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ORIGINAL ARTICLE

"Black race", "Schwarze Hautfarbe", "Origine africaine", or "Etnia nera"? The absent presence of race in European pharmaceutical regulation

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Abstract

Current scholarship on race in Europe has described race as an "absent presence". However, little is known about the dynamics of the absentness and presentness of race, including how various social processes operating at distinct levels (e.g. supranational and national) influence the uses of race and ethnicity concepts. We begin addressing this gap by examining racialised pharmaceutical regulation in the EU and its operationalisation in European countries. We analysed patterns of English-language uses of race and ethnicity terms at the EU level for all new drugs approved in 2014–2018, and systematically compared official translations into 24 languages. We found that "race" was promoted in plain sight and often retained when translated, albeit with much inconsistency across languages, creating peculiar patterns of presentness and absentness of race. Finnish, French, Swedish, and German stood out, as "race" was often translated into ethnicity terms, but even in those languages, "race" lingered despite claims that these countries vehemently opposed "race". Our findings should inform scholarly and political debates about race, ethnicity, and medicine in Europe that tend to assume, incorrectly, an anti-racialist consensus. There are also policy implications, because prescribers may interpret regulator-approved information about race and ethnicity differently because of inconsistent translations.

Keywords Race · Ethnicity · Europe · Translation · Pharmaceutical · Regulation

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Introduction

Sociologists often note that race is a social construct. Sometimes this is done by putting race between inverted commas, to indicate distance from any claim that race could exist as an a priori biological reality. The *Oxford Dictionary of Sociology* writes, for example, that inverted commas are used to emphasise that race categories are "not based on any biologically valid distinctions between the genetic make-up of differently identified 'races'" (Scott and Marshall 2009, p. 624). *The Blackwell Dictionary of Sociology* goes a step further, arguing that the "consensus" among sociologists and biologists "is that race exists as a socially constructed set of categories" (Johnson 2000, p. 249). Sociologically, concepts such as black and white are important, especially in relation to inequality and oppression, but they have no solid basis in "scientifically identifiable genetic differences" (Johnson 2000, p. 249).

In Europe, at first sight, this "consensus" extends from science to the realm of politics and law (Farkas 2017). The definition of "sensitive personal data" in the EU's General Data Protection Regulation (GDPR) includes "personal data revealing racial or ethnic origin", but the legal text immediately goes on to say that "the use of the term 'racial origin' in this Regulation does not imply acceptance by the EU of theories that attempt to determine the existence of separate human races". Some European countries have taken this argument even further. For example, with reference to this passage, Sweden recently removed "racial origin" from its national adaptation of the GDPR. This also follows on Swedish lawmakers' efforts to eliminate official mentions of race, as the race concept is said to be offensive and without support from contemporary science of human differences (SOU 2015, p. 1). Using the concept of ethnicity, lawmakers and experts suggest, is preferable as ethnicity centres the sociocultural history of a group, not biological heredity or essence. Similar anti-racialist arguments are dominant elsewhere in Europe (Goldberg 2009). Indeed, Simon (2012) has described a political and cultural "ban" on the use of race in the bureaucratic lexicon and statistical apparatuses in many European countries, although race is still recurrent in policy and everyday language in a few countries (Farkas 2017), including the UK (Smart and Weiner 2018). Of course, replacing race with ethnicity has not meant the end of racism, as much 'new racism' scholarship has shown (Balibar 1991; Lentin 2008). Neither has it meant that notions of race have disappeared. Rather, as M'charek et al. (2014, p. 462) have argued, race in Europe is best viewed as an "absent presence": active attempts to remove "the tabooed object of race" have not been completely successful, and "race keeps surfacing in various European societies".

But *how*, more precisely, does race resurface despite active attempts to remove it from policy and discourse? In other words, what are the dynamics of the "absentness" and "presentness" of race like in contemporary European societies? A large body of scholarship in medical sociology and science and technology studies—although predominantly in the USA—has shown that the persistence of race is tightly coupled to its routine use in medical research, often alongside ethnicity, rather than instead of it (e.g. Shim 2002; Fujimura et al. 2008; Pollock 2012; M'charek et al. 2014). Furthermore, some US scholarship suggests that a central

actor promoting the use of race and ethnicity in medicine and beyond is the Food and Drug Administration (FDA) (Epstein 2007; Kahn 2012; Pollock 2012; Inda 2016; Fisher 2020). The FDA has major "conceptual power" over medical research, policy, and practice (Carpenter 2014, p. 64), and, in the case of race and ethnicity, this conceptual power is seen when the FDA requires or encourages race- and ethnicity-based data collection and analysis in clinical trials using a set of established definitions and categories, when it participates in interpreting the results of these analyses, and when it promotes the dissemination of "difference findings" pertaining to racial and ethnic groups (Mulinari et al. 2021).

