies / Plans for stakeholder consultation / MGR User Toolkit format
- 10.30** **Coffee**
- 10.45** Access to Genetic Resources and Benefit-Sharing: The Nagoya Protocol (**Kathryn Garforth**, CBD Secretariat)
- 11.00** State of play of the EU Commission's legislative proposal on implementing the Nagoya Protocol in the Union (**Vassilis Koutsouris**, EC DG ENV)
- 11.20** **Discussion**  
How will this legislation affect the EU MGR practitioner? How can WP6 and the toolkit help MGR practitioners in achieving compliance with the proposed regulation?
- 12.30** **Lunch**
- 13.30** The legal framework for the oceans under UNCLOS and the on-going process within the General Assembly with regard to biodiversity in areas beyond national jurisdiction (**Charlotte Salpin**, UNDOALOS)
- 13.45** Implications for the MGR User and related WP6 MGR Workshop 1 focusing on ABS of MGR in ABNJ (**Thomas Greiber**, IUCN)
- 14.00** **Discussion**  
Focus on MGR Workshop 1 & Key questions and target groups for the targeted stakeholder interviews. IPR status of MGR from ABNJ.
- 15.00** **Coffee**
- 15.20** Biorepositories as a source MGR. The experience of MarBank - Norway's National Marine Biobank (**Kjersti Lie Gabrielsen**, MarBank)
- 15.40** **Discussion**  
Biorepositories, data collections, IPR issues, How can the PharmaSea toolkit assist the MGR User in identifying trusted collections? 'The Marine Biodiscovery Pipeline' Information paper
- 17.00** Summing Up, Next Steps, Discussion on date & location of next meeting



### ANNEX 3 LIST OF PARTICIPANTS WHO ATTENDED THE 1ST PHARMASEA APPLE MEETING

PharmaSea Project Partners	Affiliation	Present at Meeting
Marcel Jaspars PharmaSea project leader	University of Aberdeen, UK	Yes
Oonagh McMeel	eCOAST Marine Research, Ostend, Belgium	Yes
Camilla Esguerra	KU Leuven	Yes
Thomas Greiber	IUCN Environmental Law Centre – Bonn, Germany	Yes
Meredith Lloyd-Evans	BioBridge Ltd., UK	Yes
Kjersti Lie Gabrielsen	Marbank, University of Tromsø, Norway	Yes
Mike Davies-Coleman	University of Western Cape, South Africa	Unable to attend
Chris Battershill	Waikato University, New Zealand	Unable to attend
Juan Asenjo	University of Chile, Chile	Yes
Zixin Deng	Wuhan University, China	Unable to attend
Giselle Tamayo	INBio, Costa Rica	Yes
Andrew Mearns-Spragg	Aquapharm, UK	Unable to attend
Isabelle Huys	K.U.LEUVEN, Belgium	Yes
Alan Dobson	University College Cork, Ireland	Yes
Thomas Vanagt	eCOAST	Yes
Laura Lallier	eCOAST	Yes
External Members	Affiliation	
Laura Giuliano	Mediterranean Science Commission (CIESM)	Yes
Charlotte Salpin (Observer Capacity)	UN Division for Ocean Affairs and the Law of the Sea	Yes
Lyle Glowka	Secretariat of the Convention on Migratory Species	Via 'gotomeeting'
Vassilis Koutsouris	European Commission DG ENV	Yes
John Brincat	European Commission DG MARE	Unable to attend
Jan-Bart Calewaert	Independent Advisor	Yes
Michael Lodge	International Seabed Authority	Via 'gotomeeting'
Kathryn Garforth (Observer Capacity)	Secretariat of the Convention of Biological Diversity	Yes
RuAngelie Edrada Ebel	SeaBioTech - EU FP7 Project*	Yes
Arianna Broggiato	MicroB3 - EU FP7 Project*	Via 'gotomeeting'
Werner Mueller	Bluegenics - EU FP7 Project*	Unable to attend



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

### **1.1 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.

## **1.2 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.

### 1.3 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 Research Centre, Ostend. A list of APPLE members is provided on page 5.

