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Financial Transparency in Industry-Physician Relationships

Part I: Analysis and Critical Assessment of the Swiss Pharma Cooperation Code

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* We thank scienceindustries for answers provided to our many questions, but underline that this article only represents the view of the authors, and not in any way those of scienceindustries.

1 Conflicts of interest are usually defined as a situation where a person has a secondary interest (e. g., a financial interest) that could influence how this person upholds her primary interest (e. g., taking care of patients). “This definition frames a conflict of interest in terms of the risk of such undue influence and not the actual occurrence of bias”. Deborah C. Marshall et al., Disclosure of industry payments to physicians: An epidemiologic analysis of early data from the Open Payments program, 91(1) Mayo Clinical Proceedings p. 84–96 (2016). The problems possibly stemming from such conflicts have been described by David Henry in: Doctors and drug companies: still cozy after all these years, 7(11) PLOS e1000359, 2010.

2 A survey study conducted in the United States showed that: “Overall, 83.8% of all respondents reported some type of relationship with industry during the previous year [2009]. Approximately two-thirds (63.8%) received drug samples, 70.6% food and beverages, 18.3% reimbursements, and 14.1% payments for professional services. Since 2004 the percentage of each of these benefits has decreased significantly.” Eric G. Campbell et al., Physician professionalism and changes in physician-industry relationships from 2004 to 2009, 170(20) Archives of Internal Medicine p. 1820–1826 (2010). See previously Eric G. Campbell et al., A National Survey of Physician–Industry Relationships, 356 NEJM p. 1742–50 (2007). No such surveys have been conducted in Switzerland.

I. Goals of the Pharma Cooperation Code in View of the Literature

A long stream of empirical studies has confirmed that conflicts of interests[1] are common in the health sector.[2] Conflicts of interests are not inherently "evil", but they do have the potential to bias doctors' judgments – what has also been established by further empirical studies.[3]

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Indeed, if a doctor feels indebted to a pharmaceutical company which has offered her gifts, has invited her to seminars, had included her on advisory boards or has paid for her research, she may feel more inclined to choose and prescribe that company's medical products – even if they are more expensive or less adequate for the patient. If this happens, it will be most often unconscious on the part of the doctor.[4] Of course, the reverse may also occur: some doctors may refuse all offers coming from pharmaceutical companies;[5] others may accept them, but still retain their fully independent judgment. Yet, the perception by the public of rampant conflicts of interest and the perception that these conflicts lead to suboptimal treatment decisions[6] are likely to undermine patients' trust towards doctors.[7]

A survey titled "Moniteur de la santé"[8] confirms the importance of the issue in the eyes of the general public: While 88% of the respondents believe that "if physicians collaborate to pharmaceutical research, both can benefit",[9] and while 74% think that "the funding of continuing education by the pharmaceutical industry does

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3 See, e. g., James S. Yeh et al., Association of Industry Payments to Physicians With the Prescribing of Brand-name Statins in Massachusetts, 176(6) JAMA Internal Medicine p. 763–768 (2016) ("For every $ 1000 in total payments received, the brand-name statin prescribing rate increased by 0.1% (95% CI, 0.06%–0.13%; P < .001). Payments for educational training were associated with a 4.8% increase in the rate of brand-name prescribing (P = .004); other forms of payments were not. […] Industry payments to physicians are associated with higher rates of prescribing brand-name statins."); Ryann Grochowski Jones/Charles Ornstein, Matching Industry Payments to Medicare, Prescribing Patterns: An Analysis, ProPublica (2016) ("physicians in five common medical specialties who accepted at least one industry payment were more likely to prescribe high rates of brand-name drugs than physicians who did not receive any payments. […] the group receiving larger payments had a higher brand-name prescribing rate on average. Additionally, the type of payment made a difference: those who received meals alone from companies had a higher rate of brand-name prescribing than physicians who received no payments, and those who received speaking payments had a higher rate than those who received other types of payments."); Roy H. Perlis/Clifford S. Perlis, Physician Payments from Industry Are Associated with Greater Medicare Part D Prescribing Costs, PLOs one 2016 ("for each of the 12 specialties examined the receipt of payments was associated with greater prescribing costs per patient, and greater proportion of branded medication prescribing."); Ashley Wazana, Physicians and the pharmaceutical Industry: Is a gift ever just a gift? 283(3) JAMA p. 373–380 (2000) ("Attending sponsored CME events and accepting funding for travel or lodging for educational symposia were associated with increased prescription rates of the sponsor's medication. Attending presentations given by pharmaceutical representative speakers was also associated with nonrational prescribing.").

4 Studies have shown that physicians are usually unaware of being influenced by conflicts of interest. Even educational measures intended to increase their awareness of conflicts of interest often backfire, in the sense that doctors become convinced that others are at risk of undue influence, while themselves remain entirely independent. See Jason Dana/George Loewenstein, A social science perspective on gifts to physicians from industry, 290(2) JAMA p. 252–255 (2003).

5 Doctors interacting less with pharmaceutical companies are more likely to prescribe generic drugs, as shown in this relatively old (1987) study by A. D. Bower/G. L. Burkett, Family physicians and generic drugs: a study of recognition, information sources, prescribing attitudes, and practices, 24(6) J Fam Pract. p. 612–616 ("The habit of prescribing mostly generic drugs, for example, was found to be more common among family physicians who were residency trained, who relied least on drug company representatives, and who were regular readers of the New England Journal of Medicine. The ability to recognize all ten generic names was found to be highest among these same groups of physicians and also among those who relied least on journal advertisements and those who were regular readers of The Medical Letter.")

6 Some authors do not dispute the existence of conflicts of interest and further accept that these situations do influence physicians, but question whether this leads to actual harm to patients. Moreover, they warn that fear of conflicts of interest may also cause harm, notably by stifling "honest discourse" and discouraging "productive collaborations". It may even lead to discounting important and valid study findings, simply because of the industry ties of the authors. See, e. g., Lisa Rosenbaum, Understanding bias – The case for careful study, 372(20) NEJM p. 1960 (2015); Lisa Rosenbaum, Reconnecting the dots – Reinterpreting industry-physician relations, 372(19) NEJM p. 1860–1864 (2015).

7 See for example in the United States: Robert V Gibbons et al., A Comparison of Physicians' and Patients' Attitudes Toward Pharmaceutical Industry Gifts, 13(3) Journal of General Internal Medicine, p. 151–154 (1998): "Patients found gifts less appropriate and more influential than did their physicians. About half of the patients were aware of such gifts; of those unaware, 24% responded that this knowledge altered their perception of the medical profession."

8 Interpharma, *Moniteur 2018.* Yearly survey conducted by the gfs.bern polling institute on behalf of Interpharma, the most recent survey being the 2018 edition. We sometimes cite to the 2016 edition as it is more detailed.

