High level policy environment

1. What is the current policy environment for biopharmaceutical intellectual property and know-how?

   -The Netherlands is committed to a strong and balanced IP-system and sees it as an essential part of a healthy innovation environment. Our policy is aimed at strengthening the IP-infrastructure both in Europe (introduction of a unitary patent and a unitary patent court) and in the Netherlands (improving access to the IP-system for SME's).

   -Intellectual property protection has to a large extent been regulated in supranational law both worldwide (TRIPs) and at a European level (EU, European Patent Convention). In these turbulent times this is of great value.

2. What are the relevant tax policies and incentives for biopharmaceutical R&D and manufacturing?

   The Netherlands actively promotes engaging in Research & Development activities through a favorable corporate tax system and specific R&D incentives that support innovation throughout the entire R&D lifecycle. The following measures may significantly lower company R&D cost and taxable base.

   1. R&D Tax Credit (WBSO)

   Companies performing particular R&D activities may benefit from a 32% tax credit (up to 40% for startups) of the first €350,000 in R&D wage costs and other R&D expenses and investments, and 16% for those costs and investments exceeding €350,000.

   2. Innovation Box

   Companies may benefit from an effective tax rate of only 7% for income from intangible assets— including technological innovations—created by the Dutch tax payer and for which R&D tax credit was received.

   3. Allowance for public-private partnerships in R&D (PPS allowance)

   R&D partnerships between public entities and private partners may receive cash grants of 40% on the private investment costs for the first € 20,000 and 30% for the excess. The cash grant has to be invested in the R&D project of the partnership.

   4. Innovation Credit

   Innovation Credit is a risk bearing loan from the government for the technical or clinical development of a new product, process or service. Funding may vary from 25% for large-scale companies to 35% for medium sized companies, and 45% for small companies, of relevant project costs. The maximum credit per company depends on the size of the company. For clinical development projects, there is a maximum of €5 million and for technical projects, it is €10 million.

3. What are the import/export/trade/other policies for finished product and movement of material for in-process manufacturing?

   The Netherlands is an open country with an international mentality, we can explore specific policies during further conversations.

   The CIBG issues permits. This is done via Farmatec (part of the CIBG). Farmatec will register API companies and brokers in the Netherlands. More information about what needs to be registered can be found at https://english.farmatec.nl/registration

4. Are there clinical data protection and release requirements related to government funding for R&D? If so, what are they?

   Open Science is a priority for the Dutch government. Government funded research should be published in open access form. As published on the website of the Dutch Research Council (NWO), The Dutch government has set the objective that by 2018 60%, and by 2020 100% of scientific publications funded with public money must be published in open access form. NWO's granting conditions therefore state that all publications emerging from research it funds must be directly accessible via open access at the moment of publication.

The importance that the Dutch scientific community attaches to open science is reflected in the cooperation of knowledge institutions in the National Platform Open Science.

Vaccines-specific environment

1. What is the national government's current vaccines liability or indemnification policy?
   We can explain relevant EU and National legislation in more detail during further conversations. The basic principle in our health law is that everyone bears their own damage, unless someone else is liable.
2. Does the government have a vaccines injury compensation framework? If so, what is the process and what are the requirements for compensation?
   Given the basic principle mentioned above, we don't have an existing fund in the Netherlands that compensates damage as a result of vaccinations.
3. What vaccines R&D and/or manufacturing incentives are provided by government?
   Scientific research in the Netherlands is financed by the government through the first and second funding stream (universities and through the Dutch Research Council and ZonMw). In addition, there are several incentives for public-private partnerships through, for example, the top sector policy, which is managed by the ministry of Economic Affairs and Climate.
   In addition, a multi-year program has been drawn up, taking into account public interests and being able to continue to offer a total package that serves the vaccine value chain in both bacterial and viral areas, while at the same time offering room for innovation. This program is carried out by Intravacc. Intravacc translates results from fundamental research into practical application, up to and including clinical research or much earlier if an (industrial) cooperation partner continues the development, whether or not in co-development with Intravacc, up to and including market introduction.

COVID-19 environment

1. What if any regulatory flexibilities have been provided or considered in the context of COVID-19 vaccine development and manufacturing?
   See for example Accelerated procedures for COVID-19 treatments and vaccines.

   Due to the exceptional circumstances, the Ministry of Infrastructure and Water Management (I&W) has decided to speed up the licensing procedure for research into gene therapy or a medicine with a genetically modified organism (GMO) that is aimed at combating COVID-19. The EU has the intention to put the EU-rules on the use of genetically modified organisms out of operation. The final decision has yet to be made.

2. What if any regulatory guidelines have been provided for review and licensure of COVID-19 vaccines or therapeutics, including any guidelines regarding emergency use authorization?
   EMA guidance for medicine developers and companies on COVD-19, see for example Accelerated procedures for COVID-19 treatments and vaccines.
3. Are there any additional or different liability or indemnification policies being considered in the context of this pandemic or more broadly for public health emergencies of international concern?
   This is a matter being discussed among the EU Member-States and cannot be answered specifically for the Netherlands.
4. What COVID-19 specific funding opportunities have been announced or are being considered by the national government? Are they focused on R&D, manufacturing, or both? What funding, if any, has already been awarded to other companies?
   The Netherlands has (in the framework of the Inclusive Vaccine Alliance) signed an agreement with AstraZeneca and will continue to support and facilitate broad accessibility and availability in various ways.
   Of course we look at the entire value chain in the context of vaccine development and production.

5. If funding is available, what is our understanding of requirements for funding in terms of IP, dose allocation, use of manufacturing for other purposes, or other provisions?
   Can be discussed in more detail, also in context of a proposal.