### 1.4 Time Frame and Logistics

The PharmaSea project began on 01 October 2012 and will run until 31 September 2016. It is expected that the APPLE will be convened three possibly four times during this period. The first meeting will take place on September 11<sup>th</sup> 2013 in Vigo, Spain. Between these meetings exchanges with the APPLE will be managed remotely using email, skype or phone.

In advance of each APPLE meeting, members will be provided with information relevant to the work of WP6 which will be discussed at the APPLE meetings.

Following each APPLE meeting a report on the main outcomes of the APPLE meeting will be prepared and disseminated amongst all members. These will form the basis of one of the deliverables of Work package 6.

## 1.5 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 research centre, Ostend, 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 Research Centre, Ostend if he/she is representing a PharmaSea partner institution or representing another project financed by the European Commission under the Seventh Framework Programme.

## 1.6 List of APPLE members

Name	Affiliation	Role
Marcel Jaspars	University of Aberdeen, UK	Chair of the APPLE
Oonagh McMeel	eCOAST Marine Research, Ostend, Belgium	Facilitator of the APPLE
<b>PharmaSea Project Partners</b>	<b>Affiliation</b>	<b>Expertise</b>
Camilla Esguerra	KU Leuven	Drug discovery, identification of disease relevant targets and active compounds.
Thomas Greiber	IUCN Environmental Law Centre – Bonn, Germany	Environmental law / Access and benefit sharing of marine genetic resources
Meredith Lloyd-Evans	BioBridge Ltd, UK	Expert Biotechnology and IPR
Kjersti Lie Gabrielsen	Marbank, University of Tromsø, Norway	Expert on ABS Policy in Norway and Biobank/type culture collections
Mike Davies-Coleman	University of Western Cape, South Africa	Dean of Science, UWC, Natural Products Chemist Access to South African species
Chris Battershill	Waikato University, New Zealand	Professor of Coastal Science at the University of Waikato, Expert in Marine Biodiscovery Access to New Zealand species
Juan Asenjo	University of Chile, Chile	Professor and Director of the Centre for Biochemical Engineering and Biotechnology, Chile Access to Atacama trench
Zixin Deng	Wuhan University, China	Culture collection/metagenomics/genome scanning
Giselle Tamayo	INBio, Costa Rica	Regional Expert in Bioprospecting. Access to Costa Rican species
Andrew Mearns-Spragg	Aquapharm, UK	Extensive experience with marine biodiversity IP and ABS issues from an SME perspective
Isabelle Huys	K.U.LEUVEN, Belgium	Expert on legal aspects of drug discovery and IPR
<b>External Members</b>	<b>Affiliation</b>	<b>Expertise</b>
Laura Giuliano	Mediterranean Science Commission (CIESM)	ABS issues of MGR in the Mediterranean
Charlotte Salpin (Observer capacity)	UN Division for Ocean Affairs and the Law of the Sea	Law of the Sea, MSR, ABS of MGR in ABNJ
Lyle Glowka	Secretariat of the Convention on Migratory Species	ABS issues of MGR in ABNJ
Vassilis Koutsouris	European Commission DG ENV	International and European ABS issues, EU official with responsibility for the implementation of the Nagoya protocol in the EU
John Brincat	European Commission DG MARE	BBNJ, EU official with responsibility for proposed UN Implementing Agreement on ABS of MGR in ABNJ
Jan-Bart Calewaert	Independent Advisor	Marine biotechnology and marine science policy, strategy and foresight
Michael Lodge	International Seabed Authority	Legal Counsel, ISA Law of the Sea, Sea bed mining
Kathryn Garforth (Observer Capacity)	Secretariat of the Convention of Biological Diversity	Programme Officer within the Nagoya Protocol Unit. ABS issues of GR
RuAngelie Edrada Ebel	SeaBioTech - EU FP7 Project	Marine Natural Products Chemistry, marine biodiscovery
Arianna Broggiato	MicroB3 - EU FP7 Project	Legal regimes of genetic resources
Werner Mueller	Bluegenics - EU FP7 Project	Marine Biodiscovery