9 Interpharma, *Moniteur 2016,* p. 28; our translation. Original version: "Si les médecins collaborent à la recherche pharmaceutique, les deux peuvent en tirer profit".

not pose a problem if it is transparent",[10] 78% considered that "pharma companies should provide detailed information on what they pay to doctors or organisms for their presentations, consultations or collaborations to studies".[11] Only 43% of those surveyed felt that "the Swiss pharmaceutical industry informs in a transparent way about its activities".[12] This corroborates the relevance of the measures being implemented to safeguard the integrity of interactions between healthcare actors (HCAs) and pharmaceutical enterprises.

The range of available measures to achieve this goal has long been discussed among experts.[13] They go from the extreme of banning interactions between HCAs and pharmaceutical companies,[14] to less severe forms of oversight such as mandated transparency. Under this second option, various forms of interactions are left to the discretion of the involved parties, but these parties or at least one of them has the duty to disclose them publicly. Patients are then

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better able to form an opinion as to the seriousness of the situation; they may reach the conclusion that the interaction at hand is innocuous or even beneficial; on the contrary, faced with a different fact pattern, they may decide that this particular doctor is best avoided.[15] Patients thus have the option to make – and act upon – informed decisions based on detailed and reliable information. Indirectly, patients' reactions may encourage doctors and pharmaceutical companies to tailor their interactions in a way that is perceived by the public as prosocial; conversely, forms of interactions which are viewed as more problematic may be abandoned.[16] Thus, transparency may have a preventive effect.

How such transparency is to be introduced in the health care sector varies. Some countries have introduced legislations that compel certain HCAs to publish information.[17] In others, initiatives to impart information to the public are left completely to the discretion of each doctor and each firm. A middle-of-the-road approach is self-regulation, whereby trade associations convince their members to apply a uniform approach to disclosure.

Switzerland, following the lead of the European pharmaceutical trade association (EFPIA for European Federation of Pharmaceutical Industries and Associations),[18] has chosen this latter path. Its pharmaceutical industry, led by scienceindustries,[19] has enacted a self-regulatory code outlining how transparency must be carried out. Under this Pharma Cooperation Code (PCC), adhering pharmaceutical companies must publicly disclose nearly all payments (the correct and broader term is: transfers of value or ToVs) that they made in favor of HCAs. The code is binding on its members, but only after each undertaking has explicitly declared its acceptance. As of the 12th of December 2018, 59 companies out of 249 members had adhered.[20] This low

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10 Id., p. 28; our translation (original version: "Le financement de la formation continue par l'industrie pharmaceutique ne pose pas de problème si celle-ci est réalisée en toute transparence").

11 Id., p. 28; our translation (original version: "Les entreprises pharmaceutiques doivent présenter en détail ce qu'elles paient aux médecins ou organismes pour exposés, consultations ou collaboration à des études").

12 Interpharma, *Moniteur 2018,* p. 28; our translation (original version: "L'industrie pharmaceutique suisse informe de manière transparente au sujet de ses activités").

13 See, e. g., Marc Rodwin, Conflicts of Interest and the Future of Medicine: The United States, France and Japan, Oxford University Press (2011).

14 For example, California has introduced a bill which would cap the cost of meals to doctors to $ 250 per year, and would entirely ban speaking fees, gifts and travel payments to doctors. See Senate Bill SB-790 Health care providers: gifts and benefits, introduced by Senator McGuire in February 2017. Available here: https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180SB790. It is also relevant to note that professionals in certain fields (e. g. judges, prosecutors, journalists) have been traditionally prohibited from accepting any gifts. Whether physicians' independence should be viewed in the same light as that of a judge or a journalist is an important question that goes beyond the scope ascribed to this article.

15 This is of course largely theoretical as Genevieve Pham-Kanter underlined in her article: patients may experience practical as well as insurance constraints in choosing and changing doctors. *See* Act II of the Sunshine Act, PLOS, Issue 11, e1001754, 2014.

16 The opposite reaction has also been evoked in the literature: "there is also some debate as to whether an unintended consequence of transparency of physician payments may result in allowing such payments to be more rather than less influential because they have been disclosed due to discounting by informed patients or a feeling of moral license after having disclosed such a relationship." D. Marshall et al. (Fn. 1), p. 7.

17 For example: United States, France, Denmark and Portugal.

18 EFPIA was moved to enact rules on the topic, partly because several countries had adopted or were in the process of adopting laws mandating pharmaceutical transparency.

19 The full name of scienceindustries is: Business Association Chemistry Pharma Biotech or, in French, "Association économique du secteur Chimie Pharma Biotech". (https://en.scienceindustries.ch/).

20 The list of adhering companies can be found on the webpages: https://en.scienceindustries.ch/involvement/pharma-

rate of adherence is only apparent, since many members of scienceindustries do not produce or sell products targeted by the PCC, i.e. prescription-only (Rx) drugs (see subsection I.F.1).[21] In principle, it is not mandatory for pharmaceutical companies producing or selling Rx drugs to adhere to the PCC, even if they are members of scienceindustries.[22] Non-adhering companies do not face any consequences and a signatory is also free to withdraw from the system. The principle knows one exception: Pharmaceutical companies which are direct members of the EFPIA (the so-called corporate members) and operate in Switzerland have the obligation to adhere to the PCC.[23] Scienceindustries estimates that the PCC signatories represent more than 80% of the Swiss pharmaceutical market turnover.[24]

The purpose of the present article is to analyze and assess the transparency measures introduced in Switzerland. It is divided in two parts. Part I provides an overview of the origin of the PCC, its rules, presents similar initiatives in Europe and in the United States, and closes with a brief description of the legislative revision underway in Switzerland. Part II will build on the first one to outline the drawbacks of the current system and to articulate recommendations for improvement[25]. Our paper focuses solely on transfers of value to HCAs, not including patient organizations, even though the latter are subject to similar

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transparency rules in Switzerland[26] as well as in Europe.[27]

A. Introduction: How the PCC Came to Be Enacted

Most companies active in the pharmaceutical sector have chosen to adhere to one or several of four Swiss trade associations. These trade associations are scienceindustries,[28] intergenerika,[29] interpharma[30] and vips.[31] Each of these trade associations has a slightly different focus. For example, intergenerika defends the interests of companies selling generic drugs, while interpharma brings together companies investing in research and development ("R&D").

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code/pharma-cooperation-code-signatories and https://en.scienceindustries.ch/association/our-members. The list of scienceindustries members also contains branches ("Zweigniederlassung") and duplicates (e. g. two lines for BASF Schweiz AG, one time in Basel, and another time in Pfäffikon). It is interesting to note that some signatories of the PCC are not members of scienceindustries. Section 113 of the PCC explicitly allows this to encourage all companies to take part in the PCC transparency initiative.

21 As of the 12th of December 2018, the Pharma Code (PC) has been signed by 130 companies (see https://en.scienceindustries.ch/involvement/pharma-code/pharma-code-signatories). The difference between the 130 signatories of the PC and the 59 companies who adhered to the PCC probably relates to their respective scope: the PC applies to all pharmaceutical products, both prescription (Rx) and non-prescription (over-the-counter or OTC), while the PCC only targets Rx drugs.

