

To: [redacted] 5.1.2e [redacted] 5.1.2e @zva.gov.lv]; PDCO [redacted] 5.1.2e @lakemedelsverket.se]; [redacted] 5.1.2e @ema.europa.eu]

Cc: [redacted] 5.1.2e @legemiddelverket.no]; [redacted] 5.1.2e [redacted] 5.1.2e @uza.be]; [redacted] 5.1.2e [redacted] 5.1.2e @ema.europa.eu]; [redacted] 5.1.2e @eof.gr]; [redacted] 5.1.2e @eof.gr]; [redacted] 5.1.2e [redacted] 5.1.2e @legemiddelverket.no]; [redacted] 5.1.2e @fimea.fi]; [redacted] 5.1.2e @fimea.fi]; [redacted] 5.1.2e @hpra.ie]; [redacted] 5.1.2e @hpra.ie]; [redacted] 5.1.2e @aemps.es]; [redacted] 5.1.2e @aemps.es]; [redacted] 5.1.2e @anm.ro]; [redacted] 5.1.2e @anm.ro]; [redacted] 5.1.2e @chl.lu]; [redacted] 5.1.2e @bda.bg]; [redacted] 5.1.2e @eurordis.org]; [redacted] 5.1.2e @eurordis.org]; [redacted] 5.1.2e @umfcd.ro]; [redacted] 5.1.2e @umfcd.ro]; [redacted] 5.1.2e @orange.fr]; [redacted] 5.1.2e @orange.fr]; [redacted] 5.1.2e @quiron.es]; [redacted] 5.1.2e @quiron.es]; [redacted] 5.1.2e @opbg.net]; [redacted] 5.1.2e @opbg.net]; [redacted] 5.1.2e @phs.moh.gov.cy]; [redacted] 5.1.2e @phs.moh.gov.cy]; [redacted] 5.1.2e @aol.com]; [redacted] 5.1.2e @aol.com]; [redacted] 5.1.2e @ogyei.gov.hu]; [redacted] 5.1.2e @ogyei.gov.hu]; [redacted] 5.1.2e @infarmed.pt]; [redacted] 5.1.2e @infarmed.pt]; [redacted] 5.1.2e @gov.mt]; [redacted] 5.1.2e @gov.mt]; [redacted] 5.1.2e @infarmed.pt]; [redacted] 5.1.2e @phs.moh.gov.cy]; [redacted] 5.1.2e @phs.moh.gov.cy]; [redacted] 5.1.2e @ut.ee]; [redacted] 5.1.2e @ut.ee]; [redacted] 5.1.2e @amc.uva.nl]; [redacted] 5.1.2e @amc.uva.nl]; [redacted] 5.1.2e @umcg.nl]; [redacted] 5.1.2e @umcg.nl]; [redacted] 5.1.2e @kliinikum.ee]; [redacted] 5.1.2e @kliinikum.ee]; [redacted] 5.1.2e @opbg.net]; [redacted] 5.1.2e @opbg.net]; [redacted] 5.1.2e @ages.at]; [redacted] 5.1.2e @ages.at]; [redacted] 5.1.2e @gov.mt]; [redacted] 5.1.2e @gov.mt]; [redacted] 5.1.2e @fagg-afmps.be]; [redacted] 5.1.2e @fagg-afmps.be]; [redacted] 5.1.2e @ages.at]; [redacted] 5.1.2e @ages.at]; [redacted] 5.1.2e @dkma.dk]; [redacted] 5.1.2e @dkma.dk]; [redacted] 5.1.2e [redacted] 5.1.2e @zva.gov.lv]; [redacted] 5.1.2e @eof.gr]; [redacted] 5.1.2e @eof.gr]; [redacted] 5.1.2e @cbg-meb.nl]; [redacted] 5.1.2e @czd.pl]; [redacted] 5.1.2e @czd.pl]; [redacted] 5.1.2e @mhra.gsi.gov.uk]; [redacted] 5.1.2e @mhra.gsi.gov.uk]; [redacted] 5.1.2e @ms.etat.lu]; [redacted] 5.1.2e @ms.etat.lu]; [redacted] 5.1.2e @aemps.es]; [redacted] 5.1.2e @aemps.es]; [redacted] 5.1.2e @med.lu.se]; [redacted] 5.1.2e @med.lu.se]; [redacted] 5.1.2e @kbc-zagreb.hr]; [redacted] 5.1.2e @kbc-zagreb.hr]; [redacted] 5.1.2e @infektivnaklinika.mk]; [redacted] 5.1.2e @infektivnaklinika.mk]; [redacted] 5.1.2e @lakemedelsverket.se]; [redacted] 5.1.2e @bfarm.de]; [redacted] 5.1.2e @bfarm.de]; Dienstpostbus Paediatrics]; [redacted] 5.1.2e @cbg-meb.nl]; [redacted] 5.1.2e @fsm.it]; [redacted] 5.1.2e @fsm.it]; [redacted] 5.1.2e @pei.de]; [redacted] 5.1.2e @pei.de]; [redacted] 5.1.2e @ansm.sante.fr]; [redacted] 5.1.2e @ansm.sante.fr]; [redacted] 5.1.2e @sukl.sk]; [redacted] 5.1.2e @sukl.sk]; [redacted] 5.1.2e @vfn.cz]; [redacted] 5.1.2e @vfn.cz]; [redacted] 5.1.2e @sukl.cz]; [redacted] 5.1.2e @sukl.cz]; [redacted] 5.1.2e @fimea.fi]; [redacted] 5.1.2e @fimea.fi]; [redacted] 5.1.2e [redacted] 5.1.2e @cbg-meb.nl]; [redacted] 5.1.2e @aifa.gov.it]; [redacted] 5.1.2e @aifa.gov.it]; [redacted] 5.1.2e @bfarm.de]; [redacted] 5.1.2e @bfarm.de]; [redacted] 5.1.2e @vuvl.it]; [redacted] 5.1.2e @vuvl.it]; [redacted] 5.1.2e @anm.ro]; [redacted] 5.1.2e @anm.ro]; [redacted] 5.1.2e @ogyei.gov.hu]; [redacted] 5.1.2e @ogyei.gov.hu]; [redacted] 5.1.2e @kclj.si]; [redacted] 5.1.2e @kclj.si]; [redacted] 5.1.2e @pei.de]; [redacted] 5.1.2e @pei.de]; [redacted] 5.1.2e @ansm.sante.fr]; [redacted] 5.1.2e @ansm.sante.fr]; [redacted] 5.1.2e @sukl.cz]; [redacted] 5.1.2e @sukl.cz]; [redacted] 5.1.2e @bda.bg]; [redacted] 5.1.2e @bda.bg]; [redacted] 5.1.2e @libero.it]; [redacted] 5.1.2e @libero.it]; [redacted] 5.1.2e @pei.de]; [redacted] 5.1.2e @pei.de]; [redacted] 5.1.2e @chu-lyon.fr]; [redacted] 5.1.2e @chu-lyon.fr]; [redacted] 5.1.2e @kdb.hr]; [redacted] 5.1.2e @kdb.hr]; PDCO Secretariat]; [redacted] 5.1.2e @ema.europa.eu]; [redacted] 5.1.2e @ema.europa.eu]

