https://www.cbg-meb.nl/documenten/collegevergaderingen/2021/08/26/openbaar-verslag-985e-collegevergadering

https://www.ema.europa.eu/en/documents/minutes/minutes-cat-written-procedure-11-13-august-2021_en.pdf

Geachte heer Pols,

Verzoek

Op 23 februari 2022 heeft het College uw brief van 15 februari 2022 ontvangen. In uw brief verzoekt u het College, voor zover nodig op grond van de Wet openbaarheid van bestuur (Wob), om u een aantal verslagen te doen toekomen.

Op 23 februari 2022 heeft het College de ontvangst van uw verzoek bevestigd. Daarbij bent u verzocht om uw verzoek te verduidelijken omdat de nummers van de gevraagde verslagen in uw brief in de tweede zin afwijken. Het College heeft hierop geen reactie van u ontvangen. Het College is daarom bij de behandeling van uw verzoek ervan uitgegaan dat uw verzoek betrekking heeft op de openbare verslagen van de 973e, 977e, 978e, 984e, 985e, 986e, en 989e tot en met 996e Collegevergadering.

Op 24 maart 2022 is de beslistermijn van uw verzoek met vier weken verdaagd op grond van artikel 6, tweede lid, van de Wob. Op diezelfde dag bent u geïnformeerd dat de openbare verslagen van de 978e, 985e, 986e, en 989e tot en met 991e Collegevergadering op de website van het College staan gepubliceerd. Daarnaast bent u geïnformeerd dat de 984e Collegevergadering niet heeft plaatsgevonden waardoor er geen verslag zal volgen van deze vergadering.

Juridisch kader

Voor zover hier van belang:

Ingevolge artikel 1, aanhef en onder a, van de Wob heeft deze wet betrekking op de openbaarheid van documenten, zijnde een schriftelijk stuk of ander materiaal dat gegevens bevat, die bij een bestuursorgaan berusten.

Ingevolge artikel 3, eerste lid, van de Wob kan een ieder een verzoek richten tot een bestuursorgaan om informatie neergelegd in documenten over een bestuurlijke aangelegenheid.

Beoordeling en besluit

Beoordeling van het verzoek

U verzoekt het College om een aantal verslagen. Bij de behandeling van uw verzoek is het College ervan uitgegaan dat uw verzoek ziet op de openbare verslagen van de 973e, 977e, 978e, 984e, 985e, 986e, en 989e tot en met 996e Collegevergadering.

Het College maakt verslagen van Collegevergaderingen actief openbaar. Deze verslagen worden gepubliceerd op de website zodra zij zijn vastgesteld.

Een aantal van de door u opgevraagde verslagen van Collegevergaderingen is openbaar en staat op gepubliceerd op de website van het College. Het gaat hier om de verslagen van de 973e, 977e, 978e, 985e, 986e, en 989e tot en met 994e Collegevergadering. U kunt de verslagen raadplegen, bijvoorbeeld, via de koppeling 'openbaar verslag' onderaan de webpagina www.cbg-meb.nl/onderwerpen/over-cbg-het-college of door te zoeken op een gerelateerd trefwoord, zoals 'openbaar verslag', in de zoekbalk op de website van het College.

Een verslag van de 984e Collegevergadering is niet opgesteld omdat deze vergadering niet heeft plaatsgevonden. Van deze vergadering zal daarom geen verslag worden vastgesteld en dus ook niet openbaar worden gemaakt. De door u opgevraagde verslagen van de andere Collegevergaderingen zullen op de website worden gepubliceerd.

Het College is van oordeel dat hiermee voldoende wordt tegemoetgekomen aan uw verzoek.

Besluit

Het College verwijst u naar de website voor de openbare verslagen van de 973e, 977e, 978e, 985e, 986e en 989e tot en met 994e Collegevergadering. De openbare verslagen van de 995e en 996e Collegevergadering zullen ook binnenkort op de website worden gepubliceerd. Een openbaar verslag van de 984e Collegevergadering zal niet worden gepubliceerd omdat deze vergadering niet heeft plaatsgevonden.

CBG 985 25 augustus 2021

COVID-19 – ontwikkelingen op het gebied van behandelingen en vaccins

Informatie vertrouwelijk tot definitief besluit is weggelaten.
Vertrouwelijke informatie is weggelaten. De informatie betreft persoonlijke beleidsopvattingen ten behoeve van intern beraad.

