To: 5.1.2e @minvws.nl]; 5.1.2e @minvws.nl]; 5.1.2e 5.1.2 5.1.2e @minvws.nl]; @minbuza.nl[@minbuza.nl]; 5.1.2e) 5.1.2e @minvws.nl]; 5.1.2e @rivm.nl[@rivm.nl]; 5.1.2e @rivm.nl[@rivm.nl]; 5.1.2e @rivm.nl[5.1.2e @rivm.nl]; 5.1.2e 1 @minvws.nl]; 5.1.2e 5.1.2e @minvws.nl] 5.1.2e From:

Sent: Fri 3/19/2021 9:18:37 AM

Subject: FW: Coronavirus: ESI - Rapid antigen test (tenders SANTE/2020/C3/082)

Received: Fri 3/19/2021 9:18:38 AM

Van: 5.1.2e @ec.europa.eu

Verzonden: vrijdag 19 maart 2021 10:18:34 (UTC+01:00) Amsterdam, Berlijn, Bern, Rome, Stockholm, Wenen

Aan: 5.1.2e @ec.europa.eu

CC: 5.1.2e

Onderwerp: Coronavirus: ESI - Rapid antigen test (tenders SANTE/2020/C3/082)

Dear Members of the Health Security Committee,

Dear colleagues,

Concerning the ESI – rapid antigen tests of Abbott, we are sending a reminder.

If you have not already sent us your signed donation contracts, please do so as soon as possible, at the latest by **Tuesday 23**rd **March 2021**.

All Abbott donation contracts have been sent out to the Member States.

Shipments are in full swing, with deliveries already made in several Member States and further shipments expected soon. Please be reminded that shipments can only start after the Commission confirms that all parties have signed the donation contract.

Concerning Roche, we will be sending out the donation contracts to you very soon.

Kind regards,

Subject: Coronavirus: ESI - Rapid antigen test (tenders SANTE/2020/C3/082)

Dear Members of the Health Security Committee,

Dear colleagues,

Concerning the ESI - rapid antigen test, we are coming back to you with updates on Roche and Abbott.

Roche

In attachment you find the new Roche allocations (still subject to marginal changes). As previously mentioned, Roche have voluntarily decreased their price which means that we will receive higher quantities of tests than originally anticipated. Particularly for Member States which do not apply the zero-VAT (DE, DK, FI, HR, HU, MT, SE, SK), we remind of the contractual setup outlined in the email below and detailed in the donation contracts (Member State pays for their own VAT, in order to make full possible use of the EU budget).

In case you have any issues with receiving these additional tests, <u>please inform us by midday, Friday 12th March</u> by contacting:

5.1.2e @ec.europa.eu

We will be sending the donation contracts of Roche for signature from your nominated contact as soon as possible.

Abbott

Shipments are in full swing, with deliveries already made in several Member States and further shipments expected soon. All Abbott donation contracts have been sent out to the Member States. We count on your rapid signature so we can confirm the shipments with the contractor.

Please be reminded that shipments can only start after the Commission confirms that all parties have signed the donation contract.

Kind regards,

5.1.2e and the HSC 5.1.2e

From: 5.1.5 < 5.1.2e @ec.europa.eu>

Sent: Thursday, February 25, 2021 12:02 PM

To: 5.1.5 < 5.1.2e <u>@ec.europa.eu</u>>
Cc: 5.1.2e (SANTE) < 5.1.2e @ec.europa.eu>

Subject: Coronavirus: ESI - Rapid antigen test (tenders SANTE/2020/C3/082)

Importance: High

Dear Members of the Health Security Committee,

Dear colleagues,

Concerning the ESI – rapid antigen test, we have now signed the specific contract with Abbott, one of our two suppliers under the ESI procurement.

The next step is now the signature of the donation contracts, where we count on your cooperation to get signatures fast. Once signed, shipments will be able to start.

For the contract with Roche, we also have good news. They have decreased their price which means that we will receive higher quantities of tests than originally anticipated. Contracts with Roche are being modified accordingly and we will update you with the new numbers as soon as possible.

Some of you may already have been contacted by the local affiliate of Abbott to arrange practicalities of the delivery. Apologies for any confusion this may have caused. In view of the new Roche price, we have had to revise and split the donation contract into two contracts. We will individually be sending the contract to you as soon as possible.