From: [redacted] 5.1.2e

Sent: Fri 3/20/2020 10:41:56 AM

Subject: data on children around Europe, and paediatric literature COVID

Received: Fri 3/20/2020 10:43:20 AM

Dear PDCO members,

Thank you very much for all the information and initiatives, and to [redacted] 5.1.2e or proposing that people share data on children from their countries.

In agreement with PME office and with [redacted] 5.1.2e we would like to ask you to send any available data on children to me ([redacted] 5.1.2e @ema.europa.eu) and [redacted] 5.1.2e [redacted] 5.1.2e @ema.europa.eu) so that we can collect, collate and distribute to you as appropriate.

In this way we can avoid that information gets missed in the flow of e-mails

If you manage, please also specify in your mail the source of the data (e.g. your hospital; epidemiologic data form your country; etc.) and any other information that you deem relevant

Any available literature on children that you come across with, please send too.

Thanks you so much for your extraordinary response, engagement and collaboration

Kind regards!

[redacted] 5.1.2e

From: [redacted] 5.1.2e

Sent: 20 March 2020 11:13

To: PDCO

Cc: [redacted] 5.1.2e ; [redacted] 5.1.2e ; [redacted] 5.1.2e ; [redacted] 5.1.2e @eof.gr]; [redacted] 5.1.2e ; [redacted] 5.1.2e @fimea.fi]; [redacted] 5.1.2e @fimea.fi]; [redacted] 5.1.2e @hpra.ie]; [redacted] 5.1.2e @aemps.es]; [redacted] 5.1.2e @anm.ro]; [redacted] 5.1.2e @chl.lu]; [redacted] 5.1.2e @bda.bg]; [redacted] 5.1.2e @eurordis.org]; [redacted] 5.1.2e @umfcd.ro]; [redacted] 5.1.2e @orange.fr]; [redacted] 5.1.2e @quiron.es]; [redacted] 5.1.2e @opbg.net]; [redacted] 5.1.2e @phs.moh.gov.cy]; [redacted] 5.1.2e @aol.com]; [redacted] 5.1.2e @ogyei.gov.hu]; [redacted] 5.1.2e @infarmed.pt]; [redacted] 5.1.2e @gov.mt]; [redacted] 5.1.2e @infarmed.pt]; [redacted] 5.1.2e @phs.moh.gov.cy]; [redacted] 5.1.2e @ut.ee]; [redacted] 5.1.2e @amc.uva.nl]; [redacted] 5.1.2e @umcg.nl]; [redacted] 5.1.2e @kliinikum.ee]; [redacted] 5.1.2e @opbg.net]; [redacted] 5.1.2e @ages.at]; [redacted] 5.1.2e @gov.mt]; [redacted] 5.1.2e @fagg-afmps.be]; [redacted] 5.1.2e @ages.at]; [redacted] 5.1.2e @dkma.dk]; [redacted] 5.1.2e @dkma.dk]; [redacted] 5.1.2e @eof.gr]; [redacted] 5.1.2e @cbg-meb.nl]; [redacted] 5.1.2e @czd.pl]; [redacted] 5.1.2e @mhra.gsi.gov.uk]; [redacted] 5.1.2e @ms.etat.lu]; [redacted] 5.1.2e @aemps.es]; [redacted] 5.1.2e @med.lu.se]; [redacted] 5.1.2e @kbc-zagreb.hr]; [redacted] 5.1.2e @infektivnaklinika.mk]; [redacted] 5.1.2e ; [redacted] 5.1.2e @bfarm.de]; [redacted] 5.1.2e @cbg-meb.nl]; [redacted] 5.1.2e @fsm.it]; [redacted] 5.1.2e @pei.de]; [redacted] 5.1.2e @ansm.sante.fr]; [redacted] 5.1.2e @sukl.sk]; [redacted] 5.1.2e @vfn.cz];

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 5.1.2e @vuvl.lt; 5.1.2e @anm.ro; 5.1.2e @ogyei.gov.hu; 5.1.2e @kclj.si; 5.1.2e @pei.de;
 5.1.2e @ansm.sante.fr; 5.1.2e @sukl.cz; 5.1.2e @bda.bg; 5.1.2e @libero.it;
 5.1.2e @pei.de; 5.1.2e @chu-lyon.fr; 5.1.2e @kdb.hr; PDCO Secretariat; 5.1.2e; 5.1.2e

Subject: Re: Sv: Paediatric 'formulations' for COVID-19 treatment - input needed

Dear 5.1.2e

Numbers are changing day by day. To date, we have 111 COVID-19 patients here in Latvia. Three of them are paediatric patients - two teenagers and one preschool age child. All infected by their parents or family members who have returned from more seriously affected countries. All paediatric patients had mild symptoms and no one required hospitalisation or intensive care.