Post-markering signalen COVID-19 vaccins

- *Pfizer/BioNTech (Comirnaty)* – hiervoor is een nieuw signaal gestart. Het betreft een melding vanuit Denemarken betreffende een 17-jarige jongen die het *multisystem inflammatory syndrome* ontwikkelde na de tweede vaccinatie met Comirnaty. Opgemerkt wordt dat een COVID-infectie ook kan leiden tot dit syndroom.
- *Janssen-vaccin* – tinnitus is als bijwerking opgenomen in de productinformatie. Dit is gedaan op basis van klinische studiedata en postmarketing data waaruit bleek dat bij een aantal leeftijdsgroepen de *observed vs. expected* ratio boven de 1 ligt. Op basis van eenzelfde redenatie is tevens voorgesteld om Veneuze Trombo-Embolie (VTE) als waarschuwing en bijwerking toe te voegen aan de productinformatie.
- Tot slot loopt er voor alle COVID-19 vaccins een beoordeling van '*menstrual cycle disorders and postmenopausal haemorrhage following vaccination*'.

Agendapunt 13.8 **Agenda's en verslagen van comités en werkgroepen ter informatie**

Agendapunt 13.8.a **CAT-verslag 11-13 augustus 2021**

Het College heeft kennisgenomen van het verslag van de *Committee for Advanced Therapies (CAT)* en de daarin besproken onderwerpen. Graag verwijst het College voor verdere informatie naar het openbare verslag van de CAT op de website van de CAT.

Agendapunt 14 **Rondvraag**

Er zijn geen punten voor de rondvraag.

Agendapunt 15 **Sluiting**

De voorzitter sluit de vergadering en bedankt alle aanwezigen voor hun inbreng.

CBG MEB

COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Vaxzevria (COVID-19 vaccin van Astrazeneca)

Eerder werd in de productinformatie van dit vaccin een waarschuwing opgenomen voor Guillain-Barré syndroom. Inmiddels zijn een aantal goed gedocumenteerde gevallen van Guillain-Barré syndroom bekend, waarbij andere oorzaken (dan het vaccin) waren uitgesloten. Dit heeft ertoe geleid dat Guillain-Barré syndroom nu ook als bijwerking is opgenomen in de productinformatie.

Zaken ter informatie

CAT 14-16 July

7.1.2. CAT's August 2021 written procedure

Scope: August 2021: process and timelines

Action: for adoption

7.2. Coordination with EMA Scientific Committees

7.2.1. CHMP learnings that impact CAT decisions

CAT: Jan Mueller-Berghaus, Romaldas Mačiulaitis, John-Joseph Borg, Bruno Sepodes, Sol Ruíz

Scope: CHMP learnings with relevance to CAT

Action: for information

7.2.2. Scientific Coordination Board (SciCoBo) – meeting of 29th June 2021

CAT: Martina Schuessler-Lenz

Scope: feedback on the discussions in the SciCoBo meeting

Action: for discussion

7.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

7.3.1. Working Party with Patients' and Consumers' Organisations (PCWP) and Working Party with Healthcare Professionals' Organisations (HCPWP)

Scope: minutes of the PCWP/HCPWP joint meeting that took place on 01-02 June 2021

Action: for information

7.3.2. Reflection paper on criteria to be considered for the evaluation of new active substance (NAS) status of biological substances

BWP: Roeland Martijn Van der Plas

CAT 11-13 Aug 2021

8 September 2021
EMA/CAT/458500/2021
Human Medicines Division

Committee for Advanced Therapies (CAT)

Minutes of CAT written procedure 11-13 August 2021

Chair: Martina Schüßler-Lenz; Vice-Chair: Ilona Reischl

Disclaimers

Some of the information contained in these minutes is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CAT meeting reports once the procedures are finalised.