In this article, we explore this line of inquiry for Europe, where notions and classifications of race and ethnicity differ markedly between European countries and from those in the USA. To that end, we undertook a novel, systematic comparison of official translations of English-language statements approved by the European Medicines Agency (EMA) on race and ethnicity into 24 European languages. In contrast to much of the 'new racism' literature that focuses on how static notions of cultural otherness and ethnic profiling have replaced discourses of biological inferiority and racial biology (Gilroy 2003), our article contributes to the sociology of race, ethnicity and medicine by showing, first, how the concept of biological racial and ethnic differences is still very much promoted officially in Europe, even in countries that seemingly deny the scientific basis of such differences, and, second, how there is none the less remarkable variation in translations and adaptations of "race" and "ethnicity" between and within languages, creating peculiar patterns of absentness and presentness of race across Europe. In the final part of the article, we discuss how the sociological question of translations and adaptations of "race" and "ethnicity" to national contexts has important ethical and policy implications for clinical research and practice.

The enduring presence of race in pharmaceutical regulation

Studying the changing pattern of use of "race" and "ethnicity" in the medical research literature, Afshari and Bhopal (2002, 2010) showed that "ethnicity" overtook "race" in the non-US literature in 1976–80 and in the US literature some 15 years later. Based on these trends, they predicted that "[t]he concept of race, which has a fraught past, may soon be a relic of history, with the exception of studies on racism and the history of race science" (Afshari and Bhopal 2010, p. 1682).

Yet, close inspection of medical and biological research over the past two decades does not confirm this prediction (Fujimura et al. 2008; Lee 2018). Duster (2015) called this a "post-genomic surprise", given earlier promises of genomics research abolishing racial thinking. It is important to note that racial thinking in medicine need not necessarily be seen as racist. Rose (2007, p. 167) argued that contemporary biomedicine "does not seek to legitimate [racial] inequality but to intervene upon its consequences". And although discourses about differences may slip into discourses about hierarchies (Kahn 2012), this is not certain to occur (Pollock 2012). Either way, this "post-genomic surprise" is definitively true for the USA, where a distinctively biological race concept has been institutionalised in medicine since

the 1990s (Roberts 2011). For example, the official FDA (2005) definition says that while "'race' refers to a group of people who share common biological characteristics that distinguish them from other groups, 'ethnicity' refers to a social group with a shared history, lineage, heritage, sense of identity, cultural roots, and territorial identity that occurs despite racial dissimilarity" (Ramamoorthy et al. 2015, p. 263). Perhaps the most vivid example of this "post-genomic surprise" is the heart drug BiDil, approved by the FDA in 2005 for "self-identified blacks". BiDil's approval was accused of reinforcing US census categories and biologised conceptualisations among scientists and prescribers, in this way normalising ideas that race and ethnicity are integral to the proper pharmaceutical management of patients (Kahn 2012). Although no other drug has been approved for a specific race or ethnicity by the FDA, there have been several other examples of racialised pharmaceutical regulation since BiDil, demonstrating commitment to a biological race concept in the USA (Mulinari et al. 2021).

However, on the face of it, the viability of a biological race concept in Europe is much more unclear (Bradby 2003; Farkas 2017), and much less is known about the role of the European drug regulators in this area. The GDPR apparently does not approve of it, and, as mentioned, there is a consensual "ban" on the use of the race concept in many European countries (Simon 2012). On the other hand, a previous study found that racialised pharmaceutical regulation is happening in the EU too (Mulinari et al. 2021). While the EMA never approved BiDil, nor any other drug for specific races or ethnicities, the EMA sometimes alerts prescribers to racial or ethnic differences in drug response—in fact, it does so *more often* than the FDA (Mulinari et al. 2021). Furthermore, as in the USA, racialised pharmaceutical regulation in the EU is underpinned by a distinctively biological race concept in apparent contradiction to its dismissal in the GDPR and in much scientific and political discourse in Europe (M'charek et al. 2014). Thus, the EMA refers to drugs as being either "ethnically sensitive" or "ethnically insensitive" (EMA 1998). These two concepts were agreed upon internationally in 1998 by regulators and industry in the so-called International Conference on Harmonisation (ICH) as part of an international effort by industry and regulators in the EU, the USA, and Japan to harmonise technical requirements for pharmaceutical development and regulation (Kahn 2007). Kuo (2008) described how the ICH process had to resolve country representatives' divergent concepts of race and ethnicity. This includes how the EU did not want to "overemphasise diversity" between races whereas both the USA and Japan considered racial and ethnicity differences paramount (Kuo 2008, p. 500). However, at least for Europe, the ICH process helped crystallising a discourse on the nature, causes, and consequences of ethnic and racial difference, including definitions of key concepts adopted by industry and regulators globally (Kahn 2007; see also ICH 2017). Thus, ethnic sensitivity is due to "ethnic factors … relating to races or large populations grouped according to common traits and customs" (EMA 1998, p. 10). Furthermore, these ethnic factors can be either "intrinsic" or "extrinsic", and in the ICH definition, race is solely "intrinsic", and more specifically *genetic*, while ethnicity encompasses both "intrinsic" and "extrinsic" (e.g. cultural) factors (EMA 1998, p. 12). The ICH acknowledged "that this definition gives ethnicity, by virtue of its

cultural as well as genetic implications, a broader meaning than racial", which is a biological grouping (EMA 1998, p. 10).