22 Even companies which signed the Pharma Code regarding advertising, are not obliged to adhere to the PCC.

23 EFPIA Disclosure Code, under "Applicability of this Code", also confirmed by scienceindustries. There are currently 40 companies listed on the EFPIA website as "corporate members" and the list appears to include all large actors.

24 See https://fr.scienceindustries.ch/media/communiques-de-presse/_detail-626/51370%252Fdeuxieme-campagne-de-publication-des-indemnites-des-entreprises-pharmaceutiques-aux-dispensateurs.

25 Part II will be published in Life Science Recht 2/2019.

26 Section 3 of the PCC, titled "Cooperation with patient organisations and disclosure of pecuniary benefits to such recipients", sets forth the members' obligations related to patient organisations.

27 The EFPIA has enacted a distinct code for patient organisations, the so-called "EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations", whose article 5 imposes similar transparency obligations.

28 See website at https://www.scienceindustries.ch/.

29 See website at http://intergenerika.ch/.

30 See website at http://www.interpharma.ch/.

31 See website at http://www.vips.ch/.

In September 2013, these four associations agreed on a unique Code of conduct to regulate their interactions with HCAs: the Pharma Cooperation Code.[32] This Code entered into force on January 1st, 2014,[33] with the first disclosures covering transfers of value made in 2015 and being published on websites in the summer of 2016.[34]

This new Code complements a previous and older Code, the so-called Pharmaceutical Code or Pharma Code (PC). The PC was first adopted in December 2003 and has been repeatedly amended; its last version entered into force in July 2014.[35] It deals mainly with advertising for medical products.[36] There are, however, notable redundancies between the PCC and the PC.[37]

The adoption of the PCC in Switzerland closely follows an earlier European initiative.[38] The European pharmaceutical trade association, EFPIA, enacted the EFPIA HCP/HCO Disclosure Code (hereafter EFPIA Code) in June 2013; thirty-three countries have implemented its obligations.[39] As section II.A below further explains, this European Code is the model for the Swiss PCC. More accurately, as a member of EFPIA, scienceindustries was bound to transpose the EFPIA code in Switzerland and to adopt a national code closely mirrored on the EFPIA code.[40]

B. Structure and Objectives of the PCC

The PCC is divided in eight chapters, preceded by a preamble. The first chapter lists definitions and contains key principles; the second one covers interactions between pharmaceutical companies and HCAs (i.e. HCPs and HCOs) and enunciates what must be made public and how; the third chapter does the same with respect to interactions with patients' organizations (which, as previously mentioned, are outside the scope of this article); the following five chapters contain, for the most part, administrative or organizational provisions.

We here outline the key objectives of the PCC, as inferred from its preamble and chapter 1, highlighting at the same time what the Code does not seek to achieve. This sets the stage for the following sub-

chapters, which present the content of the disclosure reports under the PCC.

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32 According to scienceindustries, FMH (Foederatio Medicorum Helveticorum – Fédération des médecins suisses – Federation of Swiss physicians), CCM (Conférence des sociétés cantonales de médecine – Conference of Cantonal Medical Societies), H+ (Association Swiss Hospitals) and ASSM (Association suisse des sciences médicales – Swiss Academy of Medical Sciences) were approached and expressed their support for the PCC; scienceindustries, Annual report of the Code Secretariat 2015, p. 3, at https://en.scienceindustries.ch/_file/18116/kodex-sekretariat-jahresbericht-2015-e.pdf. In order to inform its members and encourage physicians to give consent, FMH had several articles from scienceindustries and ASSM published in its journal, the Bulletin des médecins suisses (BMS): Granwehr Jürg, *Publication des prestations pécuniaires par l'industrie pharmaceutique,* BMS 18–19/2016, pp. 658f; Amstad Hermann/Reinhart Walter H., *Lorsque l'industrie dévoile ses relations avec le corps médical,* BMS 10/2014, p. 383; Grauer Dieter, *Nouvelles règles de comportement pour les entreprises pharmaceutiques – et leurs répercussions pour le corps médical,* BMS 7/2014, pp. 239f.

33 PCC, section 821.

34 PCC, section 822.

35 Starting in July 2015, pharmaceutical companies are banned from giving physicians any gift items, unless these items are related to the practice of medicine or are writing pads or writing devices bearing no logos. See section scienceindustries, Factsheet – Code Committee, Last Call! More stringent prohibition of gifts from 1 July 2015, https://en.scienceindustries.ch/_file/16236/02-kodex-sekretariat-factsheet-geschenkverbot-2015-e.pdf.

36 According to scienceindustries, its goal is "to encourage ethically correct conduct and avoid unfair competition by pharmaceutical companies". Scienceindustries, Annual Report of the Code Secretariat 2015.

37 For example, admissible and inadmissible interactions are described both in the PCC (section 14) and PC (section 14).

38 There is also an international Code of Practice of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), last revised in 2012, but it does not address transparency through mandatory reporting of payments by pharmaceutical companies; it does however explain how to structure relationships between companies and HCAs in a professional and ethical manner.

39 These countries are listed here: https://www.efpia.eu/relationships-codes/national-codes/; they include almost all EU countries, as well as Norway, Russia, Serbia, Switzerland, Turkey and Ukraine. Although Iceland is not a member of EFPIA, it transposed the European disclosure code.

40 The deadline for national transposition was end of 2013. Scienceindustries drafted the Swiss code, to which "the partner associations Intergenerika, Interpharma and vips […] subscribed" (https://en.scienceindustries.ch/involvement/pharma-code-and-pharma-cooperation-code/disclosure-obligation).

As a starting point, it is important to underline that interactions between industry and HCAs are perceived by the PCC in an essentially positive light. The Code insists that both parties involved derive legitimate value from these interactions.[41] Moreover, these benefits are viewed as ultimately flowing to patients.

Somewhat oddly, the preamble is silent as to the possible risks or drawbacks of such interactions. Only one brief passage hints at them, by stating: "The general public, patients and other interest groups expect the pharmaceutical companies to maintain high standards of integrity in interactions with healthcare professionals, healthcare organisations and patient organisations and to arrange such interactions correctly and transparently". In other words, integrity (correctness) and transparency are presented as satisfying an expectation of third parties.[42] By way of comparison, the EFPIA Disclosure Code does mention – albeit briefly – the risk of conflicts of interests ("EFPIA recognises that interactions between the industry and healthcare professionals can create the potential for conflicts of interest."[43]).

A second noteworthy aspect of the PCC's preamble relates to the risks ascribed to transparency. Whereas the risks of interactions are barely enunciated (as we just mentioned), the risks of transparency are highlighted. According to the PCC, disclosure "may lead to problems in connection with data protection"; hence, pharmaceutical companies and their counterparties must "endeavor […] to find a suitable response to such problems".[44] The preamble adds that solutions can indeed be found that do not "sacrific[e] justified private interests, in particular of the healthcare professionals".

