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SEPTEMBER

MANIFESTO

[EN]

SARS-CoV-2 / COVID-19

2020 Corona Crisis

MANIFESTO

Call on European governments

10 resolutions for a new massive paper-strip test strategy

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Brussels September Manifesto

10 resolutions for a new massive paper-strip test strategy

SARS-CoV-2 / COVID-19 crisis measures

Call on European governments to take all the necessary measures required for

the mass production and distribution of Corona screening paper-strip self-tests

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- - - Resolution No. 01 - - -

This Brussels September Manifesto calls on European governments to take all the necessary measures required for the mass production and distribution of Corona screening paper-strip self-tests.

European citizens should be able to carry out saliva-based tests in the comfort of their own homes (24h/7d), in order to check their own SARS-CoV-2 infectiousness - or the absence of any such contagiousness.

Across Europe at present there is a need for 80 million 'rapid tests' per day. In our educational system alone, every school day at least 30 million of these paper-strip saliva tests are needed.

The failure of traditional € 100 per test diagnostic platforms (such as the classic RT-PCR tests), and the dire impact of this failure on European public opinion, shows that there is an urgent need for a new detection strategy: a massive population survey based on a sustained frequently-repeated anonymous superficial mass-screening program (in technical terms: 'COVID-19 public health surveillance').

In practice, there is simply no alternative that is as fast, cheap, user-friendly, effective, anonymous, useful and 'scalable' as the decentralized mass screening method advocated here. That is why the European authorities must finally take the decision to go all out for this preventive testing method. They must approve the do-it-yourself paper strip saliva testing regimen, and they must do so as soon as possible, bolstering its further development - with the utmost urgency - whilst also giving massive support to its production and distribution, and mass deployment.

The objective should be that European citizens can conduct at least 100 million saliva tests per day by 31 December 2020.

At a cost of less than € 1 per test, or at a total cost of less than € 100 million per day, this is - statistically speaking - the most efficient method to test whole cohorts of participants in European society, European educational institutions and overall European cultural and social life; and to get the European economy out of the doldrums by reopening society as much as possible. At the same time, the number of SARS-CoV-2 infections and the number of COVID-19 disease and death cases could be reduced extremely quickly, with a gentle hand, and sustainably.

Research shows - and on this topic there is general scientific consensus - that lowcost antigen screening tests can effectively help detect infectious 'corona cases'; and that the best (and most reliable) results are achieved when these rapid tests are applied very regularly (e.g. daily). When used sufficiently frequently by certain population groups, it may even be possible to reduce the number of COVID-19 disease cases in Europe to almost 0 ('close to zero'), because certain members of the statistically most relevant groups (at risk) and the members of these groups that have been recently infected and that should therefore be identified as potential asymptomatic virus spreaders, will immediately discover by way of such high-frequency testing that they are contagious indeed, before they can infect anyone else. This way, the virus is much less likely to spread in our society, while more medical, scientific and diagnostic resources will become available again to effectively combat the pandemic.

Thus, this kind of massive 'population screening', and the so-called 'COVID-19 public health surveillance' screening method that underpins it, not only protects the private interests of each and every individual self-test user, but also - in the first place - it will protect our common interest; starting with the public health of all Europeans.

It is, however, to be expected that the new screening regime such as the one advocated here (based on paper strip saliva tests) will - unfortunately but necessarily - have to be maintained until at least 2023; that is, either until the SARS-CoV-2 virus will have mutated in a positive way and decreased sufficiently in COVID-19 potency (which is unlikely), or until such time anti-viral or disease-modifying agents become sufficiently effective and / or until such time that durable neutralizing or non-neutralizing protective vaccines would be brought onto the market (which may be possible - by 2023 at the earliest), or until such time that all over Europe a minimum group immunity is reached after a sufficiently large cohort of the population has been vaccinated with an effective immune-sterilizing 'SARS-CoV-2 infection-protective' vaccine (which - hopefully by 2023 - is also possible).

Moreover, such expectations are to be compared and contrasted to the objectives of some purely 'COVID-19 disease-protective' emergency vaccines that are now in accelerated development (at the end of 2020), but that unfortunately will offer no or insufficient permanent protection against the viral SARS-CoV-2 infection risks, that are one of the hallmarks of this pandemic.
This is even more so because the aforementioned emergency vaccines (planned for 2021 at the earliest) offer an - in any case - uncertain outlook, even if their stated goals and expectations - in any case - are for some very limited levels of efficacy, officially: "the prevention or mitigation of DISEASE, NOT INFECTION", which in terms of effective COVID-19 disease control - according to their manufacturers' own official objectives - amounts to around 70% (and even then: only partial) protection against some major COVID-19 disease symptoms.

In other words, and so there be no misunderstandings on this issue: even if the intended rapid self-tests were to be massively introduced soon, the 'fundamental medical breakthroughs' generally hoped for by public opinion in the field of the viral SARS-CoV-2 transmission and transmissibility mitigation and / or in the field of COVID-19 treatment methods, are only - in the current state of affairs, according to the most optimistic forecasts - expected to materialize in the course of 2022-2023. That is why it will - in any case - always remain necessary, in line with the initial 'flatten the curve' 'infection-mitigation' pandemic strategy, to maintain many of the present prevention policies, in order to first reduce the number of SARS-CoV-2 infections - at all costs - and in order thereafter to mitigate them as much as possible.

- - - Resolution No. 02 - - -

Allow not only European citizens, but if useful also their schools, companies, universities and associations to carry out an (in principle non-binding) preventive paper-strip screening regimen among their members, as part of an extensive pandemic population screening, or to 'organize' massive group screenings themself. This means: allow these institutions to insist that their members should at regular times - for example every 4h / 12h / 24h / 36h / 48h, depending on the specific need - individually prove their own personal SARS-CoV-2 test NEGATIVITY.

And do this: without a doctor's prescription, based on simple antigen paper-strip saliva tests that yield a

sufficiently reliable result within 15 minutes (following the example of other paper 'litmus tests' such as the classic do-it-at-home HCG pregnancy urine tests).

In other words: completely change tack and implement a completely new, massive, decentralized screening-test regime, and distribute huge amounts of saliva tests among the population, which on the one hand can be carried out massively and quickly, without any medical intervention, and without any immediate need to call on specialized lab equipment or devices, but which on the other hand reliably demonstrate virus negativity, and thus turn into a 'VIRUS POSITIVE = NOT OK!' or 'NO GO' or 'NOT OK' test result if the user already is, or threatens to become, contagious (or in another rather exceptional situation in case of infrequent testing: if the user may just have been contagious but will certainly soon no longer be - which can then be easily verified by a new test a few hours later).

- - - Resolution No. 03 - - -

Make European citizens aware of the concrete actions that are expected following a positive "NO GO" / "NOT OK" test:

(1) Immediate self-isolation, until proof to the contrary.

(2) An instant 'confirmatory' paper-strip saliva test (i.e. a confirmatory test based on a different molecular composition, or even based on a slightly different monoclonal Ab technology).

(3) Self-tracing of the user's recent contacts since the last saliva test.

(4) Optionally an additional 'confirmatory' clinical diagnostic (RT-PCR) test.

Particularly appeal to the common sense and civic spirit of the users who carry out these saliva tests in the private sphere of their home, without any obligation to communicate the results to the competent authorities.

For important exceptions to this last principle, see the following Resolution No. 04.

- - - Resolution No. 04 - - -

Also appeal to common sense and civic duty, in case these screening tests are "organized"; for instance within the framework of educational institutions or associations, at public transportion enterprises or at the entrance of care facilities, at public offices or at private companies.

Depending on the concrete circumstances, and only so far as strictly necessary, such 'organized screening' results may be subject to direct, coercive individual or collective measures (such as, for example: isolation or quarantine), but only on condition that the privacy of each individual is respected, including certain basic social, labor law and other personal and/or collective human rights.

