Superior Health Council

YOUR LETTER DATED Mail January 26, 2022 (evening)
YOUR REF.

OUR REF. SHC 9693
DATE 28/01/2022

ENCLOSURE(S) -

Ter attentie van de Ministers van de IMC Volksgezondheid

A l'attention des Ministres de la CIM Santé Publique

SUBJECT : URGENT REQUEST - Booster vaccination against COVID-19 for children and adolescents aged 12-17 years
DEADLINE: 28 January 2022

The Superior Health Council (SHC) received on Wednesday January 26 (evening) an urgent request for advice from the Belgian Interministerial Conference on Public Health on the need of a booster dose of COVID-19 vaccination for children and adolescents aged 12-17 years.
In Belgium, booster doses are already recommended for the general Belgian population since December 2021 for all persons over 18 years of age (SHC 9683, 2021) and recently also for all immunocompromised patients over 12 years of age (SHC 9691, 2022).

CURRENT POSITION OF THE SHC

At this time and stage of knowledge, the scientific evidences supporting the administration of a booster dose of COVID-19 vaccination for children and adolescents aged 12-17 years, especially in the context of Omicron, are insufficient for the SHC to support it with a sufficient level of evidence for the usefulness, effectiveness, need and safety in terms of public health.
As already discussed at the NITAG meeting of January 20 2022 and confirmed by the Board of the SHC on January 27 2022, the SHC decided to wait for the EMA recommendation and for more scientific evidence before giving an opinion. More information could be collected on COVID-19 booster vaccination of adolescents from 12 years of age at the international NITAG webinar on the subject which will take place on February, 4.
The SHC recommends that the Belgian Authorities strongly advocate for standardization of the rules relating to CSTs and the obligation to vaccinate against COVID-19 at European Union and global level. Pending this hypothetical standardization of the rules, the SHC proposes that the FAMHP-EMA and the Belgian Vaccination Task Force take responsibility (at the safety level) for making the booster doses available (or not). And this, for all people (children - teenagers - adults) who must or wish to travel in Europe and around the world for family, friendship, leisure and/or professional reasons. The latter must be duly informed that there is no EMA approval yet.

Prof. Jean Nève.
President of the Superior Health Council

Dr. Yves Van Laethem,
President of the NITAG.

ELABORATION AND ARGUMENTATION

List of abbreviations used

CDC	Centers for Disease Control and Prevention
COSV	*Conseil d'orientation de la stratégie vaccinale* - France
COVID-19	Coronavirus disease 2019
CST	Covid Safe Ticket
EMA	European Medicines Agency
FAMHP	Federal Agency for Medicines and Health Products - Belgium
HAS	Haute Autorité de Santé – France
NITAG	National Immunization Technical Advisory Group
RKI	Robert Koch Institut - Germany
SHC	Superior Health Council - Belgium
STIKO	*Ständige Impfkommission* - Germany

1. Belgian data (Sciensano)[1]

1.1 Vaccination coverage of 12-17 year-olds

The table below shows the vaccination coverage rate on 19 January 2022 among fully vaccinated children under 18 years of age. The table also shows the number of fully vaccinated children aged 12-15 and 16-17 since the start of the vaccination campaign and in the last seven days, for Belgium and per region/community.

Leeftijds-groep		België	Brussel	Vlaanderen	Wallonië	Duitstalige Gemeenschap
12 tot 15 jaar	Aantal personen gevaccineerd	399 280	24 386	257 055	114 290	2 064
	Toename afgelopen 7 dagen	1 034	157	294	547	25
	Vaccinatiegraad volledig gevaccineerd(1) (%)	74,85%	42,22%	85,88%	66,07%	61,14%
16 tot 17 jaar	Aantal personen gevaccineerd	211 493	14 766	126 827	67 593	1 279
	Toename afgelopen 7 dagen	400	77	136	173	4
	Vaccinatiegraad volledig gevaccineerd(1) (%)	83,39%	55,29%	90,21%	79,88%	75,41%