With regards to fundamental principles, the relevant section of PCC chapter 1 does not go much further than what is already stated in the PCC Preamble, respectively much further than what is already mandated by Swiss statutes (the Therapeutic Products Act (TPA[45]) and its Ordinance on Advertising[46]). PCC section 141 states that interactions between firms, on the one hand, and health professionals or organizations, on the other hand, "must not constitute an inducement to recommend, prescribe, acquire, supply, sell or administer specific medicinal products for humans" (compare with Article 33[47] TPA, soon to become Article 55[48]).[49] How this goal is to be achieved is hardly evoked.

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41 There is some scientific evidence of (some) value being derived from interactions between health care professionals and industry. See, e. g., Colleen Carey/Ethan M. J. Lieber/Sarah Miller, Drug Firms' Payments and Physicians' Prescribing Behavior in Medicare Part D, paper on SSRN (2016).

42 A document of scienceindustries found on its website states its position more strongly: "Transparency is the key to the creation of confidence in relations with the general public and patients." See https://en.scienceindustries.ch/involvement/pharma-code-and-pharma-cooperation-code/disclosure-obligation.

43 Preamble of the European Code. The latter adds: "Consequently, professional and industry associations, including EFPIA and its member associations, have adopted codes and guidelines to ensure that these interactions meet the high standards of integrity that patients, governments and other stakeholders expect".

44 PCC preamble.

45 Recueil systématique ("RS") 812.21.

46 RS 812.212.5.

47 According to Article 33 TPA: "[1] It shall be prohibited to grant, offer or promise material benefits to persons who prescribe or dispense medicinal products or to the organisations which employ them. [2] It shall be prohibited for persons who prescribe or dispense medicinal products as well as for the organisations which employ them, to solicit or accept material benefits. [3] However, the following shall be permitted: a. material benefits of modest value and which are related to medical or pharmaceutical practice; b. commercially and economically justified discounts which directly reflect on the price."

48 According to Article 55 of the future TPA: "[1] Les personnes qui prescrivent, remettent, utilisent ou achètent à cette fin des médicaments soumis à ordonnance et les organisations qui emploient de telles personnes ne peuvent solliciter, se faire promettre ou accepter, pour elles-mêmes ou pour un tiers, un avantage indu. Il est également interdit de proposer, de promettre ou d'octroyer à ces personnes ou organisations, pour elles-mêmes ou pour un tiers, un avantage illicite. [2] Ne sont pas considérés comme des avantages illicites: a. les avantages de valeur modeste et qui ont un rapport avec la pratique de la médecine ou de la pharmacie; b. les dons destinés à la recherche, à la formation postgrade ou à la formation continue, pour autant que certains critères soient remplis; c. les compensations accordées en contrepartie de prestations équivalentes notamment celles accordées pour les commandes et les livraisons de produits thérapeutiques; d. les rabais ou ristournes octroyés lors de l'achat de produits thérapeutiques pour autant qu'ils n'influent pas sur le choix du traitement. [3] Le Conseil fédéral règle les modalités. Il peut étendre l'application des al. 1 et 2 à d'autres catégories de produits thérapeutiques" (We cite the French version, as there is no English translation yet).

49 Interestingly, the German and French versions of the PCC are somewhat different; in the German version, these interactions must *not create incentives* to recommend, prescribe, acquire, etc.; in the French version, these interactions must *not be perceived by the said counterparties* as incentives to recommend, prescribe, etc.

While the rule is stated in three lines, the exceptions to the rule cover five sections, which once again, mostly rephrase what is stated in the TPA and its ordinances. As per these exceptions, constitute admissible interactions (under section 143 PCC): i) rebates or discounts on drug orders placed by HCPs[50], ii) free samples given to HCPs[51], iii) medical gifts of moderate value offered to HCPs[52] (moderate is usually understood to be under CHF 300 per HCA and per

year[53]);[54] iv) writing materials and writing pads of modest value bearing no names nor logos[55]; v) food and beverage offered to HCPs not exceeding CHF 150 per meal per person[56]. These exceptions are further commented in subsections I.F.1 and IV.B.2 (part II) below.

C. Personal, Territorial and Material Scope of the PCC

1. Personal and Territorial Scope

The PCC applies to adhering pharmaceutical companies which produce or distribute prescription-only (Rx) drugs and which operate in Switzerland. A foreign-based company active in Switzerland can be directly subject to the Swiss PCC, if it makes transfers of value to recipients located in Switzerland.[57] When a pharmaceutical group has several companies in Switzerland (e.g. an entity for vaccines and an entity for drugs), reporting can be done either by the holding company or by each of the subsidiaries.[58]

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50 At PCC section 143.1, only HCPs are mentioned, and not HCOs, but whether the section in fact applies to both ought to be clarified.

51 Implicitly, the PCC considers that samples do not constitute undue incentives to prescribe. Again, at PCC section 143.2, only HCPs are mentioned, despite the fact that this exception seems to apply to both types of HCAs (see above, Fn. 50). Samples are further regulated by the PC, at section 27 and by the Swiss Ordinance on Advertising on Drugs (RS 812.212.5), at articles 3 and following.

52 See Fn. 50 about the need to go beyond a grammatical interpretation of this provision.

53 This threshold results from an analogical application of Article 172ter of the Swiss Criminal Code ("Minor offences against property"). The idea of applying this threshold to the TPA first came during the law's parliamentary debates in 2000 (Bulletin Officiel "BO" 2000 E 612), the 2012 Federal Council's message to the TPA's revision adopted this approach (FF 2003 1, p. 80). Later, the Swiss Supreme Federal Court confirmed the analogical application of Article 172ter (ATF 140 II 520, c. 5.2.4). The explicative report on the new Ordinance on Integrity and Transparency in the Therapeutic Products Field also applies the CHF 300 rule (Explicative report about the OITPTh [Ordinance on Integrity and Transparency in the Therapeutic Products Field; Ordonnance sur l'intégrité et la transparence dans le domaine des produits thérapeutiques; no RS number yet as it is only a draft] and the Ordinance on sickness insurance [OAMal; RS 832.102], p. 13). However, there is no fixed threshold in the codes of scienceindustries. As a comparison point, the Belgian trade association states that the value of each item must not exceed € 50 (market value including VAT), and the overall amount per year per HCP must not exceed € 150. See pharma.be, Guidelines regarding the concept 'inexpensive' in the framework of Article 29bis.

54 PCC section 132.3. The scope of this exception is actually complex to delineate, as the given products must be "intended solely for the medical or pharmaceutical activity"; alternatively, they must be "used for post-graduate or continuing education in medicine or pharmacy"; additionally, the material must "[be] beneficial to patients". The explanatory report of the Federal Council accompanying the revised ordinance (OITPTh) under the future TPA provides the following examples: thermometer, computer software, mobile phone for the emergency service, drinking fountain and journals for patients in the waiting room, toys for the waiting room of a pediatrician.