To be on the safe side in the context of extensive 'organized saliva tests', supply a number of alternative molecularly deviating 'confirmatory' saliva tests to some of these organizing bodies, which can serve as a double confirmatory test; for example in the event that one of the students, staff, teachers or other members would test positive, or in the event that a whole lot of rapid saliva tests would inexplicably show an exceptionally 'abberrant' number of positive or negative test results. Indeed, the probability of 'false positive' test results can generally be significantly reduced by means of such 'confirmatory' (double confirmation) tests. And in an effort to substantially increase quality control and out of an abundance of vigilance on the part of the 'organizing bodies' organizing and / or coordinating extensive test programs, the use of confirmatory 'validation tests' can also considerably reduce the risk of 'false negative' and/or 'false positive' test results (e.g. by implementing smart 'validation samples'). Therefore: give advance warning and sufficient information to the most obvious organizing bodies about the statistical impact of concepts such as prevalence, sensitivity and specificity on the likelihood of 'false positive' results, and make sure to explain to these 'organizing bodies' how to best monitor and deal with their group test results.

- - - Resolution No. 05 - - -

Inform all users that the massive use of rapid 1 € paper strip saliva self-tests should (in principle) not be confused with an (in principle) much more reliable medical diagnosis, nor with the (in principle) much more sensitive / specific clinical diagnostic tests (e.g. the classic 100 € RT-PCR tests), such as those carried out during the first 9 months of the pandemic (January to September 2020) as 'gold standard' of the established testing industry, on an exclusive basis by a monopoly of specialized, officially accredited laboratories.

Educate new test users of the pros and cons of rapid paper strip screening self-tests. Compare and contrast these self-tests especially with the traditional diagnostic RT-PCR tests, which are not only much more capital-, time- and labor-intensive (for example in terms of the required test equipment, medical personnel, overheads, waiting times, quality controls, etc.), but which often can also lead to life-threatening delays; for example, if an asymptomatic coronavirus super-spreader only finds out later that he / she was CORONA positive at the time of his/her test, but since that time has simply "kept walking around" while he / she (and the people in the immediate environment) from that moment onwards should have gone into urgent self-isolation (and quarantine) - a situation that still occurs all too often today, due to an (inherent) lack of sufficiently fast turnaround times of the traditional diagnostic RT-PCR tests.

Therefore, inform all the test users of the main characteristics of the intended paper strip saliva self-tests, and keep this information clear and easily understandable:

● Paper strip saliva self-tests are relatively less accurate: after all, they are slightly less sensitive and slightly less specific; which can have several consequences.

¤ On the one hand, this can give rise to a greater probability of 'false positive' results, √ which can subsequently be compensated for by an almost identical confirmatory saliva test (albeit with a different molecular composition), or by a classic RT-PCR test, or otherwise by simply repeating the same saliva test a few hours later.

¤ On the other hand, there is a limited risk of "false negative" test results - during a short period of a number of hours at the very beginning of the traditional Corona "infectivity peak", which in most cases tends to be asymptomatic; but this limited risk is in turn - certainly if considered across the entire population - offset by factors such as the following:
a) √ an anyhow relatively low individual "viral load" at the start of infectiousness/transmissibility;
b) √ a high probability of being 'caught' or 'discovered' in subsequent tests, given the typically-high (e.g. daily) test rate for a

representative user of paper-strip self-tests;
c) √ fast response times in case of the self-tests in comparison with the long turnaround times for highly specific and / or highly sensitive diagnostics where, instead of the hereproposed 15 minutes, the test results will take at least 6 to 24 hours and (all too) often even up to several days, leading to an increase of the actual risk of infection run by a 'positive' patient upon using high-quality albeit 'slow' 'test methods such as RT-PCR laboratory diagnostics, that may eventually turn out to be considerably riskier than in case the same test person - ceteris paribus - would have used a screening method based on the 'rapid' do-it-yourself saliva tests;
d) √ As a result of the massive deployment of the intended paper-strip saliva tests, many infectious virus carriers are indeed removed from the cohort (ie from the general population), and particularly at those very moments when they are the most contagious (ie during their SARS-CoV-2 infectiousness/trasmissibility peak).

● Paper strip saliva self-tests are considerably more effective: they are much easier to use (at home or outside), and they also provide their users with the intended 'GO - NO GO' test results much faster. This is particularly important when symptomatic or asymptotic Corona virus carriers are going through their viral peak (a period of approximately 60 to 72 hours, with the highest viral load and viral shedding, so with the highest transmissibility, i.e. with the highest risk of infection).

● Paper strip saliva self-tests are considerably cheaper (factor 1/100): after all, they consist (in principle) only of a paper strip test without further medical intervention. Since they are not capital-, labor- or time-intensive (and - at a rate of € 1 per test - are much more cost-effective), antigen saliva paper-strip tests make it possible to test on an individual basis much more frequently: for example daily, or on working days or school days, or prior to boarding an airplane, a bus or a taxi, or for example at very frequent, regular times: every 8, 12, 24 or 48 hours, etc.).

● Paper-strip saliva self-tests are massively 'scalable': unlike other means of testing they can be quickly and easily produced on a massive scale, almost without limits, as they consist of relatively simple paper-strips that are relatively easy to manufacture in specialized printing and packaging factories. Given the ultra-light nature of these strips, their distribution will also be lowcost and predominantly problem-free.

In particular, inform users of some key success drivers and extraordinary statistical characteristics of the self-tests:
(1) an almost 100% reliability in case of an acute increased risk of contagions, especially in the context of the rapid detection (in less than 15 minutes) of so-called 'super spreaders' during the most dangerous 'viral infectivity peak' of their infection (this is the period of 60-72 hours with the highest viral load, i.e. with the lowest RT-PCR cycle threshold, so in practice: with the highest contamination risk).
(2) a statistically advantageous leverage effect by way of the combination of 2 or more molecularly deviating saliva tests (for example from competing manufacturers): as stated above, there is a small probability indeed (less than 2%) of 'false positive' test results, but this probability will drop quickly after the initial positive test result, provided an additional confirmatory saliva test is also administered. Because of statistical effects it drops to less than 1 in 1000 (less than 0.1%) - which is certainly acceptable (e.g. from a Bayesian point of view), given all the other advantages offered by these antigen saliva tests.

Explain to the European citizens how these types of screening tests (despite their apparently somewhat less reliable characteristics and intervals) are preferable from a statistical-scientific point of view, and explain to them how this kind of test results can be put to best use.

Make sure to inform the European population about the global statistical / epidemiological added value of a rapid population screening based on saliva tests, in contrast to diagnostic tests such as the classic RT-PCR test, which in any case are too expensive, too slow and too cumbersome and too scarse to be rolled out on a similar 'massive scale', and which for that reason alone - but not only for that reason - cannot enjoy the same statistical leverage as the low-cost rapid tests. On the contrary: the high cost and the long turnaround times of high-quality diagnostic tests are undoubtedly a significant statistical-epidemiological disadvantage compared to the rapid antigenic self-tests.

With reference to these particular statistical features, convince European citizens of the economic and social necessity of individual self-testing as part of a massive, decentralized generalized pandemic population-screening that takes place hour after hour, day after day, week after week, by removing any test-positive cases 'from circulation' until they no longer test positive, and until they are therefore no longer contagious.

Inform European citizens - and this cannot be stressed enough - about the importance of following the test's user-instructions and manuals during the sample-taking and upon reading and interpreting the rapid test results; and of the statistical risks, complications and costs associated to the tests and to the test results; such as dammages associated not only with the correct or incorrect administration thereof, but also associated with the (regrettable) non-administration of said COVID-19 surveillance self-tests.

- - - Resolution No. 06 - - -

Assume that most users who test positive on their paper strip rapid self-tests, will then also very quickly want to use a traditional confirmatory diagnostic test in a professional medical environment (e.g. the classic RT-PCR test). Provide the necessary (additional) means to this end, and / or take the necessary awareness-raising measures to avoid facilities being overrun at the start of the new testing strategy.

In any case, provide sufficient 'confirmatory tests' (these are almost identical saliva tests, which differ slightly on a molecular level from the standard tests, and therefore can reliably determine whether or not the user is dealing with a 'false positive' result).
For example, with each lot of 100 standard tests, manufacturers could include at the very least 10-15 confirmation tests.
The tenders, specifications and order forms that are drawn up at the time of the purchase should provide for such an arrangement, as this 'second opinion' confirmatory backup system could very well prove very useful later on, to avoid or to solve a range of problems (for example sudden increase in 'false positive' testers) and other related inconveniences, displeasure, lack of confidence, etc. that should best be avoided.