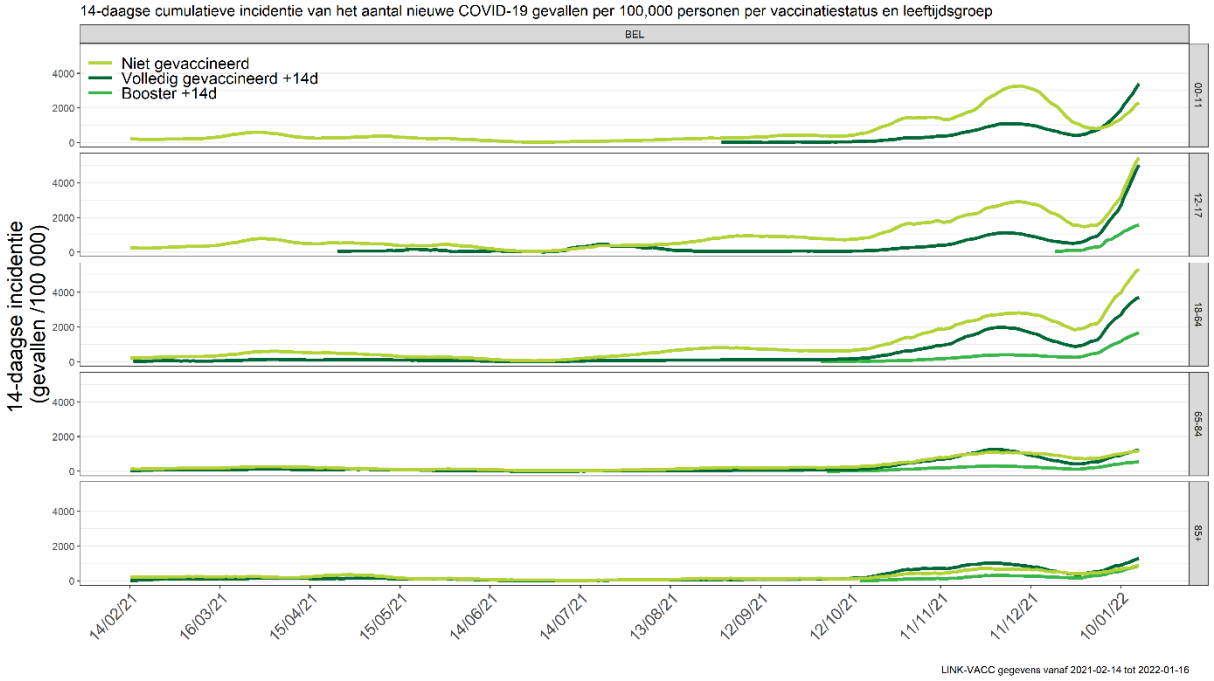
(1)De noemers zijn gebaseerd op de Belgische bevolkingscijfers van 01/01/2021 gepubliceerd door STATBEL.

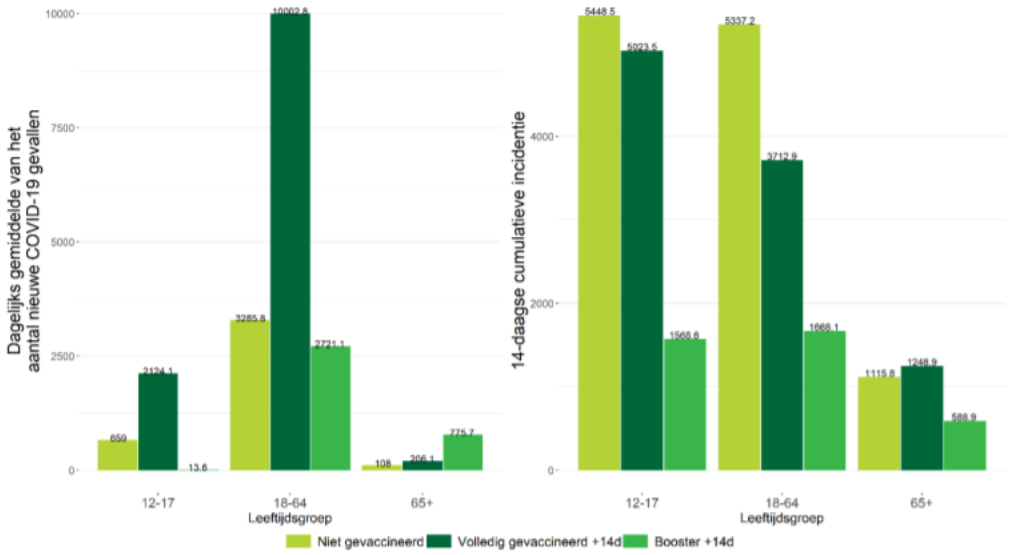
Primary vaccination against COVID-19 for children and adolescents is not evenly distributed between Belgian regions. We should continue to prioritize primary vaccination.