All the best,

5.1.2e

5.1.2e < 5.1.2e @lakemedelsverket.se> wrote: -----

To: 5.1.2e < 5.1.2e @legemiddelverket.no>, " 5.1.2e " < 5.1.2e @uza.be>, 5.1.2e
 5.1.2e @ema.europa.eu>, " 5.1.2e @eof.gr" < 5.1.2e @eof.gr>, 5.1.2e
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 " 5.1.2e @klinikum.ee" < 5.1.2e @klinikum.ee>, " 5.1.2e @opbg.net" < 5.1.2e @opbg.net>, " 5.1.2e @ages.at"
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 " 5.1.2e @sukl.cz" < 5.1.2e @sukl.cz>, " 5.1.2e @fimea.fi" < 5.1.2e @fimea.fi>, " 5.1.2e @cbg-meb.nl" < 5.1.2e @cbg-
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 " 5.1.2e @chu-lyon.fr" < 5.1.2e @chu-lyon.fr>, " 5.1.2e @kdb.hr" < 5.1.2e @kdb.hr>, PDCO Secretariat
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 < 5.1.2e @ema.europa.eu>

From: PDCO

Sent by: 5.1.2e

Date: 03/20/2020 10:47AM

Subject: Sv: Paediatric 'formulations' for COVID-19 treatment - input needed

Dear Colleagues,

If someone have data on a EU perspective, could you please provide data on how many children have been infected, how many are in need (numbers, age groups), number on requiring intensive care and if there are have been any deaths. It will then be easier to comment! Thank you!

Kind regards,

5.1.2e



5.1.2e

Therapeutics Team Leader, Senior Expert, Clinical Assessor
 Department of Efficacy and Safety 1

Swedish Medical Products Agency
 P.O. Box 26, SE-751 03 Uppsala, Sweden
 Visiting address: Dag Hammarskjöldsväg 42

Phone 5.1.2e switchboard: + 5.1.2e
 Fax: +46 5.1.2e
 5.1.2e @lakemedelsverket.se
www.lakemedelsverket.se