Out of an 'abundance of caution', the authorities could also decide that the newly developed saliva tests must initially be introduced in phases, week-by-week, in order to avoid that technical problems or teething problems (for example in the event of sudden, unexpected rise in the numbers of 'false positives') would trigger

a run on the diagnostic PCR testing infrastructure.
Hence, it is recommended that sufficient preliminary testing and quality assurance is performed by all manufacturers (in consultation with the competent authorities), including sustained quality controls, to be carried out at the time of specification, of production, of distribution and during the administration of the massively deployed saliva tests.
Such quality checks may or may not coincide with any other scientific epidemiological research that will undoubtedly take place; such as the processing of certain results (like samples) in the context of the ongoing global European SARS-CoV-2 / COVID-19 pandemic population surveys.

In any case, communication surrounding all these aspects of particular risks or of teething problems or other technical problems should always be fast, clear and transparent; to make sure that user confidence in any of these rapid corona-self-tests is not undermined.
In view of the visible and tangible nature of the paper-strip self-tests, and in view of the relatively simple technology that underlies the proposed testing strategy (certainly when compared with current diagnostic test methods such as Ab or PCR), this should not be too much of a problem.

Moreover, the aforementioned considerations should not be made abuse of as a cause for delays in the design or during the project management of the new population screening. Necessary steps such as the drawing up and standardisation of specifications, designating inspection bodies, organizing logistics, preparing awareness campaigns, etc. should be given the utmost priority. After all, there is no time to waste.

- - - Resolution No. 07 - - -

Make all required public funds available (including emergency funding) required to finalize and expedite the new testing and screening regime and to procure the many billions of paper strip tests required for this public health campaign, in order to be massively distributed under the population, so that a sufficient amount of 'do it yourself saliva tests' becomes easily available to the average European citizen.

Insofar as - as is probably the case here - there is still a need for additional investments in the field of R&D / Logistics & Distribution / Marketing & P.R. awareness-campaigns in the context of the roll-out of these paper-strip rapid tests, additional public resources should be made available to overcome any remaining technical / logistical obstacles. This should be done in a far-reaching and decisive way, including by mobilizing all available academic brainpower and military resources, including subsidies for local industry and civil society organizations, and insofar as necessary including legal requisitions or expropriations.

Just as with the distribution of corona face masks, hand outs of saliva tests should be free, following the example of the free distribution of condoms or the free provision of diagnostic tests at the start of HIV-AIDS epidemic in the mid-1980s - a virus for which no effective vaccine has yet been developed (35 years after date).
Note: Despite the fact that the SARS-CoV-2 / COVID-19 pandemic offers significantly better survival prospects in case of infection or disease than the corresponding infection or illness at the start of the HIV / AIDS pandemic, the mantra should still be that prevention is better than cure, so that for the time being the prevention of viral SARS-CoV-2 infections deserves absolute priority, over the search for COVID-19 treatments or vaccines. After all, one cannot simply assume that this ongoing corona crisis situation will definitely be resolved within the next 6 months. And even then..

Moreover, there is an increasing need for a number of humane activities without face masks: certain social and family contacts, group education, sports and cultural events, etc. Such activities can only take place if adequate precautions and preventive measures are taken.

Prioritizing 'frequent and prompt testing' is an essential part of any proper corona infection prevention policy, with the aim of isolating as many infectious individuals as possible, so that normal life can continue and in order for our health facilities not to get 'exponentially' buried under an avalanche of urgent care-intensive COVID-19 cases. The saliva self-test population screening method, as advocated here, is the most effective / efficient (if not the only practically scalable / feasible) strategy to remove from all kinds of communities all over Europe as many, as quickly and as cheaply as possible any infectious cases - everywhere and anywhere in Europe; at least until they test negative again and thus no longer pose any danger to their fellow European citizens.

The inherent strength of the screening method lies in the bio-statistical and epidemiological effects of the continuous, frequent and massive self-testing of individual citizens, who will also immediately discover the outcome of their own test results. It is therefore essential that our fellow European citizens are provided with a massive number of tests, as soon as possible, so that they can start instant-testing themselves in massive numbers.

- - - Resolution No. 08 - - -

Act locally, Think globally: coordinate all measures at the central European level, and bring these measures under the authority of existing international institutions such as the European Commission and the WHO (and perhaps, if still useful or necessary, NATO).

Then, roll out a centrally coordinated wideranging self-test screening program, on a truly massive scale, at the national and regional levels, but in accordance with additional (overarching) European guidelines.

Conduct this new massive European population screening program on a scientific basis, preferably on the basis of the subsidiarity principle, on the basis of a strict enforcement policy and on the basis of reasonable attitudes and intergenerational solidarity:

♦ Scientific basis
Adjust the testing and screening policy to the latest scientific knowledge. Let European public health (and scientific insights into this public health) take precedence over the European economy.
Take science seriously: including public health economics, public health governance, virology, immunology, epidemics and bio-statistics.
Take the necessary public measures to protect European public health, but do so in the logistically most sensible and statistically most efficient manner; even if less accurate (sub-'Gold standard', sub-RT-PCR) testing means are to be used, such as antigen rapid self-tests.
Encourage the scientific debate, but establish a rapid scientific consensus on the most urgent political challenges that require central control (such as population screening methods based on antigen home tests), and communicate about this with one clear voice.
Thoroughly inform local political and health authorities of all centrally made

decisions, as well as of the scientific basis of these decisions.

♦ Subsidiarity
Do on the local level, what can best be arranged and implemented locally. Support local authorities with their policies.
But in the event - as in the case of the corona pandemic - that certain local authorities are in danger of losing control of the situation or that they clearly do not have sufficient command of policy, do not hesitate to intervene, coordinate and organize that policy in their place (and if necessary to also implement this policy in their place) at a higher, more centralized level. In the case of the Europe-wide self-test screening method: at the level of the European Commission, and / or at the national level of the member states.
In case this threatens to degenerate into all kinds of political debates, conduct these discussions with respect for science and by taking into account the policy input and proposals put forward by scientists. That is to say, subject the political decision-making process as much as possible to the established 'applied' scientific consensus.

♦ Enforcement policy
Implement a serious enforcement policy in the context of the corona measures and mandates that have been introduced; especially in the field of the corona face masks and of the corona self-tests. Thoroughly inform local enforcement authorities of all centrally made decisions and of the scientific basis of these decisions. And inform citizens about the medical and scientific consequences of their actions, and about the possible legal consequences of these actions; or of the not performing of such actions.

♦ Reasonable attitudes - Solidarity
As far as can reasonably be expected of European citizens, appeal to their understanding, to their intergenerational solidarity, and to their common sense and moral sense of civic duty.

Remind the European citizens of their individual responsibility for regularly carrying out the new rapid self-tests (conform the manufacturer's user instructions), and of their moral duty to correctly follow-up on the results of these self-tests.

Make clear to all that this is a jointly European effort, in which everyone has his / her responsibility and in which we all have an interest: from young to old, from North to South, from East to West.

By stressing these points, promote sustainable and democratic public support among the European population with regards to the necessity of the new SCREENING method (based on massive paper-strip self-tests), and to the necessity of the considerable public funds to be set aside for and of the other European emergency measures to be applied with this purpose.

Coordinate the development, specification, procurement, production and logistics required for this centralized European screening-testing regime. Organize this massive population survey like a military campaign, and make use of all possible means to turn it into a success. Always adapt the local tactics to the situation and to the people on the ground.

In a recent contribution, F. Vandenbroucke, R. Beetsma, B. Burgoon, F. Nicoli, A. de Ruijter (2020) conclude : “The EU can play an important role for Covid-19 in organizing health solidarity through a European public procurement process."