Epstein (2007, p. 153) remained sceptical about ICH's possibility of significantly influencing uses of race and ethnicity in medicine, because "the ICH, as a weak supranational body, lacks the definitional authority often possessed by nation-states". Yet, what further underscores the importance of the supranational level for uses of race and ethnicity in medicine, but also the influence of US standards, is the Clinical Data Interchange Standards Consortium, a global standard-setting organisation for clinical research (CDISC 2019). The CDISC standard defines, among other things, how patient variables should be collected in clinical research and is required for electronic submission to regulatory authorities in the USA and Japan and is recommended by regulators in Europe and China. Regarding race, the CDISC endorses the use of five categories (i.e. the FDA requested "American Indian or Alaska Native", "Asian", "Black or African American", "Native American or other Pacific Islander", and "White") either using a direct question (i.e. "Which of the following five racial designations best describes you?") or indirectly using "expanded categories" such as Arab or White South American that are "collapsible" into the five categories, such as White, to be reported to regulators (CDISC, 2019).

Taken together, this suggests that predictions of the disappearance of race in medicine do not hold for Europe either, and that the idea of a "consensus" across science, law, and politics is, at best, overstated. However, a caveat here is that the previous analysis of racialised drug regulation covered only the supranational EU (i.e. the EMA), rather than specific European countries. What remains unknown is how racialised regulation is interpreted and operationalised in different European countries, given their highly disparate conceptions and practices related to race and ethnicity (Simon 2012; Farkas 2017). Tracing the translations and adaptations of race and ethnicity terms from the EU level to the national regulatory contexts is therefore the task of this article. Specifically, tracing such translations and adaptations offers a unique opportunity to address the broader issue of the "absent presence" of race in Europe. This includes addressing how various processes (e.g. scientific, regulatory, political, and linguistic) operating at distinct levels (e.g. global, supranational, and national) influence uses and non-uses of race and ethnicity terms and concepts across Europe. This recalls the point made by Smart and Weiner (2018), who showed how US census categories were transformed at the national UK level in the context of hypertension prescribing guidelines. The result, they wrote, is a "hybrid" that folds together elements of race/ethnicity originating from various times and places (e.g. the US and UK) and that relies on elements from globalised science (e.g. evidence from clinical trials), the state (e.g. census categories), and common sense (e.g. that North Africans are not of Black African descent). However, what this will be like in other, non-English speaking countries is unclear, particularly in countries that officially reject the use of "race", such as Sweden, Germany, and France (Farkas 2017).

Methods

Analysis of original, English-language statements

We began by investigating the uses of race and ethnicity terms in the EU's supranational pharmaceutical regulation. We did this by assessing statements about race and ethnicity for all novel drugs ($n = 184$) approved by the EMA over a five-year period, 2014–18 (see Mulinari et al. 2021). Specifically, we analysed each novel drug's English-language Summary of Product Characteristics (SmPC) for statements that contained race and ethnicity concepts. The SmPC is a key part of the marketing authorisation of all medicines authorised in the EU and the basis of information for healthcare professionals on how to use a medicine. In the US, the SmPC is known as the "label" and sometimes this term is also used in Europe, for example, when referring to "off-label" (i.e. unlicensed) uses of marketed drugs. The value of SmPCs, or labels, as data sources has been shown in sociological and policy research, including for investigating racialised pharmaceutical regulation (Mulinari et al. 2021).

The SmPC is drafted by the drug's manufacturer based on the results of studies performed to support marketing authorisation. The SmPC draft is then subject to "detailed review" by the EMA (2017, p. 2) as part of the product assessment process to ensure compliance with quality standards, and consistency with SmPC guidelines and other relevant guidelines, and also to highlight claims in need of further substantiation; given appropriate amendments, the SmPC draft is subsequently approved. Ensuring standardised use of language is one the tasks of the EMA's Working Group on Quality Review of Documents that checks the English-language SmPCs for "linguistic clarity, consistency and accuracy" (EMA 2021). This Working Group is composed of two experts per Member State, one for human and one for veterinary medicinal products, selected by each national drug regulator, with appropriate expertise in regulatory and linguistic areas, as well as in product information and labelling for medicines. For this study, drugs' English-language SmPCs were downloaded from the EMA website and imported into NVivo to be coded for race and ethnicity concepts.

Translations into 24 languages

After the EMA approves the English-language SmPC, it is translated into 24 languages, including the non-EU languages Norwegian and Icelandic (EMA 2017). Translations are conducted on behalf of the drug's market authorisation holder (i.e. the pharmaceutical company) by certified translators, and are approved by the respective national drug regulators following "linguistic review", with exceptions for countries that share official languages; for example, the SmPC used in Austria and in German-speaking Belgium is reviewed by the German drug regulator (EMA 2017). After approval by the respective national drug regulator, the SmPC will be checked again by the EMA before sending the final translations to the European Commission for final approval.

We investigated the translations of race and ethnicity terms into all 24 languages, with more in-depth analysis of the subset of languages in which we observed a clear tendency to replace "race" with another term. For this analysis, we considered an informative and manageable sample comprising all 24 drugs whose SmPCs were identified in a previous study as containing statements about *differences* between racial/ethnic groups (Mulinari et al. 2021). We downloaded the SmPCs in the various languages from the EMA website and imported them into NVivo. Five factors ensured that we were able to conduct the analysis even for languages that we do not speak. First, SmPCs are highly structured, which makes them easily searchable. Second, because race and ethnicity concepts are often present in sub-headings, they are easily identifiable. Third, the terms race and ethnicity are similar across most languages. Fourth, the same race and ethnicity terms were recurrent. Fifth, in the few cases in which we had doubts about translations, we asked colleagues proficient in specific languages for guidance to ensure that our interpretations were correct.