55 Furthermore, these materials must not refer – directly or indirectly – to a given company, nor to a given product (PCC section 143.4).

56 To be precise, the PCC further requires that the meal payment be "reasonable and modest". As we further comment in chapter IV, this high ceiling makes the exception appear quite generous. Moreover, the PCC limits this ceiling of CHF 150 to events taking place in Switzerland; if events take place abroad, the limit must be set by the local code or regulation. For events held abroad, section 143.5 *in fine* of the PCC states that: "the limits set out in the code which claims territorial validity for the host country, apply to all the participants". However, it does not spell out what is the maximal cost if the event is held in a country which does not have a similar code or if the latter does not contain a ceiling for meals and beverages. In this case, we suggest to apply the Swiss limit of CHF 150.- (see recommendation IV. B. 2 below).

57 Information provided by scienceindustries.

58 This is an important aspect, as in other countries, especially the United States, reporting is to be issued per legal entity, making it more difficult to get a global overview of the situation (e. g., the Novartis group has five distinct reporting entities in the United States). Under the EFPIA Disclosure Code, the following section under "Applicability of this Code" suggests that there should be only a single disclosure ("Separate entities belonging to the same multinational company – which could be the parent company (e. g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation – shall be

On the "receiving" end, the PCC applies to two broad categories of recipients: healthcare professionals (HCPs) and healthcare organisations (HCOs),[59] together referred here as healthcare actors (HCAs).

As per the PCC, HCPs include physicians, dentists, pharmacists, and persons who are authorized by the TPA, to prescribe, deliver or use prescription-only medicinal products for humans.[60] According to scienceindustries, individuals are considered as HCPs if they have the right to *autonomously use* Rx drugs (i.e. under their own responsibility). For example, midwifes, dental hygienists or paramedics having a federal diploma can have this right and thus be HCPs,[61] but this has to be checked on a case-by-case basis by the reporting pharmaceutical company – which seems unduly complicated. On the other hand, nurses *("infirmiers"; "Fachfrauen für Krankenpflege")* do not

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currently have this right under Swiss law and therefore do not fall under the scope of the Swiss PCC.[62 – 63]

HCOs encompass "institutions, organisations, associations or other groups of healthcare professionals which provide healthcare services or consultancy tasks or other services in healthcare (e.g. hospitals, clinics, foundations, universities or other educational establishments, scientific societies or professional associations, community practices or networks, but not patient organisations[64])". The range of HCOs is broad, and based on disclosures seen, can include: doctor group practices, medical societies, pharmacies, congresses, forums, non-profit organisations (e.g. an association developing reconstructing surgery), consulting companies, and even sport events.[65] Interestingly, a doctor who has set up her practice as a legal entity is regarded as a HCO for the purposes of the PCC, even if she is the sole practitioner therein.[66] Are not deemed HCOs (for the benefits they receive themselves for their own activities): insurance companies (e.g. sickness insurance funds), non-medical sections of universities (e.g. business school),[67] laboratories performing medical analyses, market research institutes. In general, the fact that HCPs work and/or provide services to the organisation is not a decisive criterion.[68] Depending on the situation, contract research

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deemed to constitute a single company, and is as such committed to compliance with the EFPIA Codes."). However, according to scienceindustries, the current practice of having several disclosures per group (e. g., Novartis, Alcon, Sandoz) is admissible.

59 PCC, section 139.

60 PCC, section 133.

61 According to scienceindustries, the Swiss definition of HCPs follows the practices of Swissmedic: see e. g. article 27a of the Ordinance on Drugs (RS 812.212.21) and Swissmedic Journal 06/2006, p. 617; this definition may change with the revision of the TPA and its new ordinances. Indeed, the new Ordinance on Integrity and Transparency in the Therapeutic Products Field (OITPTh), will contain a definition of HCPs. According to its explicative report, "L'utilisation professionnelle […] couvre aussi bien l'utilisation professionnelle sous la propre responsabilité de l'utilisateur (cf. Article 27a de l'ordonnance sur les médicaments [OMéd; RS 812.212.21]; Article 2, let. c, et 3 OPuM) que l'utilisation professionnelle sous la responsabilité, la surveillance, ou selon les instructions d'une tierce personne (p. ex. utilisation par le personnel soignant, les assistants médicaux ou les personnes en formation)" (Explicative report on OITPTh and OAMal, p. 13). Hence, this definition includes nurses using Rx drugs under the supervision of a qualified professional. However, in the FAQ "Intégrité, transparence et obligation de répercuter les avantages" published by the Federal Office of Public Health, the definition of HCPs does not seem to encompass nurses (p. 3). According to information provided by scienceindustries, the association will closely follow these upcoming developments and will adapt its definition of HCP accordingly. Compare with the Pharma Industry Finland – Code of Ethics, Q&A, 2/2, the disclosure of transfers of value, p. 2 (2014) (hereafter Finland Q&A).

62 See by analogy Swissmedic Journal, 6/2006, p. 617 ("En revanche, les assistants (p. ex. en pharmacie, méicaux (sic), ainsi que les infirmiers) ne tombent pas dans le champ d'application personnel de l'Article 33 LPTh: ces personnes ne disposent pas d'un droit propre d'utiliser des médicaments, dans la mesure où elles travaillent sous la surveillance et la responsabilité d'un professionnel de la santé").

63 However, according to scienceindustries, the interdiction of granting gifts to HCAs also applies to nurses to make sure that the rule is not circumvented.

64 As mentioned earlier, patient organizations are defined separately and disclosure of ToVs made to them are subject to different rules.

65 In 2015, Vifor reported a ToV made to Marchethon CF of Fribourg. However, disclosure of such ToVs does not seem to be mandatory.

66 Scienceindustries does not consider that this could be a way to circumvent the PCC's goal, as long as the following conditions are met: "the contract has been signed with the legal entity, the ToV is only provided to an account issued to this entity and the ToV is only used for purposes of this legal entity and not for personal reasons of the HCP". However, other companies may follow a different rule; for example, Takeda has the following practice: "Si la société (HCO) est détenue par un HCP, le transfert de valeur est signalé en regard dudit HCP. Si la société est détenue par plus d'un HCP, le transfert de valeur est signalé pour un HCO." Takeda, Note méthodologique 2016, point 2.1.3.

67 See in Germany FSA Q&A, p. 8.

68 Information provided by scienceindustries; compare with German FSA Q&A, p. 10.

organisations (CROs), i.e. entities providing support services in connection with pharmaceutical research activities, may be considered as HCOs, but it is uncertain when exactly this is the case.

The PCC applies to HCAs based in Switzerland, as per their primary practice or business address.[69] It means that Swiss PCC reports include pecuniary benefits paid to Swiss HCAs, irrespective of the paying company's country of incorporation and irrespective of the county where the service was provided.[70] Hence, Swiss PCC reports potentially include pecuniary benefits paid by all companies belonging to the same group and not only by the Swiss subsidiary.