Kind regards,

5.1.2e and the HSC 5.1.2e

From: 5.1.5 5.1.2e @ec.europa.eu>

Sent: Friday, February 5, 2021 9:23 PM

Tc 5.1.5 < 5.1.2e @ec.europa.eu>

Subject: Coronavirus: ESI - Rapid antigen test (tenders SANTE/2020/C3/082)

Importance: High

Dear Members of the Health Security Committee,

Dear colleagues,

Concerning the ESI – rapid antigen test, you find below information on the allocation key, value added tax (where applicable) and the donation contract.

Allocation key

Following your feedback, we have re-calculated the test units for each country (attachment). Several Member States had requested more tests. Due to the solidarity of France, Germany and Spain, we have been able to re-allocate some of their tests to the Member States requesting more. As previously mentioned, we also extend our gratitude to Finland,

Luxembourg, the Netherlands and the UK, who have also claimed less or none of their allocated share so other countries can benefit.

We thank you kindly for this act of solidarity and generosity.

We remind that the allocation key is based on healthcare workers per country (Eurostat data elaborated by the ECDC) and takes into consideration the expressed needs of the Member States. We kindly ask that you treat these as confidential and only distribute on a need-to-know basis within your competent authority. Please note that these numbers are indicative and subject to marginal changes.

Donation contract

The Commission buys the rapid antigen tests from Abbott and Roche, and afterwards donates the tests to the Member States. The donation will be formalised by signature of a donation contract. Deliveries to the Member States may only start after the donation contract has been signed.

In attachment we share with you a step-by-step guide on the donation, as well as the donation contract template and its Annexes. Please inform relevant colleagues within your competent authority.

Value added tax

Council Directive (EU) 2020/2020 [1, 2] allows Member States to apply a zero value added tax (VAT) rate on rapid antigen tests for Covid-19 diagnostics. Not all Member States have (already) made use of this possibility. For the delivery of tests to Member States, which do not apply a zero VAT rate, VAT is due at the place of delivery, according to the applicable national VAT rate and corresponding to the quantity delivered (distance-sale).

Under the Emergency Support Instrument, a budget of € 100 million is assigned to the Commission's purchase of rapid antigen tests. In order to make best possible use of the EU budget, the Commission wishes to spend the € 100 million on the tests, without payment of VAT from the EU budget.

Following consultation with DG BUDG, DG TAXUD and the Legal Service, and in agreement with the contractors who will deliver the tests, the following contractual set-up applies:

Member States which apply a zero VAT rate: The donation contract will be signed only by the Member State and the Commission, for the quantities of tests indicated in the attached allocation key (still subject to marginal changes). Please see the attached '2-party donation contract' template.

According to our <u>preliminary</u> information, the zero VAT rate applies for the following 15 Member States: AT, BG, BE, CY, CZ, EL, ES, FR, IT, LV, LT, PL, PT, RO, SI

Member States which do not apply a zero VAT rate: The Commission pays the price without VAT and the Member States pay the VAT due for their country. Please note that this is a cost-neutral transaction. While your Member State would pay VAT to the contractor who delivers the tests, the amount would be going directly back into your country via taxation. Two donation contracts would be signed with each concerned Member State, with identical terms, and for the quantities of tests indicated (still subject to marginal changes) in the attached allocation key:

- One donation contract with the Member State, the Commission and Abbott.
- One donation contract with the Member State, the Commission and Roche.

Please see the attached '3-party donation contract' template. The terms are identical to the 2-party donation contract template, with the difference that the contractors would co-sign the donation contract in order to establish a legal relationship with the Member State for the payment of the amount due as regards VAT (see Article 24 of the donation contract).

In case Member States prefer that the VAT due in their country is paid by the Commission, the amount of tests delivered to this Member State would need to be reduced accordingly. This is because the Commission has a maximum of € 100 million available for the purchase of the tests, including VAT.

According to our <u>preliminary</u> information, the following 10 Member States do not apply a zero VAT rate: DK, DE, EE, FI, HR, HU, IE, MT, SK, SE

We kindly ask all Member States to confirm by Tuesday, 9 February,

- The applicable VAT rate in their country (verifying with the national tax authority)
- If VAT is due in your country please confirm that your contracting authority is willing to agree under the donation

contract to pay the applicable VAT to the contractor (3-party donation contract)

Following you confirmation we will come back to you with the completed donation contract for your signature.