Results

Analysis of English-language SmPCs

Race and/or ethnicity terms were recurrent in the original English-language SmPCs, two-thirds (122 of 184) of which contained such terms. Race, rather than ethnicity, terms dominated: 63% SmPCs contained race terms, whereas only 19% contained ethnicity terms.

Twenty-eight SmPCs (15%) contained *both* race and ethnicity terms, and there were inconsistencies in how race and ethnicity terms were used in such cases. Sometimes they were used to mean different things, as in "White race" and "Hispanic/Latino ethnicity" or "Asian race" and "Japanese ethnicity". For example, the SmPC for semaglutide states: "race (White, Black or African American, Asian) and ethnicity (Hispanic or Latino, non-Hispanic or Latino) had no effect on the pharmacokinetics of semaglutide". However, sometimes "race" and "ethnicity" were used as synonyms. For example, the SmPC for ceftolozane/tazobactam states: "In a population pharmacokinetic analysis of ceftolozane/tazobactam, no clinically relevant differences in ceftolozane/tazobactam AUC [area under curve] were observed in Caucasians ($n=156$) compared to all other *ethnicities* combined ($n=30$). No dose adjustment is recommended based on *race*" (emphasis added).

We considered in detail the 24 (13%) SmPCs describing racial/ethnic *differences* in drug efficacy, safety, or metabolism. Most racial/ethnic differences were said to be of uncertain or no therapeutic relevance, with a few key exceptions (Appendix Table I; see also Mulinari et al. 2021). The race and ethnicity terms used in the English-language SmPCs to describe differences were "Race" ($n=13$), "Ethnicity" ($n=2$), "Race and ethnicity" ($n=1$), "Race/ethnicity" ($n=1$), "Race categories" ($n=1$), "White race" ($n=1$), "Black race" ($n=1$), "Asian race" ($n=2$), "Japanese ethnicity" ($n=1$), "Asian ethnicity" ($n=1$), and "Ethnic origin" ($n=1$).

Translation of race and ethnicity terms into European languages

Our analysis of the 24 SmPCs describing racial/ethnic differences uncovered major differences, inconsistencies, and idiosyncrasies in how the race and ethnicity terms were translated. The variable translation of some of the terms into the 24 languages is shown in Appendix II. In Figure 1, we propose a categorisation of countries based on their relative retention of the "race" concept.

In 13 of 24 languages, "Race" was translated into "Race" in all instances: Bulgarian (Paca), Croatian (Rasa), Czech (Rasa), Estonian (Rass), Icelandic (Kynþáttur), Latvian (Rase), Lithuanian (Rasė), Maltese (Razza), Polish (Rasa), Romanian (Rasă), Slovak (Rasa), Slovenian (Rasa), and Spanish (Raza).

Furthermore, in most of these languages, "Ethnicity" was translated into an ethnicity term (not shown), such as the equivalent of "Ethnicity", "Ethnic background", or "Ethnic origin", with a few exceptions in which the translation was "Race": Icelandic and Romanian in both cases, and Slovenian in one case. In Estonian, one