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EU SOLIDARITY IN HEALTH

Solidarity is explicitly recognized in EU law and policy. In the case of disasters, such as a pandemic, the European Treaties set out a clear mandate, at least in principle. Article 222 of the Treaty on the Functioning of the EU (TFEU) stipulates that solidarity demands that in case of a disaster, Member States are to provide assistance to one another and act jointly and in cooperation.
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EU HEALTH SOLIDARITY IN THE FACE OF DANGER

In order to understand the current role the EU can have with respect to organizing solidarity for responding to Covid-19, particularly with regard to the public procurement of pandemic medicines and medical countermeasures more generally, we should go back to 2009 with the global spread of a new virus, swine flu.
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In the year of the swine flu outbreak, new provisions in the Lisbon Treaty created the basis for the current EU role, by adding to Article 168 TFEU: “Union action, which shall complement national policies, shall be directed toward improving public health, [...]. Such action shall cover the fight against major health scourges, by promoting research into their courses, their transmission, and their prevention, as well as health information and education, and monitoring, early warning of, and combating serious cross-border threats to health.”
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Following Commission efforts in order to address some of the problems identified above, in 2013 Decision 1082/2013/EU of the European Parliament and the Council was adopted dealing with serious cross-border health threats. Again, however, Member States did not agree to a binding system for public procurement. Instead, Article 5 of the Decision created the legal basis for voluntary public procurement of medical countermeasures in case of a health emergency. The Joint Procurement Agreement (JPA) that further implements Article 5 entered into force in 2014. This agreement applies to joint procurement of medicines, medical devices and “other services and goods” needed to mitigate or treat cross-border threats to health.
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The EU can play an important role for Covid-19 in organizing health solidarity through a European public procurement process. The current system already has created a centralizing effect in a pre-purchase that was done with 15 Member States in 2019, and currently more of these processes are on the way.

Another route for a more central role for the EU could be under the heading of EU solidarity proper, rather than under that of the EU health law regime. The EU Civil Protection Mechanism based on Article 222 TFEU depends on the willingness of Member States to join forces. In 2019 the Mechanism was strengthened by “rescEU”, in an attempt to centralize EU capacities. Article 12 of this Decision provides for the EU to use its internal funds, pre-committed national funds, and EU co-financed Member States capacities at the disposal of EU efforts, to respond to a major emergency. This mechanism also creates the possibility for joint procurement, parallel to the JPA under the health infrastructure. Here, the Commission can assume a more central role, because the Decision allows for central EU implementation of decisions toward distribution and allocation. Nevertheless, the actual capacity of rescEU still largely depends on the willingness of Member States to contribute, and is likely substantially smaller than what can be nationally organized or through the JPA.
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POLICY SUGGESTIONS FOR AN EFFECTIVE WAY FORWARD

Across EU countries, there are large differences in healthcare systems. Systems differ not only in terms of the quality and available budgets, but also in terms of history, culture, and organization. There are valid reasons to respect the “subsidiarity principle” in healthcare matters, as deviations from this principle carry a danger of inefficiencies or may exacerbate inequalities: a central decision that ignores differences in national health arrangements could have widely varying impacts on Member States healthcare systems. The issue is different, however, when it comes to decisions related to infectious diseases, because such decisions may have large cross-border spillovers. In this case, “national prerogatives” may create a problem of collective action that yields, in the end, bad outcomes for everyone.

If the line of argument is accepted that claims based on “national prerogatives” now have to give way to true European solidarity, then the EU must prove that it can also support the Member States in a tangible way at the EU level. Therefore, the joint procurement initiatives both within the EU health regime (which can ensure size and volume) and the rescEU (which creates a central allocation authority for the Commission) are so important. However, “volume” and “central authority” do not coincide. It does not suffice for Member States to say that the EU should merely ensure the integrity of the single market and allow for unfettered free movement.

The EU will then also need to be empowered to set up real cooperation to keep citizens more safe.
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Europe is now paying the price for a lack of a centralized policy in the face of pan-European health threats. Countries are competing with each other to acquire medical countermeasures, for example by imposing export bans. The result is a decentralized outcome that is suboptimal in the sense of these products not always being allocated where they are most needed. However, in the current circumstances, legal threats from infringements of the internal market rules likely have little effect.

So what needs to be done? The EU urgently needs to develop and use a well-embedded and efficient central capacity for a truly centralized EU procurement of medical countermeasures as is outlined in rescEU, without the inefficiencies that are currently there as a result of the intergovernmental and voluntary nature of the process under the health regime and the legally embedded possibilities for behavior lacking in solidarity. Central procurement is needed for protective devices, and will certainly be needed for the vaccine against the Covid-19 virus once it becomes available. It will also be needed for future infectious diseases. Funding of the capacity can come from the EU budget or by levying a separate contribution from the Member States linked to their GDP, population, and demographics. Demographics is relevant, because countries with an elderly population make more use of medicines on average. It cannot be excluded that the proposed policy centralization has redistributive elements, which is the case when contributions are linked to per capita GDP. However, the relatively limited redistributive effects should be weighed against the benefits of centralization.

What are these benefits? First, by centralizing procurement it will be more difficult for pharmaceutical companies to play off Member States against each other by threatening not to supply to an individual Member States if it tries to negotiate lower prices. Secondly, with a common stockpile of medical countermeasures managed at the EU level, excess demand in some countries and excess supply in other countries, an obvious economic inefficiency, can no longer co-exist. Thirdly, and most importantly, because the stockpile is common and, hence, larger than any potential national stockpile, there is much greater firepower to target outbreaks of infectious diseases wherever and as soon they emerge. In other words, risk sharing against the consequences of pandemics becomes much more effective than when each country is responsible for its own stock of medicines and equipment.
..

Ideally, the EU sets up arrangements ex ante that are ex post credible. Obviously, Europe has missed the “ex ante” of the current crisis. However, this crisis may also provide a chance to get to solutions that are normally unthinkable. We have seen that during the European debt crisis when crisis arrangements like the ESM were set up. Our proposal for the centralization of procurement, stockpiling, and deployment decisions of medical countermeasures to infectious diseases is ex post credible, provided the design is right. This requires centrally controlled guidance on the use of medicines based on the pooled expertise and instructions of the European Medicines Agency and the European Centre for Disease Prevention and Control.

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(CESifo Forum 2 / 2020 July - Volume 21 - p.47-52 - F. Vandenbroucke, R. Beetsma, B. Burgoon, F. Nicoli, A. de Ruijter: 'Centralizing EU Policy in Fighting Infectious Diseases: Status Quo, Citizen Preferences, and Ways Forward' - https://dx.doi.org/10.2139/ssrn.3570550)

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- - - Resolution No. 09 - - -

Sharpen and elucidate among the European population the general basic knowledge of some fundamental scientific principles, so that our fellow European citizens - from young to old - can understand the importance of the individual paper-strip saliva auto-tests that they have to administer by them themselves, and at the same time raise the people's understanding of the global social role that each individual user of these massively deployed rapid tests can play in the context of the Europe-wide population survey.

In particular, increase the communication about basic scientific principles from the following domains: virology, epidemiology, medicine, public health, social welfare, economics, civil and human rights, civic duty and intergenerational solidarity.

Frame this foundational knowledge within the medical / scientific aspects that directly concern European citizens:

● the latest status and the latest developments in the context of all kinds of 'social distancing' and other preventive measures (lockdowns, red zones, curfews, etc.) that the authorities apparently find increasingly difficult to impose on their exhausted 'corona-ed out' citizens, in the attempt to 'flatten the curve';
● the latest state of the research into anti-viral drugs, or the lack thereof as of now;
● the current state of viral and post-viral COVID-19 medical treatment techniques (eg during hospital admissions), and their often long-term consequences (eg disability, rehabilitation, ...);
● the latest state of the research for a 100% effectively sterilizing vaccine (sterilizing effect is essential for protective SARS-CoV-2 transmission and transmissibility prevention);
● the latest state of the search for a 100% effectively neutralizing antibody vaccine (neutralizing action is essential to contain the damaging effects of the COVID-19 pandemic, and can also be fundamental to the development of sterilizing vaccines);
● the latest state of development(s) of the so-called emergency vaccine; and of the