Conversely, if the physician has her office abroad, the Swiss Code does not encompass ToVs made to her,[71] whereas a foreign statute or code may enter into consideration;[72] this rule holds even if the service was provided in Switzerland (e.g. lecture given during a seminar taking place in Switzerland). Considering that the other codes in Europe are also based on the EFPIA model, negative conflicts of jurisdiction leading to non-disclosure should not occur in Europe.

Some companies made the choice to also include in their Swiss PCC report pecuniary benefits paid to HCAs based in Liechtenstein.[73] As the latter does not have a national organisation comparable to scienceindustries, there is no code for this country and no obligation to disclose. Scienceindustries suggests that companies that serve the Liechtenstein market from their Swiss branch report their ToVs to HCAs based in Liechtenstein in their Swiss report.[74]

2. Material Scope

The PCC's disclosure obligation applies to pecuniary benefits paid in connection with medicinal products (on this notion see further subsection I.F).[75]

Pecuniary benefits can be provided as "cash, non-cash contributions, donations, grants or payments made either directly or indirectly in some other form for consultancy tasks or services, research and development, advertising, sales or other purposes".[76]

Medicinal products are defined by reference to the TPA. However, the PCC's disclosure obligation is restricted to prescription-only (Rx) drugs.[77] A handful of companies chose to include over-the-counter drugs along with prescription-only drugs.[78] Medical

devices are not covered. However, as some guidance documents from foreign national associations have pointed out, the distinction between Rx pharmaceuticals and other products is not always straightforward in practice.[79]

D. Admissible Relationships Under the PCC

The "heart" of the PCC is to be found in its chapters 2 and 3. These chapters describe the allowed interactions,[80] and then set forth administrative obligations, mostly transparency-disclosure obligations.

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69 PCC, section 139.

70 For example, if Company X headquartered in the United States pays a physician based in Switzerland for an activity performed in Italy, the corresponding pecuniary benefit is disclosed in the Swiss PCC report.

71 PCC, section 143.5.

72 In that case, it is for the foreign company or branch located in the foreign country to issue the corresponding report.

73 See, for example, Roche Methodological Note, p. 2.

74 Information provided by scienceindustries. This disclosure can be done either by having a separate report for Liechtenstein (directly based on the EFPIA Disclosure Code) or by incorporating the disclosures for Liechtenstein-based HCAs into the national report of the country from which the Liechtenstein market is being served (e. g., incorporating these disclosures in the Swiss report if the Liechtenstein market is being served from Switzerland).

75 PCC, section 137. For examples, see footnote 121.

76 PCC, section 137.

77 PCC, section 131.

78 See, for example, Almirall Methodological Note, p. 5 or Ipsen's Methodological Note, p. 8.

79 See, e. g., German FSA, Q&A on the FSA Code of Conduct on Transparency of Collaboration with Healthcare Professionals, p. 3–4, July 2016 (hereafter FSA-Q&A).

80 See section 21 for HCPs, section 22 for HCOs.

Regarding the range of permitted interactions, pharmaceutical companies may for example hire healthcare professionals (in practice, mostly physicians[81]) as consultants or as clinical researchers. A consultant may be asked to analyze a given issue and submit a paper or to participate in working groups set up by the pharmaceutical company; as a researcher, the physician may act as an investigator in a clinical trial or in some other type of medical study. Furthermore, a HCP may be invited to give conferences, or more specifically to educate colleagues or other third parties. For all these interactions, the person is entitled to "reasonable compensation for expenditure incurred by [her] in this connection according to the usual standards" *("indemnisant selon les barèmes usuels"; "nach den dafür üblichen Massstäben angemessen abgelten").* [82]

Pharmaceutical companies may also interact with healthcare organizations (HCOs),[83] by hiring the entity as consultant or as service provider in the context of research activity. HCOs may also be asked to provide services in the context of healthcare, conversely, they may receive support in such a context.[84] As per Pfizer's PCC note, typical interactions between industry and HCOs consist in "charitable contributions, business donations, educational grants […], sponsoring of speakers/faculty which by nature of purpose and funding are classified under educational grants, […] placement of a brand logo in a conference program or invitation communication in exchange for supporting the program, funding an event in return for a display booth, funding an event in exchange for advertising space, other advertisement space (in paper, electronic or other format)".[85]

The PCC lays down more detailed requirements to circumscribe the admissibility of such interactions.[86] First, the need for the service must be real ("justified need"; *"besoin justifié"; "gerechtfertigter Bedarf"*).[87] Only the necessary number of service providers may be hired.[88] Second, the person or persons chosen for the task must be duly qualified for it.[89] To be on the "safe side", the PCC reiterates: "Sham contracts designed to enable healthcare professionals to receive financial benefits without any obligation to perform a consultancy task or service are prohibited".[90] Moreover, the services which are provided must be duly documented and must be actually used "for their intended purpose".[91] These clauses are meant to ensure that only *bona fide* services are provided, preventing interactions that only serve the marketing purposes of the pharmaceutical party (i.e. that just serve to push up sales).

To make sure the aforementioned obligations are met, "administrative" instructions are added. The interactions must be based on, and described in, a written and detailed contract which includes an explanation of the services to be rendered and an account of the compensation to be paid.[92] Regarding transparency, this written contract must oblige the HCP to "self-divulge" the nature of her relationships with the hiring pharmaceutical company whenever she discusses publicly (e.g. conferences, scientific papers) themes related to her work for the said company or themes of interest to this company.[93] Although the PCC does not spell out the rule's purpose, it is meant to allow third parties to assess the independence of the speaker/author and therefore the reliability of her message.[94] This is an important obligation also because its fulfilment rests directly on the HCP,[95] the duty of the pharmaceutical company being simply to

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81 As per the definition in PCC section 133, HCPs are mostly physicians, dentists and pharmacists.

82 PCC, section 211.

83 PCC, section 22.

84 PCC, section 22.

85 Pfizer Switzerland, Methodological Note 2016, p. 4.

86 Compare with the similar requirements of the IFPMA Code of Practice, at section 7.4.

87 PCC, section 213.1.

88 PCC, section 213.3.

89 PCC, section 213.2.

90 PCC, section 213.5.

91 PCC, section 213.4.

92 PCC, section 212.

93 PCC, sections 214 and 215. There is nothing equivalent for HCOs.

94 See the analogous obligation in the guideline of the SAMW/ASSM on Collaboration between the medical profession and industry (2013), at points I. 8 and II. 7.

95 An example of such a disclosure is taken from a recent report of a clinical trial published in the New England Journal of Medicine. The last author of the study is reported having "receiv[ed] fees for serving on data and safety monitoring boards from Sanofi, Teva Pharmaceuticals, and Novartis Pharmaceuticals, fees for serving on advisory boards from Teva Pharmaceuticals, Genzyme, AbbVie, Forward Pharma, Novartis Pharmaceuticals, Bayer HealthCare, and Celgene, fees for serving on a steering committee from Roche, consulting fees from Teva Pharmaceuticals, Genzyme, Actelion Pharmaceuticals, AbbVie, XenoPort, EMD Serono, Alkermes, Forward Pharma, Novartis

include such an obligation in the written contract. However, it is worth recalling that the PCC only binds adhering pharmaceutical companies. Therefore, possible violation of this rule by an HCP can only give rise to contractual sanctions – at best.

