From: Kirsten Hjelle
Sent: 8. desember 2021 16:40
To: Johan Georg Røstad Torgersen; Morten Græsli
Cc: Ingvild Grendstad; Knut Erlend Bergan; Harald Lislevand; Bente Åshild Tautra
Subject: VS: MSD avtale Molnupiravir- tillegg til oppdrag 566

Hei

Siste tilbakemelding fra Helse- og omsorgsdepartementet er at MSD tidligst kan få en tilbakemelding i morgen.

Dette er videreformidlet til MSD.

Denne mailen legge si 360 som svar på tilleggsoppdraget til oppdrag 566.

Kirsten Hjelle

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Fra: Kirsten Hjelle
Sendt: onsdag 8. desember 2021 14:48
Til: Bakka Eirik Rødseth <Eirik-Rodseth.Bakka@hod.dep.no>; Espantaleón Katrine S. Edvardsen <Katrine-S.-Edvardsen.Espantaleon@hod.dep.no>
Emne: VS: MSD avtale Molnupiravir- tilbakemelding etter møte kl 14

Hei

Spurte om de kunne sette første leveranse til 3 uker etter signering og begrunnet dette med at HOD trenger noe mer tid.

Muntlig tilbakemelding er også at de ikke kan garantere 3 uker fra signering om vi signerer senere. De har heller ingen leveranser i romjulen. Hvis vi ikke signerer i dag får vi ikke første leveranse om 3 uker.

Se tilbakemelding fra MSD nedenfor.

Punktene nedenfor som er hentet fra kontrakten er standard for MSD.

Kirsten Hjelle

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Fra: Høeg, Anne Lebesby <anne.lebesbyhoeg@merck.com>
Sendt: onsdag 8. desember 2021 14:36
Til: Kirsten Hjelle <Kirsten.Hjelle@helsedir.no>; Bente Åshild Tautra <Bente.Ashild.Tautra@helsedir.no>
Kopi: Hustvedt, Rolf <rolf.hustvedt@merck.com>; Kvale, Terje <terje.kvale@merck.com>; Ali, Muhammed Mo <muhammed.ali@merck.com>
Emne: RE: MSD avtale Molnupiravir- tilbakemelding etter møte

Proprietary

Hei
Vedlagt følger skriftlig tilbakmelding, som vi verbalt gikk gjennom nå i møte 5.
Ved signering etter i dag er vil følgende 2 variabler endres:

- **6-8 uker leveranser**
- **Forsyningsplan vil kunne endres grunnet allokering og tilgjengelighet ved signeringstidspunktet.**

Vi vil selvsagt gjøre alt vi kan fr tidligst mulig leveranse, men kan ikke love innen 3 uker

Ser frem til snarlig tilbakemelding

Vennlig hilsen Anne

Vi ber om en skriftlig tilbakemelding på avtalepunktene nedenfor, dette skyldes behovet for tydelige leveringsforpliktelser. Avtalen kan oppfattes som uklar på leveringsbetingelser og leveringsplan.

2.2 Under the PLPA Program, MSD will supply at volumes based on capability and unmet medical need on the terms specified in this Agreement. Supply through the PLPA Program will conclude once the European Medicines Agency will have granted a marketing authorization for the Product, however MSD may supply Product in the form used in the PLPA Program until such time as local commercial packaging is available.
Innebærer denne formulering at det kan bli omprioriteringer basert på et større behov for legemidler i andre land/områder, og dermed mindre leveranser til Norge?

COMMENT from MSD: This wording is needed because we are still in a pandemic situation.
Annex 1 show the allocation for Norway.
Our proposal in Annex 1 demonstrate our commitment to secure a fast supply to Norway.

3.2 Supply Schedule.
(i) MSD shall use its best efforts to supply the Committed Quantity of the Product in accordance with the anticipated supply schedule set forth in Annex 1 of this Agreement. MSD commits to provide PRODUCT with no less than 6 months of shelf-life remaining to expiry at time of delivery to specified location.

(ii) HDIR acknowledges and agrees that the supply of the Product is subject to limitations due to manufacturing capacity and global allocation of the Product, and that the anticipated supply schedule may be adjusted by MSD. In the event the anticipated supply schedule needs to be adjusted, MSD shall use its best efforts to provide a notice to HDIR as soon as practicable.
(iii) For the avoidance of doubt, MSD shall not be liable for failure to meet the anticipated supply schedule or for any late delivery of the Product.

COMMENT from MSD: To clarify – the term " best effort" is a strict legal obligation to leave no stone unturned.

3.3 Supply Conditions. MSD shall have no obligation under any circumstances to supply the Product to HDIR under this Agreement unless:
(i) An Authorization has been granted for the Product;
(ii) It is commercially feasible to supply the Product in compliance with all specifications and conditions of the Authorization; and
(iii) The Product is exempted from requirements for the importation management including labeling requirements and test on importation requirements.
(iv) Requisite import licenses for the Product are in place, allowing the Product to be distributed and sold in the Territory; [and]
(v) Pre-license Patient Access (PLPA) is approved by competent Authority as required in Norway and in place.

COMMENT from MSD: 3.3. i , ii and iii is currently met from a Norwegian regulatory perspective.

Legemiddelforskriftens §2.5 (registreringsfritak) will be used prior to Norwegian MA is granted.
(WWW: EMA gir råd om bruk av Lagevrio (molnupiravir) - Legemiddelverket)
The MSD Wholesaler licence was expanded Dec 7, 2021. (Attached document)
Please note that EMA approval is still pending, Norwegian MA follow after that.

3.4 Impact of JPA on Committed Quantity. If (a) MSD or an MSD Affiliate enters into a Joint Procurement Agreement with the EU Commission for the purchase of the Product ("JPA"); and (b) the Government agrees to receive an allocation of Product under JPA, then any outstanding Committed Quantity under this Agreement will be reduced by the number of Patient Courses allocated to Norway under the JPA.

11.3 No Implied Warranties. MSD and its Affiliates make no other warranty with regard to the Products, including any warranties of non-infringement of intellectual property or any warranties (express or implied) of merchantability, fitness for any particular purpose, or results through use of the Product. Given the current status of the clinical development program and in light of the extraordinary circumstances of the execution and performance of this Agreement, MSD and its Affiliates do not represent or warrant that the Product will show sufficient efficacy to treat a COVID-19 infection or be without adverse events.

COMMENT from MSD:
This is standard text for medicinal products. MSD has, and will continue to transparently disclosed all data available to regulatory authorities.

Annex 1: Delivery schedule and location
1. Within 8 weeks of signature of this agreement and verification by MSD that MSD has the ability to sell, import, and distribute pre-license supply of the product.
Number of Patient Courses to be Delivered (28800):

2 Pallets (5760 Patient Courses) of UK or EU image*

2. Within 4 weeks of 1st tranche:4 pallets (11520 Patient Courses) of UK or EU image*

3. Within 4 weeks of 2nd. Tranche: 3 pallets (8640 Patient Courses) of UK or EU image*

4. Within 4 weeks of 2nd trnche: 1 pallets (2880 Patient Courses) of UK or EU image*

5. If the agreement was prolonged for 2023 : as needed - subject to the terms of Section 3.5 on Additional Quantities : UK or EU image*

* Image flexibility (UK or EU) needed to support early shipments (subject to the conditions set forth above in the body of the Agreement

COMMENT from MSD:
We propose to change #1 from 8 to 3 weeks if we sign today