rather limited objectives set by manufacturers (e.g.: no sterilizing or neutralizing effect; no long-lasting effect; only a partial protective anti-COVID-19 effect to combat some disease symptoms, and then in only 50 to 70% of the unabated SARS-CoV-2 infection cases);
● the latest state of research into the possible side effects of (all) the protective / neutralizing / sterilizing vaccines currently under development, and some of which have been the topic of doomsday reports, sometimes leading to so much fear and / or suspicion that there are not enough suitable participants (eg healthy elderly) willing to participate in the so-called phase 3 studies for these vaccines; forcing their developers and big pharma companies - despite their 'no-liability legal-immuninity vaccine mandates' - to start acting with much greater transparency and caution - in order to preserve their public credibility.
● the latest state of affairs in the global race for an emergency vaccine and / or for 100% effective SARS-CoV-2 sterilizing / neutralizing vaccines and / or for durable high-quality protective COVID-19 vaccines; where it is clear that the speed with which these vaccines are being tested and the whirlwind speeds at wich they will later be approved, distributed and deployed for emergency use, is indeed met with considerable scepsis and opposition from the European public hesitant to be vaccinated by such high-tech novelty experimental vaccines, so that here too - particularly as a result of the confusion surrounding these vaccines and their development - there is a real risk of additional obstacles to the rapid achievement of the so much hoped-for Europe-wide group immunity;
● the latest state of the art of traditional gold standard diagnostic tests (such as the classic RT-PCR test), and the inherent problems that these tests face time and again (logistical problems, long waiting times, shortage of reagents, etc.), which ensure that such highly specific / highly sensitive diagnostic tests are insufficiently 'scalable' and therefore - in practice - cannot be deployed quickly enough and / or at a sufficiently large scale;
● the current state of developments and scientific insights in the field of alternative testing methods (eg paper strip rapid saliva tests, eg home device Ab rapid tests, eg Ab lab tests, etc.); where researchers from several important international research institutions (Harvard University, Yale University, Cambridge University) are now calling for these massive screening tests to be massively developed, produced, deployed and used, or at least for these screening tests to urgently have their potential use scientifically explored. Incidentally, a number of pilot projects have also been run at the Universite de Liege and at Utrecht University, since the end of September 2020, to investigate the effectiveness of certain rapid saliva tests.

Anti-Viral Therapeutics & Emergency Vaccines:
Raise awareness and inform the European citizens, and make clear to them that both A) the current development of antivirals, and B) the development / introduction of some new emergency vaccines, will not suffice in the short to medium term to put an end to the high (exponential) risk of infection that is typical for the SARS-CoV-2 virus. Make clear to the European population that the emergency vaccines that are currently being tested are (for the time being) only aimed at a very limited scope of COVID-19 disease control objectives, but that they will certainly not be sufficient to effectively reduce the acute interpersonal SARS-CoV-2 contamination risks (which, for example, emanate from pre- and asymptomatic SARS-CoV-2 virus carriers, and particularly from the infamous Corona super-spreaders).

Hospital Treatment & Diagnostics:
Raise awareness and inform the European citizens, and make clear to them that the recent progress made in hospital treatment techniques will not suffice indeed, whereas the widespread use of traditional diagnostic testing techniques (such as RT-PCR) for purely technical-logistical reasons is simply not suitable to be expanded 50-fold, or to be transposed from the medical laboratories to the kitchen or to the bathroom, to the station, to the office or to the school campus; let alone that the time frame required for these diagnostic tests could easily be reduced to less than 15 minutes - let alone on the basis of a mere saliva sample. Nevermind the fact that the (overworked) services that run this overburdened RT-PCR test infrastructure, and which are under ever more pressure to reduce turnaround times for these testing platforms, are probably unable to guarantee the duefull protection of the privacy / anonymity of their patient data. Let alone that they could offer such privacy guarantees for the forseeable future. Incidentally, proposals are popping up all over Europe all the time that jeopardize the aforementioned anonymity / privacy of test user data.

Screening & Diagnostics:
Therefore, make clear to the European citizens that they should not be too hopefull or naive in the short to medium term. The mere "testing, testing, testing" paradigm or the mere approval of an "emergency vaccine" (whatever its ultimate efficacy may be) or the mere introduction of "new treatment techniques" will certainly not suffice to exit the crisis in the short to medium term.

Test Regimen & Pandemic Strategy:
Therefore, make clear to European citizens that they will have to adapt - in any case - to the fact that the recent profound behavioral changes, as adapted since March 2020, will also be necessary in the medium term (i.e. well into 2021 and 2022). And that thus - despite the obstacles described hereabove - the competent authorities will have to switch to a number of alternative strategies and new methods to reduce the acute (often invisible, because asymptomatic) contamination risks that arise in the context of this COVID-19 pandemic as caused by the SARS-CoV-2 virus, in their ongoing effort to mitigate the pandemic.
The most important tool - in addition to the classic face mask - to help European citizens keep up with the expected behavioral change (s) and with this kind of drastic social restrictions, is a new self-test screening regime based on paper-strip saliva tests.

ADVANTAGES of the New Screening Test Regimen:
● √ very fast test taking ~ carrying out a saliva test can be done very quickly, when appropriate or convenient (24h/7d)
● √ 'point of need' ~ carrying out the tests can be done wherever and whenever it is appropriate ~ unlike traditional (diagnostic) 'point of care' or laboratory tests
● √ routine job ~ daily users can take this test on their own in less than 1 minute on a routine basis, to read the result of the test less than a quarter hour later
● √ ready-to-use ~ new testing regime that can be immediately implemented ~ no need for new anti-viral drugs, no need for new medical treatment methods, no need for additional medically / para-medically trained personnel, no need to wait for the new 'emergency vaccines', no need for doctor visits or COVID-19 hospital admissions, no dire shortages of diagnostic test tube reagents, etc. ~ the necessary technology and infrastructure are already largely available
● √ ‘fast positives’ ~ virus positive cases get an almost instantaneous 'NO GO' or 'NOT OK' test result, and can adjust to this result immediately
● √ rapid isolation ~ virus positive testers can go into isolation immediately within 15 minutes after the test is administered, with the possibility of an additional 'confirmatory' saliva test and / or a

confirmation based on a gold standard clinical RT-PCR diagnosis
● √ possibility of immediate counter-assessments ~ direct access to a confirmatory test ~ for confirmation purposes, a limited number of identical paper-strip saliva tests are also supplied with every 100 paper strips that work on the basis of an alternative molecular composition (= double-check)
● √ "fast negatives" ~ virus negative cases get the 'GO' or 'OK' result of their test very quickly, and can continue the activities that are planned for the rest of that day in an unhindered / unabated way; albeit - evidently - without prejudice to the continued observance of the applicable preventive precautions
● √ user-friendly ~ test results are easy (and without risk of confusion or differences of interpretation) for laymen and users to read and to understand
● √ safe ~ by definition the testing protocol involves self-testing ~ in other words, no assistance from third parties or specialized personnel is required, so that these third parties can never become infected during the taking of the test ~ unlike with PCR tests, no "Martians"/PPE are required, which in turn saves a lot of time and money
● √ low cost ~ can be applied on a massive scale by the entire population (eg daily, at less than € 1 per test) ~ economic leverage effect ~ negative opportunity costs + return on investment
● √ "scalable" ~ test that can be applied massively (= by the masses + frequently) in the short to medium term ~ ideal for pandemic screening and / or population screening ~ this is a very interesting feat not just for the users, but also for their organizations and authorities
● √ statistically relevant ~ (structured) test results can assist scientists and policymakers in their decision-making ~ decentralized population screening = a cheap research, development and policy tool
● √ practical / effective triage tool ~ interplay between screening and diagnostics ~ the new paper-strip saliva test screening method is an ideal supplement and / or precursor and / or selection and triage tool for traditional diagnostic tests, which addresses the massive demand / need for RT-PCR tests, whereas at present such massive numbers of RT-PCR-tests can absolutely not be handled by hospitals and diagnostic labs
● √ anonymous ~ (in principle) no need for track & trace ~ protection of privacy ~ protection against 'big brother'and against so-called 'digital surveillance capitalism'
● √ comfortable ~ can easily be taken at home by laymen - no need for terrifying nose swabs, no need for complex lab equipment
● √ compact ~ is portable and stowable ~ can easily be carried in a pocket in a jacket or in a backpack or in a handbag
● √ child-friendly ~ comfortable for children aged 7 to 77, and possibly for those who are younger or older
● √ practical for traveling ~ eg public transportation, airplanes, etc.
● √ practical for on the road ~ eg work, school, hospital, theater, station, airport, stadium, place of worship, workshop, Christmas party at grandma's, etc.