Finally, the written contract is to stipulate that the HCA receiving a pecuniary benefit must agree to disclosure;[96] this is further analyzed in subsection I.F.1 below.

E. Obligations Designed to Ensure the Transparency of the Interactions

Under the PCC, each signatory company is required[97] to issue, every year, two separate documents: first a PCC report listing the amounts the company paid to HCAs, each amount falling within a given category (hereafter: the PCC report; on the content of the PCC report, see further subsection I.F.); second a methodological note (hereafter: the PCC Note) explaining the accounting rules the company used to generate the first document. Together, these two documents are here referred to as the PCC disclosure.

As per the PCC, each adhering company must make its PCC disclosure available on a publicly available website; the site needs not be a Swiss website (a site ending in ".ch") or even the website of the pharmaceutical company's Swiss branch.[98] There is no official PCC central repository website that collects all individual firm reports and aggregates them[99] (on this issue, see our recommendation in subsection IV.C.1.a below).[100] Sometimes, the reports are actually hard to locate since they require several "clicks" starting from the company's home page. Sometimes, locating the report requires knowing which subunit of the group is concerned, since a holding may publish one PCC disclosure for the entire group or issue separate reports for its various entities (e.g., Alcon, Sandoz and Novartis have separate reports). Fortunately, the list of PCC signatories as published on scienceindustries' website points to the relevant PCC web page of each company (a so-called "gateway").[101]

According to the PCC, disclosure must take place "within six months of the end of a reporting period",[102] encompassing all ToVs recorded during the previous calendar year.[103] For the first disclosure, scienceindustries requested in April 2016 that PCC signatories make public their data between 20th and 30th June 2016.[104] This was meant to allow a coordinated release of all disclosures and of the corresponding media campaign led by scienceindustries.[105] For the second and third round of disclosures (2016 and

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Pharmaceuticals, Takeda Pharmaceuticals, Roche, Genentech, and Strategic Consultants International, lecture fees from Teva Pharmaceuticals, Genzyme, WebMD, and AcademicCME, grant support from Sanofi-Aventis and Genzyme, and royalties from Millipore (formerly Chemicon International). No other potential conflict of interest relevant to this article was reported." See Xavier Montalban et al., Ocrelizumab versus Placebo in Primary Progressive Multiple Sclerosis, NEJM 376 p. 209–220 (2017).

96 PCC, section 232.

97 Throughout this text, we chose to use the word "required" although the PCC is only a self-regulation text.

98 PCC, section 261.

99 Fortunately, the German NGO Correct!v has set up an unofficial website, where aggregate disclosures can be consulted for Austria, Germany and Switzerland. Section IV. A below presents this private initiative.

100 Certain countries – Belgium, Czech Republic, Denmark, France, Ireland, the Netherlands, Portugal, Sweden, the United Kingdom – have set up central publication platforms, either by law or through self-regulation. See EFPIA Disclosure Code: Your Questions Answered, p. 6; see also the websites at https://www.transparence.sante.gouv.fr/, https://www.betransparent.be or http://www.transferofvalue.ie. Other European countries have retained the decentralized approach (the remaining 24 out of a total of 33).

101 According to PCC section 431, scienceindustries must receive information from each signatory company regarding the location of its internet platform.

102 PCC, section 252.

103 PCC, section 251.

104 Scienceindustries/Code Commission, *Fact Sheet: 20 June 2016 – disclosure in accordance with the PCC is getting closer!,* p. 1 (https://en.scienceindustries.ch/_file/18360/03-kodex-sekretariat-factsheet-offenlegung-2016-e-vdef.pdf).

105 Id.

2017), scienceindustries published a press release on June 15, 2017 and 2018 reminding that PCC reports were due before June 30.[106]

PCC disclosure must remain available on the companies' websites for a minimum of three years.[107] Older information may thus be erased from the company's website or refused if requested. Even for internal and compliance purposes, companies are only asked to retain for five years the data upon which their report is derived.[108]

Regarding the language of the disclosure, the PCC states that it "must be made in English and whenever possible in the German, French and Italian languages".[109] In our opinion, this requirement applies to both the PCC report and the PCC note,[110] even though this is not the practice currently followed by all PCC companies.

The PCC does not require the amounts to be stated in Swiss francs; pharmaceutical companies are free to choose the currency they want to use for their disclosure. VAT can be included or excluded to the discretion of the individual pharmaceutical company; however, the choices must be spelled out in the company's methodological note. PCC section 282 enumerates other elements left to the discretion of pharmaceutical companies. In practice, there is significant heterogeneity as to these choices.

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Nothing is specified as to the digital format of the documents and companies are free to choose the one they prefer (e.g. PDF or Excel). Regretfully, very few companies provide their data in Excel format and some use a format which make exploiting data deliberately cumbersome (i.e. scanned PDF).[111]

Regarding the structure or format of the PCC Disclosure, the Swiss Code, following the EFPIA Disclosure Code (section 2.03), requires that the template set forth by the EFPIA Code be followed.[112] PCC subchapters 25 to 29 contain additional instructions (e.g. disclosure period, individual and aggregated form of disclosure, publication of the disclosure method), whereas the Secretariat of the PCC has issued two relevant recommendation:[113] one on HCA's consent[114] and the other on pecuniary benefits offered in relation with events.[115] EFPIA has apparently prepared very detailed guidance in a Q&A format; this document is also valid in Switzerland,[116] but the document has not been made publicly available. In addition,

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106 https://fr.scienceindustries.ch/media/communiques-de-presse/_detail-626/51370%252Fdeuxieme-campagne-de-publication-des-indemnites-des-entreprises-pharmaceutiques-aux-dispensateurs for the June 15, 2017 press release and https://fr.scienceindustries.ch/media/communiques-de-presse/_detail-626/57773%252Ftroisieme-campagne-de-publication-des-indemnites-des-entreprises-pharmaceutiques-aux-dispensateurs, for the June 15, 2018 press release.

107 PCC, section 253.

108 PCC, section 292 ("five years after the end of the relevant reporting period"). This is only half the typical period (10 years) during which commercial documents must be retained (Article 958f CO).

109 PCC, section 263.

110 The provision regarding the language of the disclosure is to be found in PCC section 263, which contains general technical provisions on disclosure, whereas the PCC report is the topic of the next section (section 27) and the PCC methodological note is the subject of the following section (section 28).

111 See also Markus Grill, *Pseudo-Transparenz,* (https://correctiv.org/recherchen/euros-fuer-aerzte/artikel/2016/07/12/pseudo-transparenz/) and Yves-Alain Cornu/Bastien von Wyss, *Les pharmas ont versé 14 millions aux médecins suisses en 2016* (http://www.rts.ch/info/suisse/9313856-les-pharmas-ont-verse-14-millions-aux-medecins-suisses-en-2016.html).