Of note, these minutes are a working document primarily designed for CAT members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

Table of contents

CAT 8-10 sept

7.5. Cooperation with international regulators

7.5.1. WHO consultation on cell and gene therapy products

CAT: Ilona Reischl

Action: for information

Note: CAT members are asked to provide comments to Ilona Reischl cc. CAT secretariat by Tuesday 7 September

7.5.2. ATMP cluster teleconference with US-FDA, Health Canada and PMDA (Japan)

CAT: Martina Schuessler-Lenz

Scope: Feedback from the teleconference that took place on 22 July 2021

Action: for information

7.5.3. International Pharmaceutical Regulators Programme (IPRP) – Gene therapy and cell therapy working group

CAT: Pille Säälik

Scope: Agenda of the international teleconference that took place on 22 July 2021

Action: for Information

7.5.4. ATMP cluster teleconference with US-FDA, Health Canada and PMDA (Japan)

CAT: Martina Schuessler-Lenz

Scope: Topic for the agenda of the teleconference that will take place on 16 September 2021

Action: for discussion

7.8. Others

7.8.1. CAT stakeholder meeting on 26 October 2021

CAT: Martina Schuessler-Lenz

Scope: revision of agenda topics

Action: for discussion

Note: One of the topics is linked to the CAT work plan: Real World Data (RWD) in regulatory decision making of ATMPs.

8. Any other business

No items

Date of next CAT meeting:

06-08/10/2021

CAT 19-21 jan 2022

4.4. Finalisation of procedure

4.4.1. Non-replicating recombinant adeno-associated virus serotype 2 (rAAV2) encoding a soluble form of human CD59 (sCD59)

Intended for the treatment of geographic atrophy (via targeting the complement pathway)

Scope: The European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.2. VTXM01 messenger RNA (mRNA) encoding for an adenine base editor (ABE) and VTXG01 guide RNA (gRNA) targeting the proprotein convertase subtilisin/kexin type 9 (PCSK9) serine protease gene

Intended for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) who require additional lowering of low-density lipoprotein cholesterol (LDL-C) despite maximally tolerated lipid-lowering therapy

Scope: The European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.3. Autologous anti-CD19 chimeric antigen receptor T-cells

Intended for the treatment of CD19-expressing B-cell malignancies

Scope: The European Commission raised minor comments. ATMP scientific recommendation

Action: for adoption

4.5. Follow-up and guidance

No items

7.4. Cooperation with the EU regulatory network

7.4.1. Accelerating Clinical Trials in the EU (ACT EU)

Scope: This business-change programme aims to strengthen the European environment for clinical trials and was recently endorsed at both HMA November 2021 and EMA Management Board December 2021 meetings, including the accompanying paper outlining the objectives and priority actions for the ACT EU.

Action: for information

7.5. Cooperation with international regulators

7.5.1. Joint EMA-FDA Q&As on PRIME/Breakthrough applications (control strategy, process validation, stability, GMP)

DG members: Mats Welin, Sean Barry, Marcel Hoefnagel, Tone Agasoster, Kristofer Olofsson, Jobst Limberg, Giampiero Lorenti

Scope: Joint EMA-FDA Q&As on PRIME/Breakthrough applications

Action: for adoption

7.5.2. ATMP cluster teleconference with US-FDA, Health Canada and PMDA (Japan)

CAT: Martina Schuessler-Lenz

Scope: Agenda of the teleconference that will take place on 24 February 2022

Action: for information

EU 1234/2008

Article 21

Pandemic situation with respect to human influenza

1. By way of derogation from Articles 12, 18 and 19, where a pandemic situation with respect to human influenza is duly recognised by the World Health Organisation or by the Community in the framework of Decision 2119/98/EC of the European Parliament and of the Council ([9]), the relevant authorities or, in the case of centralised marketing authorisations, the Commission may exceptionally and temporarily accept a variation to the terms of a marketing authorisation for a human influenza vaccine, where certain non-clinical or clinical data are missing.

2. Where a variation is accepted pursuant to paragraph 1, the holder shall submit the missing non-clinical and clinical data within a time limit set by the relevant authority.

Article 22

Urgent safety restrictions

1. Where, in the event of a risk to public health in the case of medicinal products for human use or, in the case of veterinary medicinal products, in the event of a risk to human or animal health or to the environment, the holder takes urgent safety restrictions on its own initiative, it shall forthwith inform all relevant authorities and, in the case of a centralised marketing authorisation, the Commission.

If no relevant authority or, in the case of a centralised marketing authorisation, the Commission has raised objections within 24 hours following receipt of that information, the urgent safety restrictions shall be deemed accepted.

2. In the event of a risk to public health in the case of medicinal products for human use or, in the case of veterinary medicinal products, in the event of a risk to human or animal health or to the environment, relevant authorities or, in the case of centralised marketing authorisations, the Commission may impose urgent safety restrictions on the holder.