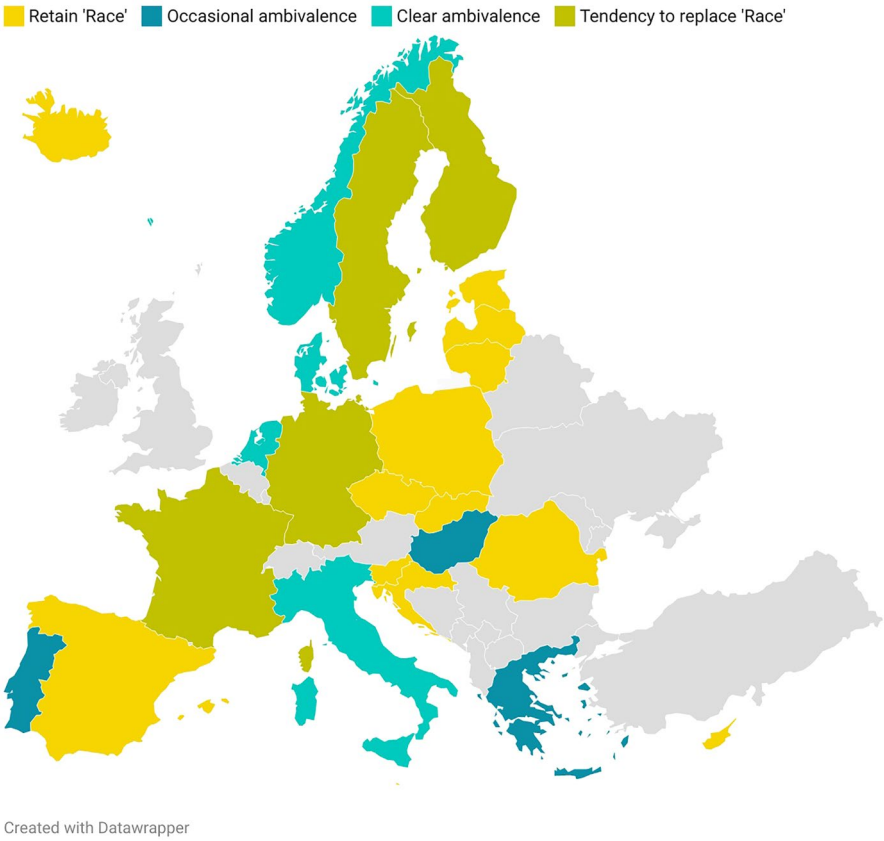

Fig. 1 Retention or replacement of "Race" in SmPCs

translation of "Ethnicity" was "Rahvus", which means nation and was also used to translate "Ethnic origin".

Adding further inconsistency in the translation of "Race", in Greek there was one translation into "Ethnic origin"; in Hungarian and Portuguese there were two translations into "Ethnic group" or "Ethnicity"; and in Dutch and Norwegian there were three, in Danish four, and Italian six cases of translation into "Ethnicity", "Ethnic background", or "Ethnic origin", respectively. One SmPC contained two separate racial/ethnic difference statements that both included the term "Race". Illustrative of the inconsistencies observed, in the Norwegian, Portuguese, and Danish SmPCs, one instance of "Race" was translated into "Race" and the other into "Ethnicity".

Furthermore, there were many inconsistencies within and between languages in how "White race", "Black race", and "Asian race" were translated (Appendix II). For example, in Czech, "Asian race" was translated into "Asijského původu [origin]" and "Asijského etnického [ethnicity]", but in Slovak both translations were "Ázijskej rasy [race]". In Hungarian, "Ázsiai etnikumú [ethnicity]" and "Ázsiai rasszba [race]" were both used. Similarly, two distinct translations were used in other languages: Spanish, "Raza asiática" and "Origen asiático"; Icelandic, "Asískum uppruna [origin]" and "Asískum kynstofni [race]", and Norwegian, "Asiatisk rase" and "Asiatisk avstamning [descent]". In contrast, in Dutch, Polish, and Portuguese and some other languages, "Asian race" (e.g. "Aziatische ras" in Dutch) was used in both translations.

Translation of race and ethnicity terms in Finnish, French, Swedish, and German

Four languages stood out, as in those languages "Race" was more often translated into ethnicity terms: Finnish ($n=8$ of 13), French ($n=10$), Swedish ($n=11$), and German ($n=12$). The preferred translation of "Race" was "Etninen tausta [background]" in Finnish, "Origin ethnique" in French, "Etnicitet" in Swedish, and "Ethnische Zugehörigkeit [belonging]" in German. However—and further underscoring the inconsistent and idiosyncratic nature of translations—the few French, Swedish, and German SmPCs that retained "Race" were for different drugs (i.e. French: daklatasvir, lurasidone, ixazomib; Swedish: bedaquiline, nintedanib; and German: peramivir).

Furthermore, there were major inconsistencies in how "Black race", "White race", and "Asian race" were translated into the four languages. For example, in Swedish, the translations were "Svart etnicitet", "Kaukasisk etnicitet", and "Asiatisk etnicitet", but in German, the same terms were translated into "Schwarze Hautfarbe [skin colour]", "Weißer Abstammung [descent]", and "Asiatischer Abstammung" and "Asiatischen Patienten"—and in French, "Origine africaine", "Race blanche", and "Race asiatique" and "Patients asiatiques". Similar inconsistencies were seen for translations of "Black race" (Table 1, Figure 2).

The uniqueness of these four languages—but also the variable translations between and within them—was confirmed when looking at translations of the 28 SmPCs that contained *both* race and ethnicity terms. In 23 of 28 (82%) German

Table 1 Translations of 'race' and 'ethnicity'—three examples

English	German	French	Swedish	Finnish
Body weight, sex, **race, and ethnicity** did not have a clinically relevant effect on the PK of baricitinib	Körpergewicht, Geschlecht, **Rasse und ethnische Herkunft** hatten keinen klinisch relevanten Effekt auf die Pharmakokinetik von Baricitinib	Le poids corporel, le sexe, **la race et l'origine ethnique** n'ont pas eu d'effet cliniquement pertinent sur la pharmacocinétique du baricitinib	Kroppsvikt, kön, **ras och etnicitet** hade inte någon kliniskt relevant effekt på baricitinibs farmakokinetik	Paino, sukupuoli, **rotu ja etninen tausta** eivät vaikuttaneet kliinisesti merkittävästi barisitinibin farmakokinetiikkaan
race (White, Black or African American, Asian) and **ethnicity** (Hispanic or Latino, non-Hispanic or -Latino) had no effect on the pharmacokinetics of semaglutide	**ethnische Zugehörigkeit** (weiß, schwarz, afroamerikanisch, asiatisch, hispanisch oder lateinamerikanisch, nicht-hispanisch oder -lateinamerikanisch) hatten keine Auswirkung auf die Pharmakokinetik von Semaglutid	**l'origine ethnique** (Blanc, Noir, Afro-Américain, Asiatique, Hispanique ou Latino, non-Hispanique ou non-Latino) n'ont eu aucun effet sur la pharmacocinétique du sémaglutide	**ras** (vit, svart eller afroamerikan, asiat) och **etniskt ursprung** (spansk eller latinamerikan, icke- spansk eller icke-latinamerikan) hade ingen effekt på farmakokinetiken för semaglutide	**rotu** (valkoihoinen, mustaihoinen tai afroamerikkalainen, aasialainen) ja **etninen tausta** (latinalaisamerikkalainen, ei-latinalaisamerikkalainen) eivät vaikuttaneet semaglutidin farmakokinetiikkaan