Classified as internal/staff & contractors by the European Medicines Agency

Från: 5.1.2e <5.1.2e @legemiddelverket.no>

Skickat: den 20 mars 2020 00:12

Till: 5.1.2e <5.1.2e @uza.be>; 5.1.2e <5.1.2e @ema.europa.eu>; 5.1.2e @eof.gr; 5.1.2e <5.1.2e @legemiddelverket.no>; 5.1.2e @fimea.fi; 5.1.2e @fimea.fi; 5.1.2e @hpra.ie; 5.1.2e @aemps.es; 5.1.2e @anm.ro; 5.1.2e @chl.lu; 5.1.2e @bda.bg; 5.1.2e @eurordis.org; 5.1.2e @zva.gov.lv; 5.1.2e @umfcd.ro; 5.1.2e @orange.fr; PDCO <5.1.2e @lakemedelsverket.se>; 5.1.2e <5.1.2e @lakemedelsverket.se>; 5.1.2e @quiron.es; 5.1.2e @opbg.net; 5.1.2e @phs.moh.gov.cy; 5.1.2e @aol.com; 5.1.2e @ogyei.gov.hu; 5.1.2e @infarmed.pt; 5.1.2e @gov.mt; 5.1.2e @infarmed.pt; 5.1.2e @phs.moh.gov.cy; 5.1.2e @ut.ee; 5.1.2e @amc.uva.nl; 5.1.2e @umcg.nl; 5.1.2e @kliinikum.ee; 5.1.2e @opbg.net; 5.1.2e @ages.at; 5.1.2e @gov.mt; 5.1.2e @fagg-afmps.be; 5.1.2e @ages.at; 5.1.2e @dkma.dk; 5.1.2e @zva.gov.lv; 5.1.2e @eof.gr; 5.1.2e @cbg-meb.nl; 5.1.2e @czd.pl; 5.1.2e @mhra.gsi.gov.uk; 5.1.2e @ms.etat.lu; 5.1.2e @aemps.es; 5.1.2e @med.lu.se; 5.1.2e @kbc-zagreb.hr; 5.1.2e @infektivnalinika.mk; 5.1.2e @lakemedelsverket.se>; 5.1.2e @bfarm.de; 5.1.2e @cbg-meb.nl; 5.1.2e @fsm.it; PDCO <5.1.2e @lakemedelsverket.se>; 5.1.2e @pei.de; 5.1.2e @ansm.sante.fr; 5.1.2e @sukl.sk; 5.1.2e @vfn.cz; 5.1.2e @sukl.cz; 5.1.2e @fimea.fi; 5.1.2e @cbg-meb.nl; 5.1.2e @aifa.gov.it; 5.1.2e @bfarm.de; 5.1.2e @vuvl.lt; 5.1.2e @anm.ro; 5.1.2e @ogyei.gov.hu; 5.1.2e @kclj.si; 5.1.2e @pei.de; 5.1.2e @ansm.sante.fr; 5.1.2e @sukl.cz; 5.1.2e @bda.bg; 5.1.2e @libero.it; 5.1.2e @pei.de; 5.1.2e @chu-lyon.fr; 5.1.2e @kdb.hr; PDCO Secretariat <5.1.2e @ema.europa.eu>; 5.1.2e @ema.europa.eu; 5.1.2e @ema.europa.eu

Ämne: Paediatric 'formulations' for COVID-19 treatment - input needed

Dear colleagues,

As you know, the PaedForm project focuses on collecting and publishing a paediatric formulary (production monographs) for highly needed formulations for children.

Right now, however, we are focusing on the COVID-19 setting, where children are in need for treatment (more or less well documented), but where suitable formulations most likely are not available. No high quality monographs anywhere, but still need for sound information and guidance.

The group would like to collect available approaches and where relevant to give additional advice on how to manage this challenging situation.

We therefore would like to ask your input on the following issues, based on your national experience, your own or from colleagues:

- **When treating younger children with any of the treatment options – what do you do, or recommend, or have available?**
 - **Authorised products? (paed formulations are few)**
 - **Manipulation/extemporaneous strategies and recommendations/experiences?**
 - **Hospital compounded products?**
- **For chloroquine, for hydroxychloroquine, for Lopinavir/Ritonavir (Kaletra), for Camostat, for other...?**

Thanks for your input, needed the sooner the better, to provide useful information to HCP throughout Europe.

Kind regards

5.1.2e

Šis elektroniskā pasta sūtījums un tajā esošie dokumenti var saturēt ierobežotas pieejamības informāciju. Ja neesat elektroniskā pasta sūtījumā norādītais adresāts, ar šo paziņojam, ka elektroniskā pasta sūtījumu esat saņēmis kļūdas rezultātā, un pilnīga vai daļēja iepazīšanās ar tā saturu, elektroniskā pasta sūtījuma izmantošana vai tālāka izplatīšana jebkāda veidā ir stingri aizliegta. Ja esat saņēmis šo vēstuli kļūdas dēļ, lūdzu nekavejoties sazināties ar sūtītāju, nosūtot atbildes e-pasta vēstuli, pēc tam vēstuli izdzēsiet (ieskaitot visus pielikumus). Drošības apsvērumu dēļ Zāļu valsts aģentūra var veikt elektroniskā pasta sūtījumu un tiem pievienoto dokumentu saturu monitoringu. Šis elektroniskā pasta sūtījums var būt pakļauts datu bojāšanai, pārtveršanai, neatļautai pielikumu pievienošanai, novēlotai vai nepilnīgai saņemšanai un citām nelikumīgām darbībām vai vīrusiem, par ko Zāļu valsts aģentūra nekādu atbildību neuzņemas.

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