CONS of this new (less accurate) public screening rapid testing regimen:
● x limited risk of "false negatives" if the test is not administered correctly and / or if the test results are not correctly read and / or misinterpreted
~ ¤√ However: all kinds of precautions can be taken by the user himself/herself (e.g. assistance of children and the elderly, 4-eyes principle within the same family, pointing-and-calling method, test in a quiet room such as a bathroom, etc.). Organizing organizations can also take extra precautions. And in the first place, the manufacturers themselves will of course take the best precautions - as much as possible and as useful as possible. In addition, the government and the media can also raise awareness among the population about the risks of 'false negatives', which will always exist anyway (as they do with other tests), and which of course should not be underestimated. ~ Past experience with other self-tests (such as pregnancy tests, HIV tests, etc.) shows that this type of risk does not have to be an insurmountable problem, and that in developed countries (such as the EU member states) these risks practically can be reduced to almost zero. But even then, even if something goes wrong now and then, the ultimate global effect of this screening method remains predominantly positive, and its ultimate impact remains much better than anything that has been tried so far.
● x limited risk of 'false negatives' at the (in any case asymptomatic/presymptomatic) very beginning of the 'highly-virus-infectious phase'; this is the 'Virus Infectious / Transmissible Phase with high viral loads and high viral shedding' = 'Ultra-Ansteckende Phase'
~ ¤√ However: during their so-called 'viral peak' (60-72h with highest risk of infection) this 'initial risk' for false negatives in virus-positive test users is not statistically relevant (thus negligible) from an epidemiological point of view; although it may be useful to remind each test user at an individual level of the existence of the (limited) probability of 'false negatives' at the very beginning of the virus-contagious phase: this risk is not to be 100% neglected indeed, so that other precautions must still be permanently observed.
● x likelihood of "false positives" (especially given certain typical Bayesian effects), which may give rise to an increasing demand for additional RT-PCR tests, as well as give rise to unnecessary panic, anxiety, work disabilities, school quarantines, etc.
~ ¤√ However: this risk is largely offset by the additional special 'confirmatory tests' that are included with each batch of standard tests, and that reduce the probability of 'false positive' test results (after a double saliva test) to less than 1/1000 (~ <0.1%).
● x risk of unexpected escalations and / or other 'butterfly' or 'bullwhip' effects as a result of some technical details that currently still need to be - at long last - clarified (and preferably as soon as possible), because otherwise they could cause confusion / disinformation with the users of the respective tests, as they will be marketed by different manufacturers. Obviously, what we are dealing with here are simple screening paper-strip tests and not diagnostic devices, but nevertheless there exists a risk for some (admittedly technically-scientifically perfectly explainable) differences in the field of test criteria (specs / specifications) as used by the different Ag saliva test manufacturers; which could indirectly lead to confusion and / or misplaced dissatisfaction among test users, a phenomenon that should therefore be avoided as much as possible.
After all, there is a real possibility of:
(a) divergent test results of scientific samples, (partially due to :)
(b) divergent quantitative and qualitative benchmark and threshold specifications as used by the various saliva test producers.
On this very issue, some notable suggestions were launched in recent weeks (among others by certain academic circles in the US and in Berlin), but today the transparency needed to make rapid progress in this field is still lacking.
This concerns, for example, the criteria (to be applied) for 'viral loads & shedding' / 'RT-PCR-ct cycle threshold equivalents'; and this both in terms of the relevant ct values and the VL / ct calibration methods. These are important in delineating what actually constitutes a "positive" and what actually constitutes a "negative" saliva test.
In addition, there is a real possibility that the various saliva test producers apply different criteria with regard to the exact method/protocol to be followed by the individual private users for administering the saliva test; among other things each depending on possibly divergent test specifications (e.g. as a result of

differences in the molecular composition of the actual antigenic test strips, which may or may not be open source), in function of diverging views on quality control, in function of user support 'at the point of use', etc.
~ ¤√ However, this mainly concerns scientific-philosophical discussions. Those can quickly (and easily) find a technical / economic / administrative solution: within the acceptable safety margins and within the probability intervals for screening tests; especially in the framework of the pandemic emergency situation Europe finds itself in. Moreover, the quasi-100% reliability of the saliva tests at the time of a so-called 'viral peak' (i.e. the period of 60-72 hours with the highest risk of infection) must also be considered as a key success driver for the lowcost antigen tests. Hence, possibly divergent criteria and, later on, the risk of divergent tests-results between the different saliva test platforms - in case of a virus-positive test - are actually statistically irrelevant (and therefore practically negligible from an epidemiological point of view); whereby it can not or may not be expected that each test user would (wish to) take these differences into account on his/her individual level. Nevertheless one should caution against a cacophony of differing expert opinions or differences in diagnostic interpretations, which may lead to the test users losing confidence or becoming confused and disinformed. In any case, it would be intellectually dishonest for certain public authorities and / or certain academic bodies and / or certain big-pharma companies to abuse this kind of backbench discussions to block the necessary transition to the new screening test-regime. Such hesitations simply amount to culpable negligence on the part of those responsible. After all, what we are dealing with here are (by definition slightly less accurate) mass public health surveillance screening tests, and not (by definition highly accurate) clinical diagnostic tests. This is precisely the crux of the story, and one should therefore refrain from confusing the population / citizens / test users about the tradeoffs at hand ...
● x limited risk of technical problems and teething problems, whether or not in combination with incorrect use and / or incorrect interpretation of the confirmatory tests supplied with each batch of standard tests, and whether or not organized by 'test-organizing' organizations. This is all the more so, because the 'viral cell load' of a simple saliva sample can be lower than an equivalent nasopharyngeal swab, possibly leading some to conclude 'that opportunities or signals are being missed'
~ ¤√ However, these risks can be managed to a significant degree, by way of a phased-in deployment of this new low-tech testing technology, by way of preliminary testing and simulations, by way of sampling and quality control, by way of appropriate training and by way of a Europe-wide awareness-raising campaign that is aimed at the individual testers, at the organizing organizations, as well as at some of the health care personnel. Speed and ease of use are precisely the drivers required for widespread public support for these antigen auto-tests as they will underpin their massive, frequent use, eventhough they are less reliable to begin with. After all: one should not put the cart before the horse; and what clearly prevails here is that the European population continues to frequently test itself in massive numbers, without quitting or giving up because of all kinds of discomforts or inconveniences. What counts is that the decentralized population screening and public health surveillance programs can continue unabated. In other words, and as strange as this may sound: in the case of the modern Ag SARS-CoV-2 saliva tests (and this is particularly true from an epidemiological point of view) the ease of use and the fast turnaround times prevail over the accuracy of the test, which comes in second place. Obviously, one must continue to take as much care as possible (or as useful) to avoid testing incidents and testing accidents, yet especially the speed, the massive numbers and the high frequency, but also the low cost and the comparative ease of use, should prevail over the fact that these Ag saliva tests are somewhat less accurate than the gold standard RT-PCR tests.
● x limited risk of dangerous behavior and / or a careless attitude in some who think that - in the case of a negative, ie "OK" or "GO" test result - they can let go and start taking unnecessary risks: both in the context of social distancing and personal prevention measures, and in the context of the testing strategy; e.g. in case they no longer continue to regularly observe the frequency and the user instructions such as they apply for the respective saliva test regimens.
~ ¤√ However, once again, an appropriate enforcement policy, in combination with a Europe-wide awareness-raising campaign, can work miracles, especially among certain population groups (e.g. among children, among the elderly, among tourists, among university students, among the homeless, among refugees, among drug addicts. or also: in the case of schools, associations, airlines, bus companies, organizers of sporting events, etc.). In addition, past experience with other home tests (pregnancy tests, HIV tests, etc.) in developed countries such as the EU member states demonstrates that this kind of risks is certainly manageable, and that it is possible to rely on the common sense and civic spirit of our fellow Europeans.

- - - Resolution No. 10 - - -

Do not treat European citizens like a bunch of idiots, but treat them with respect and with openness: also in the field of prevailing industrial, macro-economic or geopolitical interests, such as those that tend to 'inform' policy.

Finally, offer more clarity and openness about the vaccines that are currently under development, about which European public opinion has a poignant lack of understanding, and for which it harbours a lot of naive or misleading expectations. For example, most Europeans today still seem to believe - all too often encouraged by certain (state) media and/or Facebook disinformation campaigns - that most, if not all, of the soon to be approved 'Phase 3 emergency vaccines' will be 100% immunizing from 2021 onwards, assuming these vaccines will offer all kinds of neutralizing and/or sterilizing effects, which in turn would contribute to some - generally hoped for, and in the same media all too often hyped - group immunity; whereas the number of sustainably neutralizing and/or sterilizing emergency vaccines by industry observers expected by 2021 is actually estimated to be exactly 0 (zero).