[1] https://covid-19.sciensano.be/sites/default/files/Covid19/COVID-19_Weekly_report_FR.pdf
https://covid-19.sciensano.be/sites/default/files/Covid19/COVID-19_Weekly_report_NL.pdf

1.2 Monitoring of confirmed COVID-19 disease cases

The graphs below show the daily average and the cumulative 14-day incidence for the number of cases, by vaccination status and age group, for the period from 3 January to 16 January 2022.

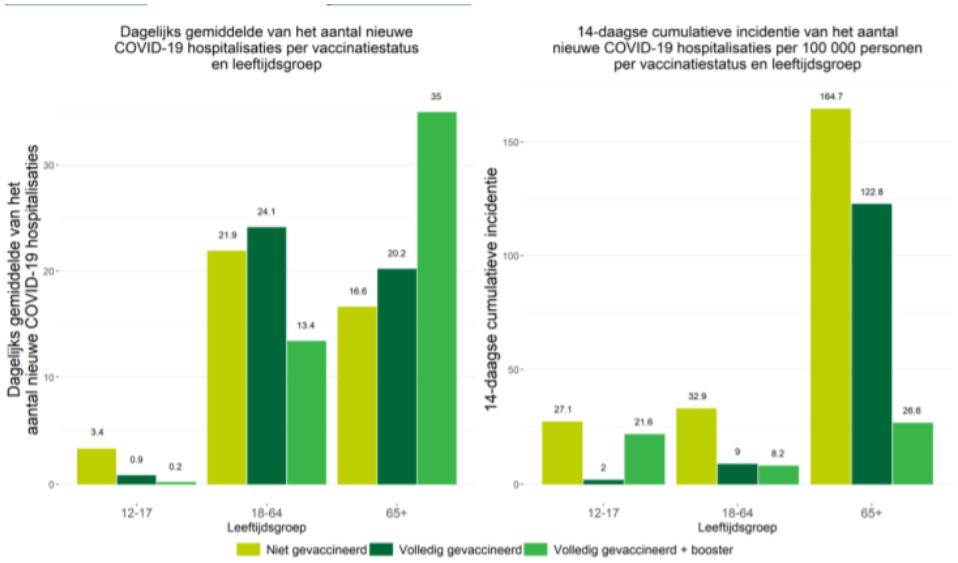


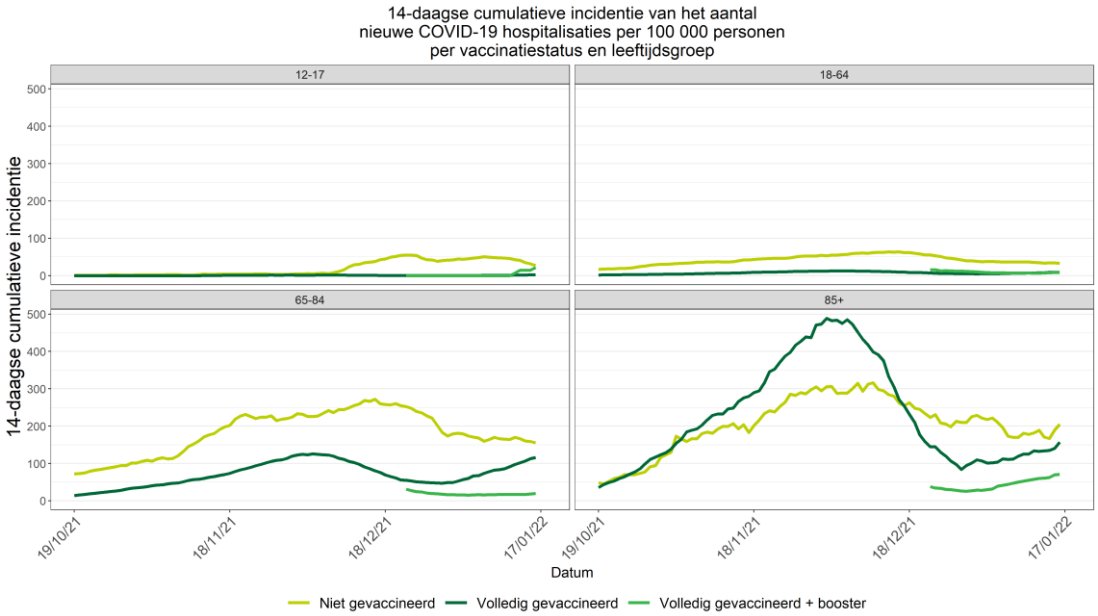


The incidence rate is rising in 12-17 years for vaccinated and un-vaccinated children and adolescents. Shortly after booster vaccination, a reduction in COVID-19 cases is noticed.

