

Odprto pismo mednarodnih organizacij Svetovni zdravstveni organizaciji o problemu varnosti cepiv

Za Svetovno zdravstveno organizacijo in vse udeležence Globalne mreže laboratorijev za nadzor kakovosti cepiv (Rim, 25. – 27. september 2018).

Za evropski parlament, Evropsko agencijo za zdravila in Evropski direktorat za kakovost zdravil.

Spoštovani člani Svetovne zdravstvene organizacije,

s prispevanjem k znanosti in s prizadevanji za boljše zdravje, je vaša organizacija oplemenitila življenje milijonov ljudi, za kar smo vam hvaležni. Z zagotavljanjem kakovostnejše prehrane, čiste vode, boljših sanitarnih razmer in dostopa do zdravniške oskrbe, sta umrljivost in širjenje nalezljivih boleznih močno upadla. Vaša izjemna komunikacijska kampanja za odkrivanje primerov bolezni in ljudi, ki so bili v stiku z njo, ter njihova osamitev, je končno pripeljala do izbrisa nekoč uničujočih črnih koz.¹ To so resnično veliki dosežki, h katerim je treba stremeti tudi v prihodnje. Vendar pa se danes soočamo z novo epidemijo – epidemijo kroničnih bolezni. V Združenih državah Amerike vsaka druga odrasla oseba trpi za kronično boleznijo, vsaka četrta pa jih ima dve ali več.²

Debelost, astma, rak, imunske in avtoimunske bolezni ter nevrološke in razvojne motnje so t.i. »bolezni življenjskega sloga«, ki jih povečini povzročata ali poslabšujeta slaba prehrana in kopičenje toksičnih snovi v telesu. Zdravniki cepijo zdrave osebe, da bi preprečili okužbe, pri tem pa nimamo ocene dolgoročnih vplivov cepiv na imunski sistem in njihove potencialne vloge pri razvoju kroničnih bolezni. Tveganje za slab izid okužbe, pa tudi samega cepljenja, močno variira med posamezniki, masovno cepljenje brez ustreznega razločevanja na ravni posameznika pa je že vodilo k poškodbam, smrtim in drugim nehotenim posledicam. Pred kratkim so neodvisni raziskovalci in laboratoriji odkrili, da so številna cepiva kontaminirana z retrovirusi³ in onesnažena z nanodelci.⁴ Visoke vsebnosti aluminija, povezane z adjuvansi v cepivih, so našli v možganih

avtističnih otrok ali pri ljudeh, ki trpijo za nevrološkiimi motnjami, kot je Alzheimerjeva bolezen.^{5, 6}

Na svojem prejšnjem zasedanju ste se zavzemali za manj neodvisnih testiranj, češ da so »odveč«, s čimer ste hoteli pospešiti dobavo izdelkov.⁷ Nedavno cepljenje z 250.000 pomanjkljivimi cepivi na Kitajskem,⁸ tragedija kampanje z oralnimi cepivi proti otroški paralizi v Indiji, ki je pustila za sabo 450.000 primerov paraliziranosti in smrti,⁹ škoda, ki jo je povzročilo cepivo proti mrzlici denga na Filipinih,¹⁰ ter poročila o kroničnih bolečinah in paraliziranosti po cepljenju s cepivom proti virusu HPV, ki prihajajo z vseh koncev sveta,^{11, 12} kažejo na hudo ravnodušnost glede varnosti in učinkovitosti cepiv v tej gonji za čim hitrejšo pridobivanje dovoljenj in certifikatov za cepiva.

Če hočemo razvijati standarde in usklajevati najboljše načine dela med nadzornimi organi, je treba ohraniti testiranja v nacionalnih in neodvisnih laboratorijih, saj obstaja možnost prevar in tehničnih tveganj pri skladiščenju ali transportu, zaradi katerih morda ne bi odkrili pristranskih interesov ali prišli do novih dognanj. V svojem poročilu navajate: »Opazili smo, da so cilji mreže skladni s predlogom industrije za testiranja tveganj pri cepivih in za mreženje.«¹³ Vendar se zdi takšen pristop, povezan z zmanjševanjem zahtev pri testiranju cepiv, ki naj bila »nizko tvegana«, nevarno početje.