If you have any questions please contact 5.1.2e @ec.europa.eu

[1] COUNCIL DIRECTIVE (EU) 2020/2020 of 7 December 2020 amending Directive 2006/112/EC as regards temporary measures in relation to value added tax applicable to COVID-19 vaccines and in vitro diagnostic medical devices in response to the COVID-19 pandemic

ELI: http://data.europa.eu/eli/dir/2020/2020/oj

[2] https://ec.europa.eu/commission/presscorner/detail/en/ip 20 2299

Kind regards,

5.1.2e and the HSC 5.1.2e

From: 5.1.5 5.1.2e @ec.europa.eu>
Sent: Tuesday, January 19, 2021 5:07 PM
To: 5.1.5 5.1.2e @ec.europa.eu>

Subject: Coronavirus: ESI - Rapid antigen test (tenders SANTE/2020/C3/082)

5.1.2e @ec.europa.eu>

Importance: High

Dear Members of the Health Security Committee,

Dear colleagues,

5.1.2e (SANTE) <

Concerning the ESI – rapid antigen test, you find below information on the allocation key, value added tax (or its exemption) and the donation contract.

Allocation key

We received complaints from the Member States concerning the allocation key for the ESI rapid antigen tests, which had been circulated last week. While we did our best to accommodate specific wishes, this became very complex and we have now revisited the calculations for more fair and equal treatment.

In attachment you find the new allocation key, based on healthcare workers per country (Eurostat data elaborated by the ECDC). For countries not claiming their full or only a partial share (FI, LU, NL, UK), the sum has been equally re-distributed amongst the remaining Member States. This approach actually favours the smaller Member States, many of which had asked for more tests. An alternative would have been a pro-rata re-allocation.

Please review the new numbers and confirm with us if your Member State wants:

- a) more tests (specifying the minimum number you need)
- b) less tests (specifying the number minimum number you want to keep)

Based on the previously provided information, we are seeking at least 2.780.124 tests, which we could re-allocate from Member States needing less to those expressing the need for more. Please note that these numbers are indicative and subject to change in view of the value added tax considerations below.

Value added tax and exemptions

It has been brought to our attention that value added tax (VAT) may be due on the value of the donation for certain Member States. A new Council Directive was adopted [1,2] in December and many Member States have started applying zero-VAT for the purchase of tests related to COVID-19. A significant number do not (yet) apply the zero-VAT, hence VAT may be due for these Member States. We are verifying how we can best address this issue and will get back to you as soon as possible.

Donation contract

Many of you have been asking about the donation contract. Unfortunately, we first need to clarify the VAT matters and we kindly ask for your patience a little while longer.

For all future correspondence concerning the ESI rapid antigen test we are addressing our emails to the HSC contact point and the focal points nominated by you. Please inform us if we need to keep additional contacts in copy.

[1] https://ec.europa.eu/commission/presscorner/detail/en/ip 20 2299

[2] https://ec.europa.eu/taxation customs/sites/taxation/files/201028 commission proposal vat vaccines tests.pdf

Kind regards,

5.1.2e and the HSC 5.1.2e

From 5.1.5 < 5.1.2e @ec.europa.eu>

Sent: Tuesday, January 12, 2021 1:16 PM

To: 5.1.5 5.1.2e @ec.europa.eu>

Subject: Coronavirus: ESI and rapid antigen tests - Commission signs contract

Importance: High

Dear Members of the Health Security Committee,

Dear colleagues,

We thank you for replies sent concerning the ESI rapid antigen test.

Following your feedback, we have re-calculated and finalised the test units for each country (attachment).

Several Member States had requested more tests and we are pleased to inform that we have been able to accommodate these needs. This has been possible because Finland, Luxembourg, the Netherlands and the UK have kindly offered to take less or none of their allocated share so other countries can benefit. We thank you kindly for this act of solidarity and generosity. After addressing the extra needs, we allocated the remaining shares equally amongst the participating countries. You will find that the numbers are higher than the previous estimate.

We remind that the finalised allocation key is based on healthcare workers per country (Eurostat data elaborated by the ECDC) and takes into consideration the expressed needs of the Member States. We kindly ask that you treat these as confidential and only distribute on a need-to-know basis within your competent authority.

We are in-contact with Abbott and Roche and will inform you once we have an update on the delivery schedule. We are doing our upmost to have these sent to you as soon as possible.

For any questions do not hesitate to contact us via: 5.1.2e @ec.europa.eu

Your nominated focal points are also in BCC of this message.