Table 1 (continued)

English	German	French	Swedish	Finnish
Race/Ethnicity In population pharmacokinetic analyses, elbasvir and grazoprevir AUCs are estimated to be 15% and 50% higher, respectively, for Asians compared with Whites. Population pharmacokinetics estimates of exposure of elbasvir and grazoprevir were comparable between Whites and Black/African Americans. These changes are not clinically relevant; therefore, no dose adjustment of elbasvir/grazoprevir is recommended based on **race/ethnicity**	**Hautfarbe/ethnische Abstammung** In populationspharmakokinetischen Auswertungen wurde bei Patienten asiatischer Abstammung im Vergleich zu Patienten mit weißer Hautfarbe eine um 15% höhere AUC von Elbasvir und eine um 50% höhere AUC von Grazoprevir ermittelt. Die populationspharmakokinetische Schätzung der Elbasvir- und Grazoprevir-Exposition war bei Menschen weißer Hautfarbe und bei Menschen schwarzer Hautfarbe bzw. Afro-Amerikanern vergleichbar. Diese Veränderungen sind nicht klinisch relevant; daher werden keine auf **der Hautfarbe oder der ethnischen Abstammung** basierenden Dosisanpassungen von Elbasvir/Grazoprevir empfohlen	**Race/Origine ethnique** Dans les analyses de pharmacocinétiques de population, les ASC estimées de l'elbasvir et du grazoprevir sont plus élevées de respectivement 15% et 50% chez les sujets asiatiques par rapport aux sujets blancs. Les estimations de pharmacocinétique de population de l'exposition à l'elbasvir et au grazoprevir étaient comparables entre les sujets blancs et les sujets noirs/afro-américains. Ces modifications ne sont pas cliniquement pertinentes; par conséquent, aucun ajustement de la dose d'elbasvir/grazoprevir en fonction **de la race ou du groupe ethnique** n'est recommandé	**Etnisk tillhörighet** I populationsfarmakokinetiska analyser beräknades AUC för elbasvir och grazoprevir vara 15% respektive 50% högre hos asiater jämfört med kaukasier. Populationsfarmakokinetiska beräkningar av exponeringen av elbasvir och grazoprevir var jämförbara mellan kaukasier och svarta/afroamerikaner. Dessa förändringar är inte kliniskt relevanta och därför rekommenderas ingen dosjustering av elbasvir/grazoprevir baserat på **etnisk tillhörighet**	**Etninen tausta** Populaatiofarmakokineettisissä analyyseissä elbasviirin AUC-arvon arvioidaan olevan 15% ja gratsopreviirin AUC-arvon 50% suurempi aasialaisilla kuin valkoihoisilla tutkittavilla. Populaatiofarmakokineettisissä arvioissa elbasviiri- ja gratsopreviirialtistukset olivat samanlaiset valkoihoisilla ja mustaihoisilla/afroamerikkalaisilla tutkittavilla. Nämä muutokset eivät ole kliinisesti merkittäviä, joten elbasviiri-gratsopreviirihoidon annosta ei tarvitse muuttaa **etnisen taustan** perusteella

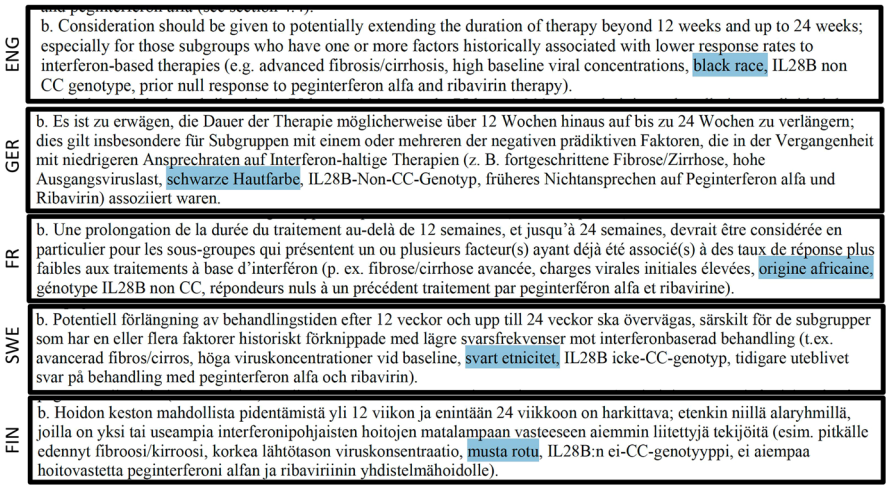

Fig. 2 Translation of "Black race" in hepatitis C drug sofosbuvir's SmPC

SmPCs, the race term was removed, versus 14 (50%) of the Swedish and French but only 10 (36%) of Finnish SmPCs.