Številne zdravstvene oblasti se pritožujejo nad negotovostjo cepiv, kljub temu pa javnosti ne morejo zagotoviti varnostnih podatkov, ki jih zahteva. Milijoni ljudi po svetu so podpisali peticije, s katerimi zahtevajo večjo varnost, transparentnost in neodvisne raziskave, toda tisti, ki sprejemajo odločitve, so raje izbrali hitrejšo pot.

Da bi obnovili izgubljeno zaupanje, vztrajamo, da je treba pred vsakršnim priporočilom ali odobritvijo VSA cepiva, ki jih predkvalificira ali priporoči Svetovna zdravstvena organizacija, vključiti v:

- izčrpne klinične poskuse, ki jih bodo opravili neodvisno od proizvajalcev cepiv,
- srednje in dolgoročne študije o učinkovitosti in varnosti, ne zgolj »nekajdnevne« študije,
- testiranja za rakotvorne lastnosti,
- testiranja glede plodnosti,
- testiranja za nosečnost, spontani splav in razvijajoči se zarodek,
- testiranja za mutagene učinke (spremembe sprožene v DNK),
- testiranja za učinke na nevrološki sistem in razvoj možganov,
- preverjanje s pravim inertnim placebom, ki skoraj nikoli ni opravljeno pri cepivih.

Vztrajamo tudi, da bi morala Svetovna zdravstvena organizacija zagotoviti študije o:

- adjuvansih in konzervansih, kot sta aluminij in živo srebro, ter njihovih biokumulativnih učinkih,

- drugih uporabljenih toksičnih snoveh, kot so polisorbit, Tween 80, formaldehid idr.,
- varnosti cepiv in starosti oseb, ki so cepljene,
- vplivu polnega cepilnega programa na globalno zdravje populacije,
- primerjavi cepljenih in necepljenih populacij v smislu globalnega zdravja,
- virusnem prenosu pri ljudeh, ki so pred kratkim prejeli cepivo z živim virusom, denimo virusom ošpic, mumps, rdečk, noric in gripe ali oralno cepivo proti otroški paralizi.

Še posebej prosimo, da se temeljito razišče uporaba večvalentnih cepiv ter vnos več različnih cepiv v enem dnevu. Statistični podatki iz Indije kažejo, da se je število smrtnih žrtev v treh dneh po cepljenju s petvalentnim (5 v-enem) cepivom, kot nadomestilo za trivalentno cepivo DTP, podvojilo. Sklepa se, da bodo tovrstne spremembe povzročile med 7.020 in 8.190 smrtnih primerov letno pri dojenčkih v Indiji.¹⁴ Nadalje zgleda, da je proizvajalec GSK v zaupnih periodičnih varnostnih poročilih šestvalentnega cepiva proti otroški paralizi Infanrix, predloženih EMA, v svojih poročilih izbrisal več primerov smrti.¹⁵

V zvezi s cepivom proti ošpicam, mumpsu in rdečkam in njegovo povezavo z avtizmom, obstaja na vaši spletni strani v razdelku o avtizmu le ena omenjena referenca, in sicer zastarel francoski članek, ki vsebuje prevode novinarskih trditev, te pa so leta 2012 ovrgli z odločitvijo Vrhovnega sodišča Združenega kraljestva v Angliji.^{16, 17} Prav tako je William Thompson, strokovnjak iz CDC, v letu 2014 priznal, da je manipuliral s podatki ključne referenčne študije, vendar se od takrat še vedno niso izvedle nadaljnje preiskave.¹⁸ Ker je trenutno v ZDA eden od 36 otrok diagnosticiran z motnjo avtističnega spektra¹⁹, je tovrstna raziskava prednostna, prav tako pa tudi neodvisno laboratorijsko testiranje ter novi klinični preizkusi, ki morajo nadomestiti pretok »nezadostnih« statističnih podatkov.