1.3 Hospitalization

The graphs below show the average number of hospital admissions per day and the cumulative incidence over 14 days, by vaccination status and age group, for the period from 3 to 16 January 2022.





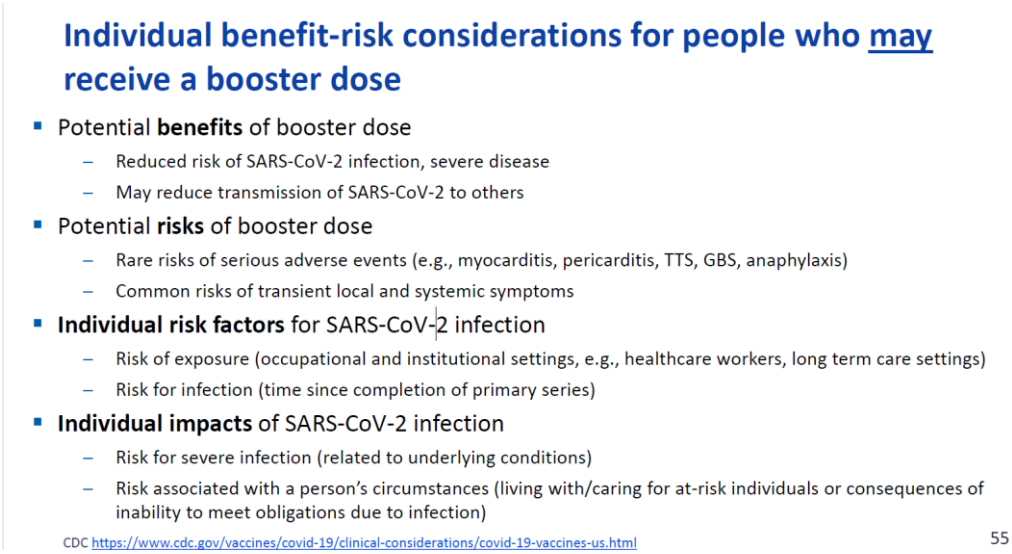
The hospitalization admission cumulative incidence remains low for children and adolescents between 12-17 years (too low numbers to draw conclusions at this moment)

2. Country recommendations booster dose of COVID-19 vaccination for children and adolescents aged 12-17 years

2.1 United States[2]

A booster dose of COVID-19 vaccine is recommended by CDC for everyone aged 12 years and older (Pfizer-BioNTech for ages 12–17; an mRNA vaccine preferred for ages 18 years and older):

- At least 5 months after completion of an mRNA vaccine (Pfizer-BioNTech or Moderna) primary series.
- At least 2 months after completion of a Janssen COVID-19 Vaccine primary dose.
- This decision was based on individual benefit-risk considerations acknowledging that there is limited data directly on the impact of boosters in adolescent population.



(slide 55 from presentation S Oliver, CDC)

2.1 France

December 24, 2021, The HAS recommends the administration of a booster dose in adolescents aged 12 to 17 years suffering from immunodeficiency (pathological and drug-induced) or a co-morbidity at risk of a severe form of the disease, in the same way as adults. The HAS will decide later on the administration of this booster to all adolescents aged 12 to 17. Indeed, the clinical trial conducted by the Pfizer laboratory to assess the efficacy and safety of a booster dose in adolescents is underway. Furthermore, the dosage schedule (full dose or paediatric dose) has not yet been determined[3].

[2] Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

[3] https://www.has-sante.fr/jcms/p_3306924/fr/avis-n-2021-0088/ac/sespev-du-23-decembre-2021-du-college-de-la-haute-autorite-de-sante-relatif-a-la-diminution-du-delai-entre-primovaccination-et-administration-d-une-dose-de-rappel-et-a-l-administration-d-une-dose-de-rappel-chez-les-adolescents-fragiles-ages-de-12-a-17-ans

On January 24, 2022 the **COSV**[4] considered that the national immunisation strategy must give particular importance to the protection of young people. The current protection of 12-17 year old is undermined both by the high viral circulation linked to Omicron and the partial decline in immunity among those who were vaccinated at the start of the campaign during the summer of 2021. **Therefore, COSV recommends access to the booster for 12-17 year old. This booster could be given as early as 3 months after the primary vaccination,** in order to be consistent with other age groups.