Kind regards,

HSC 5.1.2e

From: 5.1.5 5.1.2e @ec.europa.eu>

Sent: Friday, January 8, 2021 5:10 PM

To 5.1.5 5.1.2e @ec.europa.eu>

Subject: Coronavirus: ESI and rapid antigen tests - Commission signs contract

Importance: High

Dear Members of the Health Security Committee,

Dear colleagues,

We thank you for replies sent concerning the ESI rapid antigen test.

Following your feedback, we have re-calculated the estimated test units for each country (attachment). You may observe

differences to the previous estimation, which is mainly due to the UK being included (we received a clarification that they are also eligible to benefit from ESI funding) and further clarity from our contractors. We remind that the allocation key is based on healthcare workers per country, using Eurostat data, which had been extracted by the ECDC. Please note that these numbers are subject to change and we kindly ask that you treat these as confidential and only distribute on a need-to-know basis within your competent authority.

We particularly wanted to thank Finland, Luxembourg and the Netherlands. They have kindly offered to take less or none of their allocated share so other countries can benefit. We have re-allocated these shares equally amongst the other participating countries.

We have received requests from several Member States for more tests. Unfortunately we are limited by the ESI budget ceiling of 100m EUR. We therefore kindly ask if any Member State is willing to give up part or all of their share to help countries requesting more. We are seeking almost 3 million tests to cover their needs.

We invite you to help us with this request. Please contact us via: 6.1.2e @ec.europa.eu as soon as possible, at the latest by Monday 11th January 2021.

Your nominated focal points are also in BCC of this message.

Kind regards,

HSC 5.1.2e

From: 5.1.2e (SANTE)

Sent: Wednesday, December 30, 2020 11:53 AM

To: 5.1.2e @ec.europa.eu>
Cc: 6.1.2e @ec.europa.eu>; 5.1.2e (SANTE) < 6.1.2e @ec.europa.eu>

Subject: RE: Coronavirus: ESI and rapid antigen tests - Commission signs contract

Importance: High

Dear Members of the Health Security Committee,

Further to the correspondence on the ESI rapid antigen test below, we are sending a kind reminder. Many thanks to the Member States that have already returned their completed forms.

If you have not yet done so, please complete and return to us the attached templates in order for your Member State to benefit from the rapid antigen test donation under the ESI.

The deadline for submission was yesterday. We will extend the deadline until Monday the 4th of January 2021.

Kind regards,

HSC 5.1.2e

From: 5.1.5 5.1.2e @ec.europa.eu>

Sent: Tuesday, December 22, 2020 10:05 AM

To 5.1.5 5.1.2e @ec.europa.eu>

Subject: Coronavirus: ESI and rapid antigen tests - Commission signs contract

Dear Members of the Health Security Committee,

We are pleased to inform you that the Commission has signed a contract for the supply of rapid antigen tests for up to 100,000,000 EUR for donation to the Member States.

Drawing on the Emergency Support Instrument, the Commission mobilised 100m EUR of funding and reached a framework agreement with healthcare companies Abbott and Roche, which would allow the purchase of more than 20 million tests. From the first quarter of 2021, these tests will be made available to Member States, with the coordination and support of the Commission.

More specifically, the test of Abbott is the Panbio COVID-10 Ag Rapid Test Device and for Roche it is the SARS-CoV-2 Rapid Antigen Test. Further technical details are in attachment (Minimum requirements RAT). The World Health Organisation has recommended use of both of these tests for antigen-detection of SARS-CoV-2 infection:

https://extranet.who.int/pqweb/sites/default/files/documents/201002 eul sars cov2 product list.pdf

These rapid antigen tests will help to cover current testing needs and will be distributed amongst the Member States, based on an allocation key, taking into account advice from the European Centre for Disease Prevention and Control, which was based on healthcare workers per country. In the attached PDF you find an approximation of the number of tests for each Member State. These numbers are subject to change and we kindly ask that you treat these as confidential and only distribute on a need-to-know basis within your competent authority.

The European Commission will sign individual donation contracts with Member States who are interested to receive tests. Deliveries can take place only upon signature of the donation contract.

To organise distribution of the tests, we will require from you:

- Confirmation that your country wants to receive a rapid antigen test donation
- Focal point: name and contact details (email and phone number)
- Confirmation of delivery locations (maximum of 2 per country)
- Information needed to prepare the donation contract

Please provide this information in the two attached templates.

We invite you to provide the requested information by e-mail to 5.1.2e @ec.europa.eu as soon as possible, at the latest by 29 December 2020.

We would be thankful if you could acknowledge the reception of this email.

Kind regards,