Also better explain all policy areas and all applicable policy measures, in a transparent, serious and fair manner. Including in the media: offer news- and policy-analysis based on scientific knowledge, explained by people with knowledge.

In doing so, highlight the following points:

● First, the enormous need among European citizens to be able to individually test and demonstrate - in a quick, cheap and easy way - that they and their families are Corona virus NEGATIVE; and this each to themselves, as well as to their respective family members, extended families, companies, schools, universities, employers, sports clubs, cultural associations, transport companies, ... which these citizens have to deal with every day during the ongoing Corona pandemic.

● Associated with this: the concern of European citizens to protect their loved ones as much as possible (children, grandparents, colleagues, neighbors, friends, students, spectators, customers, etc.), and the persistent anxiety that affects these citizens, who are very well aware that they are at constant peril of being infected - even unconsciously / asymptomatically - by these very same people in their close environment.

● And directly associated with this: finally inform the European population sincerely and honestly about the expected efficacy (or not) of the emergency vaccines currently under development (~ no protection against SARS-CoV-2 virus contamination / ~ no protection against SARS-CoV-2 virus transmissibility / ~ only 20% extra (so very limited) effectiveness against COVID-19 disease symptoms / ~ 50 to 70% or 80% protective effectiveness against COVID-19 hospitalization or mortality).

Finally, once and for all, make clear to the European public opinion that no real contribution to effective 'herd immunity' can be expected by way of these initial corona emergency vaccines; i.e. from none of the emergency vaccines that are currently under development by 2021. All the more so since the first neutralizing / sterilizing vaccines that are currently also under development - and which could therefore contribute to this kind of Europe-wide group immunity (i.e. that are protective against SARS-CoV-2 virus infection and infectivity) - according to some public statements by their own developpers can only be expected by 2023, at the earliest, so that until then a number of drastic "mitigating" "flattening-the-curve" prevention measures will probably have to remain in place and / or will need to be introduced. This includes extra so-called 'social distancing' measures, stricter 'face mask' mandates, and evidently a new massively-expanded 'public health surveillance' testing regime. One should be a lot more sincere about this, and one should stop acting silly when educating or elucidating members of the public about these issues.

● In addition, despite popular confidence in the quality of our European health care: there is an enormous aversion on behalf of many in the E.U.'s public opinion towards 'the whole Corona thing' and towards 'the whole Corona industry'. And for sure, this does not only concern all kinds of polemics and debates surrounding the development of emergency vaccines (eg Putin v. Trump), or surrounding the usefulness of repurposed therapeutic treatments (eg hydroxychloroquine). Are also meeting increasingly stiff opposition: the current 'nose-swab' RT-PCR testing regime with its frightening, slow, expensive and cumbersome diagnostic tests, apparently aimed at attaining 100% accuracy when testing symptomatic people for suspected Corona-virus POSITIVITY, without however being able to successfully mitigate the exponential infection curves, as part of a set of current policies and measures - of which this diagnostic RT-PCR testing-strategy still is one of the basic pillars. This is a very regrettable development as it becomes painfully clear that we are not only losing a lot of time, but apparently are also at risk of losing sight of 'the bigger picture'.

- - ♦ For instance, an RT-PCR test (total cost: up to 100 €) will sometimes turn out a positive result, up to many weeks after the original symptomatic SARS-CoV-2 virus infection, i.e. at a time when the tested individual has probably not been contagious for weeks, because RT-PCR testing can sometimes still detect 'ineffective' genetic virus RNA fragments, which - given the typical 'gold standard' high specificity and particularly (in casu:) the 'gold standard' high sensitivity of the RT-PCR test - will often lead to a misleading 'positive result', and thus also might lead to all kinds of (misplaced) anxiety, discomfort and inconvenience for the tested person and his/her environment.

example (1): the case where a former COVID-19 patient relying on the diagnostic RT-PCR test (cost: 100 €) still tests positive 7 weeks after disappearance of the disease symptoms, (long) after having ceased being virus contagious, and thus without being able to transfer the virus to people in his / her environment. In a case like this, the RT-PCR test will give a "false true positive" result (since - in some cases - RNA fragments from a fragmented corona virion can still be detected by the RT-PCR many weeks after the initial COVID-19 disease), while a modern antigen paperstrip saliva test (cost: 1 €) would - ceteris paribus - simply test "truly true negative" for SARS-CoV-2-tranmissibility. Evidently, the latter situation offers a much more useful / soothing answer to the test users concerned - while this antigenic paper strip self-test platform is much cheaper, convenient and faster, to start with.

- - ♦ For instance, taking an RT-PCR test (cost: 100 €) can be very time consuming, forcing the test user having to deal with very long waiting lists, queues, testing times, protocols and response times (the so-called total 'turnaround times'), so that it can take an unreasonably long turnaround time before one obtains the test result. Yes, even to the extent that the RT-PCR turnaround times are sometimes so long that the tested individual may long since have been at the origin of further contagion in his/her personal environment. Again, a modern antigenic paper-strip saliva test (cost: 1 €) - ceteris paribus - is likely to give the test-user a compelling "NOT OK" / "NO GO" test result within 15 minutes (not accounting for another 15 minutes for an additional confirmatory test in case the first test is positive indeed), giving the self-test user the opportunity to become immediately aware of the real risk of contamination posed by him/her and of the absolute need for immediate self-isolation. From this point of view, in these concrete circumstances, the antigenic saliva self-test-user and his/her environment are objectively-statistically consisiderably better (safer) off. The availability of much faster (and also much cheaper and easier-to-use) tests, characterised by their almost immediate 'instant' turnaround times, should also allow and motivate large swaths of the population to carry out their own tests massively and frequently (e.g. on a daily basis), thus being one of the most important success factors for this new 'public health' testing strategy. See also Mina et al .: 'Test sensitivity is secondary to frequency and turnaround time for COVID-19 surveillance' (medRxiv preprint doi: https://doi.org/10.1101/2020.06.22.20136309, September 8, 2020).

example (2): the case of a nasal swab RT-PCR test administered in a hospital: this test is administered by specialized staff in the hospital, before being analysed according to a time-consuming protocol/procedure that is handled with highly specialized equipment operated by highly trained para-medical personnel; with a total reporting and response time back to the tested clinical 'patient' that is all-too-often exceeding 24 hours. Such diagnostic laboratory tests are - in any case - relatively expensive, with an estimated total cost (even without internalizing every external cost) of more than € 100 per test; instead of less than 1 € for a paper strip saliva test.

● Furthermore: the imperatives of public security and public health care policies. These aspects of public governance consist primarily of contagion prevention strategies based on "social distancing" restrictions, hygiene guidelines, PPE such as "face masks", and the slowly expanding "corona testing" programs; whereby such (preventive) corona testing can be done according to 2 mutually complementary test paradigms:

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- TESTING PARADIGM 1 - the test method based on a public SCREENING:
in fact, this boils down to a continuous population-scale self-examination, which should lead to the most transmissible cases being immediately "removed from circulation" for several days, as a precautionary measure, by going into self-isolation on their own initiative. This practically concerns those with the lowest ct-values in the classic RT-PCR tests, and thus with the highest viral loads (which often lead to high viral shedding), who, upon using these rapid, convenient, lowcost and commonly available antigen saliva self-tests, evidently will become immediately aware of their condition.

- - MACRO testing ~ 1 € paper strip tests ~ COVID-19-public-health-surveillance ~ Quick & Dirty ~ European population screening ~ the 'SCREENING method':

This public mass screening method mainly focuses on the 'social demonstration' of "Corona test NEGATIVITY": this testing-strategy relies on the individual test users themselves to carry out the tests easily, quickly and cheaply. After all, all is needed is for the individual users to administer the paper-strip tests themselves (cost: approximately € 1 per test). This test method can also be used in an 'organized' way by organizing institutions.

example: the case of a school: a daily paper strip self-test of all students and of all staff members (estimated cost: less than 1 € per test) can be done before leaving home in the morning, or otherwise immediately upon arrival at school. Indeed, the individual users (or their parents) would each find out the 'GO' / 'NO GO' or 'OK' / 'NOT OK' result on the paper strip within 15 minutes after taking their self-test.