2.2 Germany

On 20.1.2022, the 17th update of the COVID-19 vaccination recommendation was published.[5]

The current situation with the rapidly increasing SARS-CoV-2 case numbers due to the omicron variant and the feared consequences for the health care system in Germany, makes an expansion of the vaccination campaign necessary. The STIKO therefore recommends booster vaccination for 12- to 17-year-old children and adolescents with the mRNA vaccine Comirnaty in the age-appropriate dosage (30 µg). **The 3rd vaccine dose should be administered at a minimum interval of 3 months from the previous vaccination.**

Protection against SARS-CoV-2 infection by currently available vaccines decreases after a few months, even in the 12- to 17-year-old age group. In addition, the efficacy of vaccination in preventing symptomatic infections is significantly reduced by the omicron variant compared with delta infections. Booster vaccination (3rd vaccination) will again improve vaccine protection and also reduce the likelihood of transmission of SARS-CoV-2 infections. The goal is to mitigate the current exponential increase in SARS-CoV-2 infections as well as to reduce severe COVID-19 illnesses in the general population of Germany as much as possible.

STIKO points out that data on the effectiveness and safety of booster vaccination in 12- to 17-year-olds are still limited. However, the risk of severe vaccine side effects is considered to be very low; vaccine reactions are to be expected as after the 2nd vaccine dose or after the booster vaccination in 18- to 25-year olds.

- Children and adolescents with pre-existing illnesses should receive their booster vaccination as early as possible. In this way, symptomatic SARS-CoV-2 infections and illnesses can be reduced as far as possible during the current wave of infections.
- For children and adolescents without pre-existing conditions, the STIKO recommends a preferably longer vaccination interval of up to 6 months, as this provides better long-term protection for immunological reasons.

Only Comirnaty should be used for vaccination, since in this age group the risk of occurrence of myo/pericarditis after vaccination with Spikevax is higher than after Comirnaty.

[4] cosv-addedum-18_janvier2022-avis-23-decembre_2021-rappel-vaccinal-chez-les-adolescents-ages_de12-17_ans.pdf (solidarites-sante.gouv.fr)
[5] Epidemiologisches Bulletin 3/2022 (rki.de)

No current data are available on either the incidence of PIMS under omicron or the efficacy of booster vaccination in preventing PIMS in children and adolescents. However, it is plausible that booster vaccination also has a protective effect against PIMS.

2.3 Israel[6]

Start of the booster vaccination campaign in 12-17 years old since November 2021. A booster is given **three months after primary vaccination**. The decision was based on the opinion of their Ministry of Health's expert panel.

2.4 Italy

Decision of 5/01/22, same booster interval as for adults. Ministero della Salut "We confirm what was communicated in circular letter no. 41416 of 14/09/2021 and specify that it is possible to any of the two m-RNA vaccines authorised in Italy, Comirnaty BioNTech/Pfizer and Spikevax Moderna, can be used as an additional dose in subjects aged over 50 years. In Italy, Comirnaty by BioNTech/Pfizer and Spikevax by Moderna, can be used as an additional dose in subjects aged ≥ 12 years". http://www.quotidianosanita.it/allegati/allegato5348186.pdf

2.5 Switzerland

Switzerland[7] recommends booster vaccination 4 months after full vaccination (initial immunisation) for everyone aged 12 or over.

3. EMA

At this moment (January 27 2022), booster vaccination against COVID-19 for children and adolescents aged 12-17 is not yet approved by EMA. A recommendation by EMA is expected by next month.

4. Clinical evidence for boosting 12-17 year olds (real-world data)

At our knowledge, there is no scientific paper available on clinical effectiveness. Pfizer is conducting a study for this age group however results are not available yet (expected in at least 2 months).

5. Safety of vaccination against COVID-19 of children and adolescents aged 12-17 years

A recent published letter to the editor in the New England Journal of Medicine described myocarditis incidence in Israeli Adolescents. The risk estimates of myocarditis among male recipients in the 21 days after the first and second doses were 0.56 cases per 100,000 after the first dose and 8.09 cases per 100,000 after the second dose; the risk estimates among female recipients were 0 cases per 100,000 after the first dose and 0.69 cases per 100,000 after the second dose. The risk of myocarditis after receipt of the second vaccine dose

[6] Vaccines - Corona Traffic Light Model (Ramzor) Website (health.gov.il)
[7] Vaccination (admin.ch)

among male adolescents 12 to 15 years of age was estimated to be 1 case per 12,361; the corresponding risk among female adolescents was estimated to be 1 case per 144,439 (Mevorach et al., 2022).