Three examples of variable translation are shown in Table 1. The first case illustrates the retention of "Race" in all four considered languages (i.e. Rasse, Race, Ras, Rotu). The second illustrates the collapse of the two-level US racial and ethnic standard in German and French translations, but not in the Swedish and Finnish ones, in which the distinction between "Race" and "Ethnicity" is retained in the SmPCs. The third example illustrates how "Race/ethnicity" is varyingly translated into "Skin colour/ethnic origin" in German, into "Race/origine ethnique" or "Groupe ethnique" in French, into "Ethnic belonging" in Swedish, and "Ethnic origin" in Finnish.

Discussion

The presence of race in European pharmaceutical regulation

Current scholarship on race in Europe often depicts race as "buried", "tabooed", "un-named", "slippery", or "silenced" (e.g. Lentin 2008; M'charek et al. 2014; Yanow et al. 2016; Balkenhol and Schramm 2019; Maneri 2021), but our study shows that, on the contrary, the concept of race is being promoted in plain sight by Europe's foremost regulatory agency. More specifically, this study suggests that EU pharmaceutical regulation ensures the continued presentness of race in Europe, contradicting predictions of a general shift away from race (Afshari and Bhopal 2010). Consistent with this presentness, we found that over 60% of new drugs were approved alongside one or more statements that included race terms. Although some statements reflect the uptake of US racial/ethnic standards, such as the use of the compound term "race/ethnicity" or the two-level US racial and ethnic census

standard, it is incorrect to reduce the use of race and ethnicity in EU pharmaceutical regulation to a mere US import. The EMA independently and openly encourages companies to collect and communicate data based on race and ethnicity, for example in labelling guidelines instructing companies on how to report racial differences (Mulinari et al. 2021, p. 4), and the EMA has also approved statements about racial/ethnic differences more often than the FDA has in recent years (Mulinari et al. 2021, p. 5). Furthermore, the EMA has helped develop, and has adopted and/or recommended international race and ethnicity standards for clinical research, i.e. issued by ICH and CDISC. Our study thus underscores the importance of *both* US and EU regulatory practices together with overarching transnational standardisation efforts for the continued presentness of race in Europe.

In European debates about the race concept, the fact that the EMA encourages the racial sorting and profiling of patients in research and clinical praxis should create "cognitive dissonances" (Winant 2015) for anyone who claims that only divisive 'identity politics' would seek to subcategorise the human race, and who, based on this argument, seeks to disallow or undercut critical studies of race and racism (Fassin 2021). This fact should also cause unease among those who want state bureaucracies across Europe to increasingly use a social race concept to measure inequality and racism (Makkonen 2007), as such a concept would need to co-exist with the already institutionalised uses of race exposed here. This is important because evidence from US pharmaceutical regulations shows that social and biological race concepts are not kept separate. Thus, the FDA (2013, p. 4) justifies its racialised regulation with reference to consistency "with the principle of justice", which is said to demand the "inclusion and analysis of demographic subgroups in clinical trials". That is, concerns about social inequality and concerns about biological differences easily become intertwined in pharmaceutical regulation; in fact, as argued by Kahn (2012), political needs for inclusiveness have tended to strengthen the ideas of biological differences between socially constructed categories in US pharmaceutical regulation.

Lost and found in translation

While the presentness of race was evident at the level of EU pharmaceutical regulation, its absentness started to emerge more clearly downstream, at the country level. A general feature of contemporary European politics of race is the frequent discursive coding of race in other terms, such as nation and ethnicity (Lentin 2008; Balkenhol and Schramm 2019). This is also a key mechanism by which race becomes an "absent presence" in pharmaceutical regulation. For example, "Race" was sometimes translated into skin colour, as in "Schwarze Hautfarbe" in German, or into geographic origin, as in "Origin africain" in French, or a mix of both as in Norwegian—"Mørkhudete av afrikansk opprinnelse [dark-skinned of African origin]". Yet, the most preferred modified translation of "Race" was into an ethnicity term, for example, "Etnia nera" in Italian. It should be noted that "race" and "ethnicity" were sometimes used as synonyms even in English. Arguably, using "ethnicity" as a synonym of "race" infuses ethnicity, a concept developed to highlight cultural

differences, with biologised meaning. That is, at least in pharmaceutical regulation and pharmaceutical medicine, any shift from "race" to "ethnicity" does not appear as a shift from biology to culture; it is simply a more accepted or alternative way to say "race" in some languages and contexts.

