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**From:** [redacted] 5.1.2e  
**Sent:** Thur 12/2/2021 1:53:02 PM  
**Subject:** FW: Flash report HSC meeting 01/12 11:00-13:00 + presentations  
**Received:** Thur 12/2/2021 1:53:04 PM  
[3.c COVID-19 paediatric vaccination questions.pdf](#)  
[CH 20211201\\_hsc.pdf](#)  
[UK 20211201\\_HSC update-FinalV1.0.pdf](#)  
[2.a HSC ECDC Omicron 1 December 2021.pdf](#)  
[3.a EMA Cavaleri 5 11yrs HSC 1Dec2021.pdf](#)  
[3.b Pharris ECDC Childrens vaccination HSC 1 Dec 2021.pdf](#)

Beste collega's,

Bijgaand vinden jullie ook het flash report en de PowerPoint-presentaties van de tweede HSC-bijeenkomst van woensdag 1 december.

Met vriendelijke groet,

[redacted] 5.1.2e

**Van:** [redacted] 5.1.2e <[redacted] 5.1.2e @minvws.nl>

**Verzonden:** donderdag 2 december 2021 14:43

**Aan:** [redacted] 5.1.2e <[redacted] 5.1.2e @minvws.nl>; [redacted] 5.1.2e <[redacted] 5.1.2e @minvws.nl>; [redacted] 5.1.2e <[redacted] 5.1.2e @minvws.nl>; [redacted] 5.1.2e @rivm.nl; [redacted] 5.1.2e @rivm.nl;  
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**Onderwerp:** FW: Flash report HSC meeting 01/12 11:00-13:00 + presentations

**Van:** [redacted] 5.1.5 @ec.europa.eu

**Verzonden:** donderdag 2 december 2021 14:42:24 (UTC+01:00) Amsterdam, Berlijn, Bern, Rome, Stockholm, Wenen

**Aan:** [redacted] 5.1.5 @ec.europa.eu

**Onderwerp:** Flash report HSC meeting 01/12 11:00-13:00 + presentations

Dear members of the Health Security Committee,  
 Dear colleagues,

Please find below the Flash report of yesterday's HSC meeting that took place from 11:00 to 13:00, as well as the presentations that were displayed. You will also find at the bottom of the message all the links from WHO's presentation.

Kind regards,

[redacted] 5.1.2e

**Health Security Committee 01/12/2021 – EU/EEA countries and observers**  
**Audio meeting**  
**Draft Summary Report**

**1. Latest updates on the Omicron variant**

Since 26 November 2021, the variant Omicron has been rated as Variant of Concern and the Member States have applied travel restrictions from selected African countries. ECDC informed the HSC that so far 135 cases are detected in the EU/EEA, of which 57 cases are confirmed and 78 considered as probable case. More data is needed regarding vaccination efficacy and severity of

disease among confirmed and probable Omicron cases. UK and CH provided updates. The COM highlighted that it would be important to discuss enhanced testing, quarantine and contact tracing over the next two weeks.

## 2. World Health Organization on Covaxin

As WHO recently added COVAXIN to the list of COVID-19 vaccines for emergency use, it provided the HSC with an overview of the features of prequalification and the Emergency Use Listing, non-clinical and clinical studies carried out for the approval of the COVID-19 vaccines, as well as an overview on the COVAXIN quality review, vaccine efficacy, Immunogenicity, vaccine safety and a benefit/risk assessment. A background [document](#) on the Bharat Biotech BBV151 COVAXIN vaccine is available in public domain. The document provides granular data from clinical studies on vaccine efficacy and safety.

## 3. Paediatric vaccination

On 25 November, EMA [published](#) their position on children's vaccination, granting an extension of indication for Comirnaty to include use in children aged 5-11 years. EMA informed the HSC about the study population, immunogenicity, vaccine efficacy and the safety database. So far, the benefit risk is positive, the reactogenicity is acceptable, no particular safety concerns, no cases of myocarditis. The study size did not allow detection of rare adverse events.

In line with EMA, ECDC has published its latest [report](#) on COVID-19 vaccination for children 5-11 years old. Children aged 5-11 years who are at risk of severe COVID-19 should be considered a priority group for vaccination against COVID-19. COVID-19 vaccine safety data in children in this age group are currently limited. Before taking policy decisions on COVID-19 vaccination for children, potential harms and benefits should be considered alongside the vaccine uptake and epidemiological situation in a particular region.

AT is the only EU country that has actually started to vaccinate children 5-11 years old. Many other countries (e.g. DE, NO, IT, FR) are assessing the EMA opinion nationally and will make national recommendations. They would likely use existing structures like specific vaccination centres but also schools to deliver the vaccines. Specific communication materials for parents/carers are under preparation.

### WHO's links:

PQT/VXA procedure [TRS 978, Annex 6 (2013)]

[http://www.who.int/entity/immunization\\_standards/vaccine\\_quality/TRS\\_978\\_61st\\_report\\_Annex\\_6\\_PQ\\_vaccine\\_procedure.pdf](http://www.who.int/entity/immunization_standards/vaccine_quality/TRS_978_61st_report_Annex_6_PQ_vaccine_procedure.pdf)

Programmatic Suitability for Prequalification

[http://www.who.int/immunization\\_standards/vaccine\\_quality/pspq2\\_v140512.pdf](http://www.who.int/immunization_standards/vaccine_quality/pspq2_v140512.pdf)

EUL Procedure and Questions and Answers

[https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/EUL\\_PQ\\_Vaccines/en/](https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/EUL_PQ_Vaccines/en/)

Target product profile

[https://www.who.int/docs/default-source/blue-print/who-target-product-profiles-for-covid-19-vaccines.pdf?sfvrsn=1d5da7ca\\_5&download=true](https://www.who.int/docs/default-source/blue-print/who-target-product-profiles-for-covid-19-vaccines.pdf?sfvrsn=1d5da7ca_5&download=true)

Evaluation criteria and EOI.

[https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/resources/1\\_EOI-Covid-19\\_Vaccines.pdf?ua=1](https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/resources/1_EOI-Covid-19_Vaccines.pdf?ua=1)

Roadmap

<https://www.who.int/publications/m/item/roadmap-for-evaluation-of-astrazeneca-azd1222-vaccine-against-covid-19>

Contact: 5.1.5 [@who.int](#)