In a presentation by S Oliver (CDC) based on Israeli data, it is **suggested that rates of myocarditis after a third dose <u>are likely lower</u> that what is seen after the second dose** (slide 28, Oliver S., CDC).

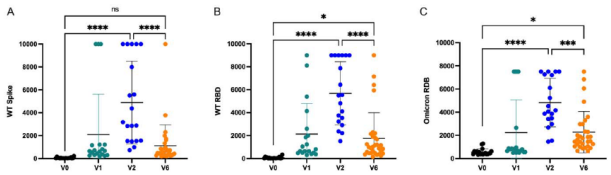
Data on safety of booster vaccinations for children are limited at this time.

6. Waning effectiveness of vaccination against COVID-19 for children and adolescents aged 12-17 years

A recent preprint study suggests that, compared to those who are unvaccinated, adolescents aged 12 to 16 who received two doses of the BNT162b2 vaccine have a lower risk of contracting SARS-CoV-2 infection, as detected by PCR, and a lower risk of symptomatic infection.
However, like adults, vaccine-induced protection against both SARS-CoV-2 infection and symptomatic infection wanes with time, starting three months after inoculation and continuing for more than five months (Prunas et al., 2022).

Burns et al. show that as seen in adult populations, mRNA vaccine-induced immunity wanes over a 6-month time period in adolescent children to near pre-vaccination levels. This finding demonstrates a vulnerability for infection in adolescent children ages 12-15 years, many of whom have now received their vaccine series over six months ago (Burns et al., 2022, figure below).

Figure 1: Adolescent anti-SARS-CoV-2 antibody responses over time. Humoral responses to a) Wildtype (WT) Spike b) WT Receptor Binding Domain (RBD), and c) Omicron RBD are quantified prior to vaccination, 2-3 weeks following the first vaccine dose, 2-4 weeks following the second mRNA vaccine dose, and 6 months following the second mRNA vaccine dose. Displayed as international units. Analysis by ANOVA. ns = not significant, * P < 0.05, *** P < 0.001, **** P < 0.0001

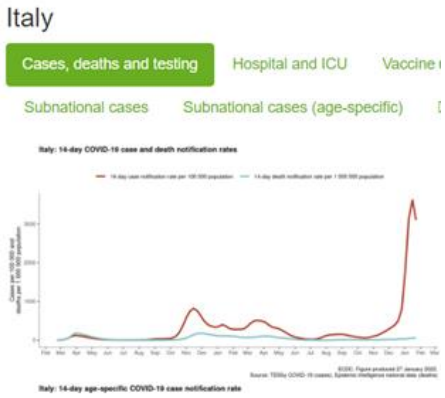


Preliminary studies show waning of effectiveness of COVID-19 vaccination after the second dose as previously also observed in the adult population.

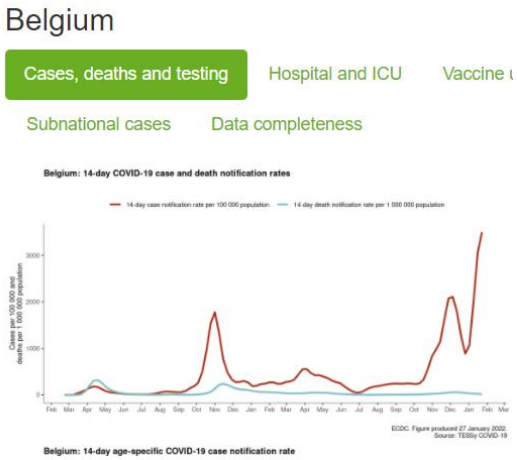
8. ECDC country overview: 14-day COVID cases

According to the latest ECDC data, the peak of Omicron (14-day COVID-19 cases) is already reached in these countries: Ireland, Finland, Cyprus, Greece, Italy and Spain (https://www.ecdc.europa.eu/en/covid-19/country-overviews).

Example of Italy (ECDC website consulted on 28/01/2022):



It is expected that in Belgium the peak will be reached in the coming week(s):



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