3. Where an urgent safety restriction is taken by the holder or imposed by a relevant authority or the Commission, the holder shall submit the corresponding application for variation within 15 days following the initiation of that restriction.

ANNEX III

Cases for grouping variations referred to in Article 7(2)(b)

1. One of the variations in the group is an extension of the marketing authorisation.

2. One of the variations in the group is a major variation of type II; all other variations in the group are variations which are consequential to this major variation of type II.

3. One of the variations in the group is a minor variation of type IB; all other variations in the group are minor variations which are consequential to this minor variation of type IB.

4. All variations in the group relate solely to changes of administrative nature to the summary of product characteristics, labelling and package leaflet or insert.

5. All variations in the group are changes to an Active Substance Master File, Vaccine Antigen Master File or Plasma Master File.

6. All variations in the group relate to a project intended to improve the manufacturing process and the quality of the medicinal product concerned or its active substance(s).

7. All variations in the group are changes affecting the quality of a human pandemic influenza vaccine.

8. All variations in the group are changes to the pharmacovigilance system referred to in points (ia) and (n) of Article 8(3) of Directive 2001/83/EC or points (k) and (o) of Article 12(3) of Directive 2001/82/EC.

9. All variations in the group are consequential to a given urgent safety restriction and submitted in accordance with Article 22.

10. All variations in the group relate to the implementation of a given class labelling.

11. All variations in the group are consequential to the assessment of a given periodic safety update report.

12. All variations in the group are consequential to a given post-authorisation study conducted under the supervision of the holder.

13. All variations in the group are consequential to a specific obligation carried out pursuant to Article 14(7) of Regulation (EC) No 726/2004.

14. All variations in the group are consequential to a specific procedure or condition carried out pursuant to Articles 14(8) or 39(7) of Regulation (EC) No 726/2004, Article 22 of Directive 2001/83/EC or Article 26(3) of Directive 2001/82/EC.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

FOR THE MONTH OF APRIL 2022

COMMISSION FILE NUMBER 001-39081

BioNTech SE
(Translation of registrant's name into English)

An der Goldgrube 12

Emergency Use Authorization

Emergency uses of the vaccine have not been approved or licensed by FDA, but have been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID 19) in either individuals 12 years of age and older, or in individuals 5 through 11 years of age, as appropriate. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Pfizer Disclosure Notice

The information contained in this release is as of April 14, 2022. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's efforts to combat COVID-19, the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine, the BNT162b2 mRNA vaccine program, and the Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY (COVID-19 Vaccine, mRNA) (BNT162b2) (including a potential application submission to the FDA for EUA of a potential booster dose of the Pfizer-BioNTech COVID-19 vaccine for children 5 through 11 years of age, qualitative assessments of available data, potential benefits, expectations for clinical trials, potential regulatory submissions, the anticipated timing of data readouts, regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply) involving substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data (including Phase 1/2/3 or Phase 4 data) for BNT162b2 or any other vaccine candidate in the BNT162 program in any of our studies in pediatrics, adolescents or adults or real world evidence, including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the ability to produce comparable clinical or other results, including the rate of vaccine effectiveness and safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial and additional studies, in real world data studies or in larger, more diverse populations following commercialization; the ability of BNT162b2 or any future vaccine to prevent COVID-19 caused by emerging virus variants; the risk that more widespread use of the vaccine will lead to new information about efficacy, safety, or other developments, including the risk of additional adverse reactions, some of which may be serious; the risk that preclinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when additional data from the BNT162 mRNA vaccine program will be published in scientific journal publications and, if so, when and with what modifications and interpretations; whether regulatory authorities will be satisfied with the design of and results from these and any future preclinical and clinical studies; whether and when submissions to request emergency use or conditional marketing authorizations for BNT162b2 in additional populations, for a potential booster dose for BNT162b2 or any potential future vaccines (including the potential application submission to the FDA for EUA of a potential booster dose for children 5 through 11 years of age and