Italijanska parlamentarna komisija je potrdila nujnost te prednostne naloge, ko je pred kratkim objavila podatke o številnih smrtih, avtoimunskih boleznih in raku, ki so se pojavili po večkratnem cepljenju pri vojaškem osebju, in je zahtevala več raziskav in previdnostnih ukrepov.²⁰ Dolgoročnih učinkov cepiv se še vedno ne proučuje in nedavna revizija klasifikacije »Neželenih stranskih učinkov po cepljenju« (Adverse Events Following Immunisation) ne dopušča natančnega poročanja o primerih smrti ali neželenih učinkih, ki jih proizvajalec predhodno ni navedel.²¹ Nujno je takojšnje odgovorno ukrepanje zaradi zaskrbljujočega povečanja kroničnih bolezni, imunskih, avtoimunskih in razvojnih motenj po svetu.

Evropski parlament v svoji nedavni resoluciji o previdnosti glede cepljenja zahteva »transparentnost in izjavo o navzkrižju interesov, vključno z raziskovalci, ki delajo za Svetovno zdravstveno organizacijo in Evropsko agencijo za zdravila«. Parlament predlaga, da so »raziskovalci, ki so predmet navzkrižja interesov, izključeni iz

ocenjevalnih svetov«; nadalje poziva k »odpravi zaupnosti posvetovanj odbora za ocenjevanje Evropske agencije za zdravila« in predlaga, da »je treba javno objaviti znanstvene in klinične podatke, na katerih temeljijo zaključki odbora, katerega anonimnost je zagotovljena vnaprej«. ²² Vendar pa pod vprašanje postavlja pristranskih poročil. ²³

Ko gre za odobritev ali priporočanje novega cepiva, vemo da:

- študije pred izdajo licenc izvajajo izključno proizvajalci, ki so nato vezani na dobiček. To predstavlja očitno navzkrižje interesov.
- Študije pred izdajo licenc ne zajamejo in ne morejo zajeti vseh neželenih učinkov, ki se bodo sicer pojavili v praksi.
- Strokovno pregledane znanstvene publikacije imajo ogromno navzkrižij interesov in večina študij je pristranskih ali napačnih ^{24, 25, 26}
- Postmarketinško spremljanje je izredno pomanjkljivo v vseh državah. Zabeleženih je samo 1 do 10% stranskih učinkov. Obvezna dveletna varnostna poročila o cepivih v ZDA, ki naj bi jih ameriška zdravstvena organizacija US Health & Human Services (HHS) pošiljala kongresu, preprosto nikoli niso bila napisana.²⁷

Financiranje vaše organizacije temelji na pomembnih zasebnih donacijah, kot je na primer GAVI zavezništvo, partnerstvo z bankami in industrijami. Samo dejstvo, da tudi to srečanje financira zasebni vlagatelj, Fundacija Billa in Melinde Gates ²⁸, je zelo vprašljivo. Zaradi tega imanentnega navzkrižja interesov je torej imperativno, da so v odobritev cepiv in cepilnih protokolov vključene neodvisne študije in neodvisni strokovnjaki. V kolikor Svetovna zdravstvena organizacija jamči za varnost cepiva, katerega odobri vnaprej, mora tudi prevzeti odgovornost za stranke učinke po cepljenju.

Spodbujanje obveznega cepljenja celotne populacije s proizvodi, ki se za njihovo splošno varnost in učinkovitost v bistvu zanašajo na podatke proizvajalcev cepiv, je očitna kršitev previdnostnih načel in kot taka postane prisilni medicinski poskus.

Zdravstveno tveganje cepljenja v celoti nosijo posamezniki, zato mora Svetovna zdravstvena organizacija zagotoviti, da je to tveganje minimalno in da je pojasnilna dolžnost opravljena v polnosti.