An additional argument for this so-called 'COVID-19 surveillance' method is the private, anonymous nature of the antigenic 'disposable' saliva tests: in principle, each user takes the test on his/her own - at their own initiative and with respect of their personal privacy. In other words, this decentralized anonymous public health 'surveillance' is based on the so-called auto-screening principle (in reality this comes down to an epidemiological population survey). Therefore it should certainly not be confused with other (digitized) forms of 'digital surveillance state' aspects of our modern European healthcare, some of which - as became apparent in the course of the ongoing corona pandemic - are all too often lurking around the corner: telephone appointments, telephone consults (whether or not based on video conference calls), electronic 'track & trace' guest lists, corona apps with geo-location and / or bluetooth recognition, electronic patient files, robotized invoice processing, automatic data exchange between institutions and labs, cloud computing, artificial intelligence, digital outsourcing, data mining, etc. All of which is - by definition - completely out of the question here,.. since everything is still - literally - settled on paper.

- O -

- TESTING PARADIGM 2 - the test method based on individual DIAGNOSTICS:
in fact, this boils down to meticulously detecting - past or current // symptomatic or asymptomatic - cases of infection, on an individual basis (based on concrete circumstances) relying on traditional 'gold standard' diagnostic RT-PCR laboratory tests.

- - MICRO testing ~ 100 € laboratory tests ~ SARS-CoV-2 detection ~ Lean & Clean ~ useful for scientific or medical research ~ the 'DIAGNOSTIC method':

This private diagnostic laboratory detection method focuses mainly on the medical demonstration of 'Corona test POSITIVITY': one will be able to rely on very precise, very accurate (highly-sensitive / highly-specific) clinical technology that is typically used in hospitals or in clinical laboratories, using capital-, labor- and time-intensive equipment, protocols and reagents (total cost: approx. € 100 per test). This test method is not only expensive, but also inherently slow and cumbersome; and it is therefore difficult to use in an 'organized' way, which means that it will usually be taken on an individual basis.

example: the case of a so-called 'testing street with Martians in PPE': a professional basketball player came back from vacation 2 weeks ago, participated in a meeting with the coaching staff 1 week ago, and in the meantime found out that some of the fellow guests at his vacation-hotel on their return home were showing COVID-19 symptoms. The basketball player has never fallen ill himself, but the club management wants to make 100% sure (also in order to protect the coaching staff) whether the athlete in the meantime became infected (albeit asymptomatically), and whether the athlete himself could possibly also have posed and/or still poses an infection risk for his immediate enviroment. This can - in this specific case - be verified very precisely by means of an RT-PCR test carried out on all those involved; while the individual 'infectiousness' of each of them could easily be screened for by means of a do-it-yourself saliva test - e.g. in an 'organized' setting: every day in the morning and in the afternoon, at the beginning of each basketball training session.

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● Consequently: if the European governments want to shift the testing focus from the micro-diagnostics method to the macro-screening method, they will have to plan for such a transition and make sufficient resources available for this to happen. In a break with the past, they should ensure that the new preventive corona testing strategy can be carried out effectively, efficiently, massively and cheaply. This is currently not (or insufficiently) the case. Overall, there is a need for a paradigm shift towards a better, faster, cheaper, and of course much more massive testing strategy.

● Nevertheless, the baby should not be thrown out with the bath water; it is clear that the currently advocated modern antigen testing regime (just like other, slower and sometimes still cumbersome alternatives that rely, for example, on the use of monoclonal Ab Antibodies) really comes down to a massive front-running operation and to an extension of and/or addition to the current PCR testing strategy. After all, there will continue to be a future need for a reliable, well-oiled diagnostic RT-PCR test infrastructure; for example to confirm or to contradict increasing numbers of (hopefully rapidly decreasing) virus-positive antigenic saliva tests.

It is therefore essential that prompt centralized decisions are taken at the European policy level, after careful consideration of the respective advantages and disadvantages of both the traditional diagnostic and modern screening tests, as explained hereabove.

● These outstanding decisions are an important point of attention in certain academic / scientific circles, especially in Germany, in the U.K. or in the U.S. For example, M. Mina, D. Larremore, B. Wilder, E. Lester, S. Shehata, J. Burke, J. Hay, M. Tambe & R. Parker (2020) in a leading preprint article of 27 June 2020: "Test sensitivity is secondary to the frequency and turnaround times of the 'COVID-19 surveillance' screening test method" - "Effective surveillance depends

largely on frequency of testing and the speed of reporting, and is only marginally improved by high test sensitivity. ... surveillance should prioritize accessibility, frequency, and sample-to-answer time; analytical limits of detection should be secondary. "

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.. Our results lead us to conclude that surveillance testing of asymptomatic individuals can be used to limit the spread of SARS-CoV-2.

.. Finally, the exact performance differences between testing schemes will depend on whether our model truly captures viral kinetics and infectiousness profiles, particularly during the acceleration phase between exposure and peak viral load. Continued clarification of these within-host dynamics would increase the impact and value of this, and other modeling studies.

"A critical point is that the requirements for surveillance testing are distinct from clinical testing.

Clinical diagnoses target symptomatic individuals, need high accuracy and sensitivity, and are not limited by cost. Because they focus on symptomatic individuals, those individuals can isolate such that a diagnosis delay does not lead to additional infections.

In contrast, results from the surveillance testing of asymptomatic individuals need to be returned quickly, since even a single day diagnosis delay compromises the surveillance program’s effectiveness.

Indeed, at least for viruses with infection kinetics similar to SARS-CoV-2, we find that speed of reporting is much more important than sensitivity, although more sensitive tests are nevertheless somewhat more effective.

The difference between clinical and surveillance testing highlights the need for additional tests to be approved and utilized for surveillance. Such tests should not be held to the same degree of sensitivity as clinical tests, in particular if doing so encumbers rapid deployment of faster cheaper SARS-CoV-2 assays. We suggest that the FDA, other agencies, or state governments, encourage the development and use of alternative faster and lower cost tests for surveillance purposes, even if they have poorer limits of detection. If the availability of point-of-care or self-administered surveillance tests leads to faster turnaround time or more frequent testing, our results suggest that they would have high epidemiological value."

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(medRxiv preprint doi: https://doi.org/10.1101/2020.06.22.20136309 . version posted June 27, 2020)

● At the same time, it is to be expected that many European citizens - upon having carried out a virus-positive confirmatory test - will probably still want, or even need to, call on the services of the traditional diagnostic laboratory platforms (be it for professional or for purely medical reasons).

European citizens should therefore be aware that the classic diagnostic 'hospital' and 'laboratory' tests (such as RT-PCR) will not be abolished (on the contrary), but that the current laboratory tests will in fact be further expanded to accomodate for the extra demand created by the massive home testing program that is advocated here.

In other words, even the macro-testing / population-screening strategy will, at least in part, rely on the diagnostic micro-testing platforms (for certain positive SARS-CoV-2 infectious cases and for certain clinical COVID-19 cases), albeit often only in a subsequent, later stage of detection, ie after a previous double (ordinary + confirmatory) saliva test.

● Finally, the European population as a whole is getting increasingly confronted with the social, psychological, socio-economic, socio-cultural impact of the corona crisis, compounded by all kinds of debates, conspiracy theories, academic disagreements, ever-changing policy decisions, etc. which all too often lead to confusion and disorientation and sometimes even to complete and total indifference; or in the case of other people: to all kinds of peripheral secondary symptoms such as depression, social isolation, lethargy, domestic violence, suicide, alcoholism, etc.

Therefore: encourage and support the European citizens - because people are losing hope and patience. It is of paramount importance that European policymakers offer the European population a new perspective in the short to medium term, in particular by deploying a new preventive testing regime that on the one hand is able to ensure that the population is adequately and reliably informed about their own SARS-CoV-2 virus-infection status, and that on the other hand protects them from the most acute transmission and transmissibility risks (e.g. by decisively reducing the risk of so-called 'corona spreaders', who ought to be instantly isolated from the rest of society). In other words: pursue the hereproposed new testing paradigm that incorporates a combination of these two objectives and two testing strategies that could lead to the sustainable reopening of European society, in a socially and psychologically, medically and economically acceptable way. And this - unfortunate as it may be - despite some important personal precautions that will still need to be advocated (eg the 6 basic hygiene rules) and despite some collective precautions that may still have to be enforced (eg in the field of "social distancing" or of other social restrictions), but which - thanks to the adoption of this new 'public health surveillance' massive screening method - can hopefully be phased out as quickly as possible.

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