potential future annual boosters or re-vaccinations) and/or other biologics license and/or emergency use authorization applications or amendments to any such applications may be filed in particular jurisdictions for BNT162b2 or any other potential vaccines that may arise from the BNT162 program, including a potential variant based, higher dose, or bivalent vaccine, and if obtained, whether or when such emergency use authorizations or licenses will expire or terminate; whether and when any applications that may be pending or filed for BNT162b2 (including the potential application submission to the FDA for EUA of a potential booster dose for children 5 through 11 years of age or any requested amendments to the emergency use or conditional marketing authorizations) or other vaccines that may result from the BNT162 program may be approved by particular regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine's benefits outweigh its known risks and determination of the vaccine's efficacy and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of a vaccine, including development of products or therapies by other companies; disruptions in the relationships between us and our collaboration partners, clinical trial sites or third-party suppliers; the risk that demand for any products may be reduced or no longer exist; risks related to the availability of raw materials to manufacture a vaccine; challenges related to our vaccine's formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; the risk that we may not be able to successfully develop other vaccine formulations, booster doses or potential future annual boosters or re-vaccinations or new variant based vaccines; the risk that we may not be able to maintain or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand for our vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine within the projected time periods as previously indicated; whether and when additional supply agreements will be reached; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; challenges related to public vaccine confidence or awareness; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

“Risico's en onzekerheden zijn onder andere de onzekerheden die inherent zijn aan onderzoek en ontwikkeling, waaronder het vermogen om te voldoen aan verwachte klinische eindpunten, aanvangen/of voltooiingsdata voor klinische proeven, indieningsdata van regelgeving, wettelijke goedkeuringsdata en/of lanceringsdatums, evenals risico's geassocieerd met preklinische en klinische gegevens (inclusief fase 1/2/3 of fase 4-gegevens) voor BNT162b2 of een ander vaccinkandidaat in het BNT162-programma in een van onze studies in kindergeneeskunde, adolescenten of volwassenen of bewijs uit de echte wereld, ***inclusief de mogelijkheid van ongunstige nieuwe preklinische, klinische of veiligheidsgegevens en verdere analyses van bestaande preklinische, klinische of veiligheidsgegevens”;***

"het vermogen om vergelijkbare klinische of andere resultaten te produceren, inclusief de snelheid van vaccineffectiviteit en veiligheids- en verdraagbaarheidsprofiel dat tot nu toe is waargenomen, in aanvullende analyses van de Fase 3-studie en aanvullende studies, in gegevensstudies in de echte wereld of in grotere, meer diverse populaties na commercialisering."

“het vermogen van BNT162b2 of een toekomstig vaccin om COVID-19 te voorkomen veroorzaakt door opkomende virusvarianten; het risico dat een breder gebruik van het vaccin zal leiden tot nieuwe informatie over de werkzaamheid, veiligheid of andere ontwikkelingen, waaronder het risico op extra bijwerkingen, waarvan sommige ernstig kunnen zijn.”

“het risico dat preklinische en klinische onderzoeksgegevens onderhevig zijn aan verschillende interpretaties en beoordelingen, waaronder tijdens het peer het risico dat preklinische en klinische onderzoeksgegevens zijn onderhevig aan verschillende interpretaties en beoordelingen, ook tijdens de peer review-/publicatieproces, in de wetenschappelijke gemeenschap in het algemeen en door regelgevende instanties, review/publication process, in the scientific community generally, en door regelgevende instanties;”

“of en wanneer aanvullende gegevens uit het BNT162 mRNA-vaccinprogramma zullen worden gepubliceerd in wetenschappelijke tijdschriftpublicaties en, zo ja, wanneer en met welke wijzigingen en interpretaties; of de regelgevende instanties tevreden zullen zijn met het ontwerp en de resultaten hiervan en alle toekomstige preklinische en klinische studies”

“of en wanneer indieningen om noodgebruik of voorwaardelijke marketing aan te vragenvergunningen voor BNT162b2 in extra populaties, voor een potentiële boosterdosis voor BNT162b2 of mogelijke toekomstige vaccins (inclusief de mogelijke indiening bij de FDA voor EUA van een potentiële boosterdosis voor kinderen van 5 tot en met 11 jaar en”

“potential future annual boosters or re-vaccinations) and/or other biologics license and/or emergency use authorization applications or amendments to any such applications may be filed in particular jurisdictions for BNT162b2 or any other potential vaccines that may arise from the BNT162 program, including a potential variant based, higher dose, or bivalent vaccine, and if obtained, whether or when such emergency use authorizations or licenses will expire or terminate;”