Da bi ponovno vzpostavili zaupanje javnosti v zdravstvene organe in izboljšali mednarodno javnozdravstveno politiko, prosimo za ukrepe in odgovore, ki ustrezajo našim zahtevam. Zahvaljujemo se častnim članom te skupščine za njihovo pozornost in upamo, da bodo našemu sporočilu odprli svoja srca in um.



Open Letter from International Organisations to the WHO on the Issue of Vaccine Safety

To the World Health Organisation and those attending the meeting of the Global Vaccine Quality Control Laboratories Network (Rome 25th-27th September 2018).

To the European Parliament, the European Medicines Agency and the European Directorate for the Quality of Medicines

Dear members of the World Health Organisation,

By sharing science and joining efforts towards better health, your organisation has improved the lives of millions of people, and we are grateful for this. Providing better nutrition, clean water, improved hygiene, and access to medical care, mortality and infectious disease have been drastically reduced. Your extraordinary communication campaign to detect cases of disease and their contacts, and isolate them, finally led to the eradication of the once devastating smallpox.¹ These are great achievements and these noble goals should be further pursued. Today however, we are facing a new epidemic: chronic disease. In the USA, one in two adults has a chronic disease and one in four has two or more.²

Obesity, asthma, cancer, immune and autoimmune diseases, neurological and developmental disorders, are 'lifestyle diseases' mainly caused or aggravated by bad nutrition and toxic load. Vaccines are administered to healthy individuals to prevent targeted infections, but their long-term impact on the immune system and their potential role in chronic disease is not being evaluated. Individual risk of poor outcomes to both infection and vaccination varies widely and mass vaccination without proper discrimination at the individual level has led to injuries, death and unintended consequences. Recently, independent researchers and laboratories have discovered that many vaccines are contaminated with retroviruses³ and polluted by nanoparticles⁴. High levels of aluminium associated with vaccine adjuvants have been found in the brains of autistic children or in people suffering from neurological disorders such as Alzheimer's disease.^{5,6}

In your previous meeting you advocated for less independent testing, considered 'redundant', in order to speed up the supply of products.⁷ The recent administration of 250,000 defective vaccines in China⁸, the tragedy of the oral polio campaign in India with over 450,000 cases of paralysis and death⁹, the damage caused by the Dengue vaccine in the Philippines¹⁰, reports from all over the world of chronic pain and paralysis after administration of the HPV vaccine^{11, 12}, show that vaccine safety and efficacy are being tragically disregarded in this drive for fast-tracking approval and easy certification.

If developing standards and sharing best practice amongst controlling bodies is needed, testing by national and independent laboratories must be maintained, since fraud and technical hazard from storage or transportation can still occur and biases or new findings would not be detected. According to your report, «It was noted that the aims of the network are a good fit with industry's proposal for risk-based testing and networking».¹³ But this 'risk-based' approach geared to reducing test requirements for vaccines considered of 'low risk', seems a dangerous pursuit.

Many health authorities complain about vaccine hesitancy, but fail to reassure the public by providing the safety data they request. All over the world, millions of people have signed petitions demanding more safety, transparency and independent research, but decision makers chose fast-tracking instead.

To restore confidence lost, we insist that before any kind of recommendation or authorisation is issued, ALL vaccines pre-qualified or recommended by the WHO will be submitted to:

- Extensive clinical trials conducted by bodies independent from the manufacturers
- Medium- and long-term studies on efficiency and safety, not 'days'.
- Tests for carcinogenic properties
- Tests around fertility issues
- Tests on pregnancy, spontaneous abortion and the developing foetus
- Tests for mutagenic effects (changes induced in the DNA)
- Tests for effects on the neurological system and development of the brain
- Real inert placebo testing, which is almost never conducted on vaccines

We also insist that the WHO should provide studies on:

- Adjuvants and preservatives such as aluminium and mercury and their bioaccumulation
- Other toxic material used, such as polysorbate, Tween 80, formaldehyde etc
- Vaccine safety and the age of vaccine administration
- The impact of full vaccine schedules on the global health of a population

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- The impact of full vaccine schedules on the global health of a population

- The comparison of vaccinated versus unvaccinated populations in global health terms
- Viral transmission of people recently vaccinated with live virus vaccine such as measles, mumps, rubella, varicella, influenza or oral polio vaccine for example.