Still, "race" was used more often than "ethnicity" in English-language SmPCs, and "race" was usually retained when translated into the 24 languages, albeit with large variation between and within languages. This large variation is remarkable given the highly structured nature of the regulatory document investigated, the SmPC, as well as the elaborated "linguistic review" of the SmPCs carried out by EU and national regulators (EMA 2017), and which are supposed to ensure that drug regulators speak with one voice to prescribers across Europe (Mulinari and Davis 2017). Thus, the EMA (2017) states that it will "ensure high quality and consistent product information…in all Member States (p. 1)" including by "monitor[ing] the quality of the translations, the [linguistic] review by the Member States and industry's compliance with Member States' comments as part of [Agency] Key Performance Indicators (p. 13)". Relatedly, the Agency's Working Group on Quality Review of Documents mentioned above is responsible for "verifying the terminology used in translations and their consistency with the original versions" in product information and labelling (EMA 2021)—but our study found much inconsistency across languages. We interpret this variation as confirming that national political culture is a powerful filter through which racial/ethnic terms are accepted, modified, or rejected in medicine (Smart and Weiner 2018). One objection to this interpretation could be that the observed pattern of variable translation reflects linguistic effects, not political and cultural ones. However, this is refuted by evidence showing how it is perfectly possible to translate "race" into "ethnicity" in all languages, namely: first, the inconsistencies and idiosyncrasies in translations in most languages and, second, the use of ethnicity terms in all languages.

Another key finding was the idiosyncratic removal and retention of the race terms in different languages for *the same drug*, since this shows that the variable translations are not a company effect either, e.g. Gilead allowed highly variable translation of "Black race" for its hepatitis C drug sofosbuvir (Figure 2). Equally important, our analysis shows that even in countries where political and scientific elites are said to vehemently oppose the race concept, it lingers in plain sight. For example, in translations of SmPCs that contained *both* race and ethnicity terms, around 20% of German, 50% of Swedish and French, and 85% of Finnish SmPCs retained the race terms despite recurrent claims that the countries have "banned" race. Taken together, this suggests that the pattern of variable translations emerges primarily at the micro-level from the decisions of translators preparing the texts, who are filtering national political cultures, not from the companies and national regulatory agencies reviewing and approving them.

Implications for clinical research and practice

The sociological question of translations and adaptations of race and ethnicity concepts to national contexts has important ethical and policy implications for clinical

research. According to drug regulators, the reason for collecting data on race and ethnicity in the first place is to allow for reliable communication between different actors involved in clinical trials and to present evidence-based recommendations to prescribers and patients (Ramamoorthy et al. 2015). At the same time, the FDA (2013) acknowledges that "from a strictly scientific perspective, there are important limits to the use of race/ethnicity in predicting medication response". This is also consistent with statistical analyses showing that even relatively large average differences between racial/ethnic groupings do not translate into good individual-level predictions of response (Mulinari et al. 2018).

In addition, regulators, scientists, and industry readily acknowledge that the racial/ethnic categories used in clinical research may not be relevant in most countries and cannot be applied consistently in pharmaceutical research globally (Kahn 2007; Ramamoorthy et al. 2015). This point was nicely illustrated by the decision in July 2018 by the Pharmacogenomics Knowledgebase (PharmGKB)—the leading public repository of genotype and phenotype information relevant to pharmacogenetics—to stop using impractical US-centric categories (Huddart et al. 2019). Instead, PharmGKB recommended a new genetically based taxonomy that consists of nine groups: seven genetic ancestry groups (i.e. American, Central/South Asian, East Asian, European, Near Eastern, Oceanian, and Sub-Saharan African) and two groups for African American/Afro-Caribbean and Latino populations "which have arisen more recently and are genetically distinct from the seven geographical groups". That is, PharmGKB eschews the concepts of race and ethnicity, replacing the dominant US standard with one in which African Americans and Afro-Caribbeans are grouped together but are conceptualised as *genetically admixed and distinct* from Sub-Saharan Africans, and in which "Asians" and "Whites" are divided into four ancestry groups. Obviously, this novel taxonomy would radically alter the racialisation of pharmaceutical regulation, because it would mean a reorganisation and proliferation of categories as well as a questioning of the current practice of extrapolating differences between US racial groups to European contexts, and vice versa.

Such important "technical" issues notwithstanding, our study indicates another major problem with race and ethnicity concepts and classifications that is also likely to adversely affect their therapeutic usefulness, namely, that prescribers in different countries may interpret information from companies and regulators about race and ethnicity in different ways because of variable and inconsistent translations. Additionally, if uses of concepts are inconsistent and idiosyncratic, to the extent that concepts may become practically uninterpretable, the question is whether it is ethically and scientifically justified to routinely record racial and ethnic origin in clinical trials, as is the current praxis.

What is more, the practice that we have analysed is only one link in multiple chains of interpretative work, often connecting many different countries, that extend from bench to bedside, and in which the SmPC forms a crucial link between the "upstream" bench and the "downstream" bedside. Upstream, in increasingly globalised clinical studies (Huang and Temple 2008), patients are allocated to different races or ethnicities (Epstein 2008; Fisher 2020), but how does this practice work in countries that officially reject "race" compared with those that do not? Downstream,

in clinical decision-making, prescribers interpret professed "difference findings", or the lack thereof, but this is also a process fraught with inconsistencies and idiosyncrasies (Hunt et al. 2013; Smart and Weiner 2018). Ultimately, we should be able to lay bare the "spongy" chains of interpretative work extending from bench to bedside that culminate in the decision of a doctor to treat their patients differently, or not, based on perceived race or ethnicity. This article has hopefully contributed to achieving that goal by exposing the curious dynamics of the absentness and presentness of race (and ethnicity) in European pharmaceutical regulation.

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