In particular, we ask that the use of combined vaccines and the same-day administration of multiple vaccines be thoroughly investigated. Figures from India show that the number of deaths within three days following vaccination doubled when using a Pentavalent (5-in-one) vaccine rather than a triple DTP vaccine. It is projected that this change will cause between 7,020 and 8,190 deaths each year in infants in India¹⁴. It further appears that in confidential periodic safety reports of the hexavalent Infanrix polio vaccine submitted to the EMA, the manufacturer GSK had deleted a number of death cases between reports.¹⁵

Concerning the measles-mumps-rubella vaccine and its link with autism, the only reference mentioned on the autism section of your website is an out-dated French article translating press claims that have been disproven in a decision from the English High Court in 2012.^{16, 17} At the same time, William Thompson, an expert from the CDC, confessed in 2014 to having manipulated the data of a key reference study but as of present date, no further investigations have been made.¹⁸ With one in 36 children diagnosed with an Autistic Spectrum Disorder in the USA¹⁹, this study is an absolute priority and independent laboratory testing and new clinical trials must now replace the flow of 'inconclusive' statistics.

Confirming this priority, an Italian Parliamentary Commission recently reported numerous deaths, autoimmune diseases and cancers in military personnel after multiple vaccines had been administered and called for more research and precautionary measures²⁰. The long-term effects of vaccines are not studied and the recent revision of the classification of "Adverse Events Following Immunisation" does not allow for accurate reporting of death cases or of side effects not previously declared by the manufacturer.²¹ With the alarming rise in chronic diseases, immune, autoimmune and developmental disorders worldwide, immediate responsible action is imperative.

In its recent resolution on vaccine hesitancy, the European Parliament calls for "transparency and declaration of conflicts of interest, including researchers working for the World Health Organisation and the European Medicines Agency". It proposes that "researchers subject to a conflict of interest be excluded from evaluation panels"; further calls for "the confidentiality of the deliberations of the EMA evaluation panel to be lifted" and proposes that "the scientific and clinical data which inform the conclusions of the panel, and whose anonymity is guaranteed in advance, be made public".²² It fails however to question biased reports.²³

When it comes to approving or recommending a new vaccine, we know that:

- Pre-licensure studies are exclusively carried out by the manufacturers who stand to profit. This is a clear conflict of interest.
- Pre-licensure studies do not and cannot capture all adverse events that will occur in real world situations.
- Peer reviewed scientific journals have huge conflicts of interest and most studies are biased or false ^{24, 25, 26}
- Post-marketing surveillance in all countries is woefully inadequate. Only 1 to 10% of adverse events are being reported. In the USA, the mandatory biennial safety reports from US Health & Human Services to Congress on vaccine safety have simply never been written. ²⁷

The funding of your organisation relies on important private donations, such as the GAVI alliance, a partnership with banks and industries. The fact alone that this very meeting is funded by a private investor, the Bill and Melinda Gates Foundation²⁸, is highly questionable. Given this inherent conflict of interest, it is therefore absolutely imperative that independent studies and experts be involved in the approval and recommendation of vaccines and vaccine policies. And if the WHO guarantees the safety of the vaccine it is pre-qualifying, it should also assume liability for adverse events following vaccination.

Promoting mandatory vaccination for entire populations with products that essentially rely on manufacturers' data for their general safety and efficacy is an evident breach of the precautionary principle and as such becomes a forced medical experiment.

Since the health risk of vaccination is entirely borne by individuals, the WHO must ensure that it is minimal, and that fully informed consent is observed.

In order to restore public trust in health authorities and improve public health policies worldwide, we therefore demand actions and answers that meet our requests.

We thank the honorable members of this assembly for their attention and pray they will open their hearts and minds to our message.

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