112 There is no template for the Methodological Notes, and their format vary greatly among companies; some are very short while others are quite lengthy.

113 The authority of the Code Secretariat to issue recommendations is derived from PCC section 242. A third recommendation pertains to the "Support by pharmaceutical companies for patient organisations: contractual provisions and disclosure of pecuniary benefits" (available at: https://en.scienceindustries.ch/_file/15509/pkk-pk-praxis-empfehlungen-3-pkk-unterstuetzung-patientenorganisationen-defv-okt14-e.pdf); it is therefore beyond the scope of this article.

114 Scienceindustries, Recommendation No. 1 concerning the Pharma Cooperation Code (PCC) on the failure of healthcare professionals and healthcare organisations to consent to disclosure, available at https://en.scienceindustries.ch/_file/15045/pkk-pk-praxis-empfehlungen-1-pkk-fehlende-einwilligung-in-die-offenlegung-defv-okt14-e.pdf.

115 Scienceindustries, Recommendation No. 2 concerning the Pharma Cooperation Code (PCC) on the Organisation of events: disclosure of pecuniary benefits, available at https://en.scienceindustries.ch/_file/15046/pkk-pk-praxis-empfehlungen-2-pkk-offenlegung-von-veranstaltungen-defv-okt14-e.pdf.

116 Information provided by scienceindustries.

certain national trade associations have enacted their own Q&A documents in part based on the EFPIA Q&A.[117] Our effort to obtain the scienceindustries Q&A remained vain, as the trade association strictly reserves this document to its members.

F. The Specific Disclosure Obligations Under the PCC

In the following five subsections, we explain what must be disclosed, respectively what must not be disclosed (subsection 1 and 2), we specify how reports must be structured (subsection 3), we describe the treatment of pecuniary benefits related to events lasting less than one day (subsection 4), and examine the procedural safeguards related to the disclosure (subsection 5).

1. The Principle and Its Exceptions

Subchapters 23 to 28 of the PCC details both the content of, and the procedures for, the specific disclosure obligations. The general principle is simple: adhering pharmaceutical companies must publicly disclose each interaction with a HCA, for which they granted a pecuniary benefit (ToV).[118]

This broad principle is limited by several exceptions. A first set of exceptions broadly corresponds to the interactions which were described above (subsection I.B) as not giving rise to undue advantages (i.e. rebates in connection with drug orders, free samples, medical gifts of moderate value, writing implements, and meals).

In addition to these exceptions, several other situations fall outside the scope of disclosure (some of which were already alluded to above):

− To begin, pecuniary benefits which are not made to HCAs (e.g. payments to individual patients) are not targeted.[119] Moreover, the Swiss PCC has made the somewhat odd choice not to include nurses[120], whereas the latter are explicitly included under the EFPIA Code.[121] Similarly, benefits received by third parties, which are however connected to a HCA, without being an intermediary, fall outside the PCC's scope (e.g. the money is not paid to the doctor, but to a charity whose work the doctor appreciates).

− Second, only interactions involving directly or indirectly[122] a prescription-drug are covered;[123]

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drugs which are available over-the-counter (OTC; without the need for a prescription) are not concerned; thus, an arrangement to conduct a clinical trial on an existing OTC drug would not need to be disclosed.[124] Similarly, if a pecuniary benefit is not related to any Rx drug, it does not have to be disclosed. However, as soon as a link with such a drug is possible, the ToV has to be disclosed. In other words, when in doubt, pharma companies are advised to disclose their ToVs.[125] It is unclear how and if

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117 Because we could not access the EFPIA FAQ, we cite to the national FAQ documents whenever helpful.

118 Whether the company gave the pecuniary benefit (cash or non-cash) itself (directly) or indirectly (through a third party used as conduit) is indifferent. See PCC section 137.

119 PCC, section 231. This situation arises for example when pharmaceutical companies donate not yet approved or not yet reimbursed drugs to patients in need.

120 HCPs are defined as "physicians, dentists and pharmacists […] and persons who are authorized by Swiss law on therapeutic products, to prescribe, deliver or use prescription-only medicinal products for humans." PCC, section 133. As explained above (see subsection I. C. 1), nurses are not included since, by law, they cannot autonomously use Rx drugs. See for example the Eli Lilly Methodological Note ("As per the Swiss trade association guidance, nurses are excluded from the report").

121 EFPIA Disclosure Code, Schedule 1.

122 The PCC does not use the expression "directly or indirectly" in this context, but one can imagine various situations where the work of the health care professional is not directly related to a given drug. For example, the doctor gives advice on how drug representatives should address fellow physicians; she is invited in a workshop presenting psychological-only approaches to treating depression; she is asked to review a medical paper depicting the natural course of a yet untreatable disease. It would be an unreasonable approach to limit the scope of the PCC to situations where a given Rx drug is directly mentioned.

123 PCC, section 131. However, as mentioned earlier, some pharmaceutical companies decided to include both Rx and OTC drugs in their PCC reports (e. g. Almirall).

124 If the drug is still under development, it has no Rx/OTC status yet; it may even be difficult to anticipate what will be its distribution status if and once approved. In that case, scienceindustries considers that in case of doubt, disclosure should be the rule.

125 Information provided by scienceindustries.

pecuniary benefits related to a drug under development and thus lacking an Rx/OTC status are to be reported.

− Third, no disclosure is to occur "if it is incompatible with the provisions of data protection law or other State legal provisions".[126] This exception is analyzed in the next section as it concerns chiefly the consent of HCAs.

2. Consent for Individual Disclosure

The PCC is based on the assumption that ToV will be disclosed individually, i.e. indicating the precise identity of the HCA beneficiary. However, for such individual disclosure to occur, the beneficiary must have explicitly consented. Conversely, no individual disclosure, i.e. only aggregate disclosure, is to occur when a HCP or a HCO refuses that his, her or its identity be disclosed. The PCC is based on the premise that the pharmaceutical companies' counterparty must explicitly accept the disclosure.[127]

As mentioned above, the agreed-upon contracts between the company and the HCA must normally include a clause whereby the latter does consent to the disclosure.[128] However, contracts signed before the entry into force of the PCC may not contain such a clause;[129] similarly, interactions that took place before that date may not have been recorded in a written contract. A company may have forgotten to update its contracts to include the necessary clause. Furthermore, a HCA presented with such an offer of contract may still voice an objection to disclosure, which the company can accept if it appears legitimate ("justified reservation"; *"sans motif convainquant* [sic]*"; "ohne begründeten Vorbehalt"*).[130] Finally, an HCA can withdraw the previously issued consent, which scienceindustries tolerates.[131] In each of these four situations, the HCAs is entitled to block the individual disclosure, leading to aggregate disclosure. While the FMH is encouraging physicians to support transparency and give consent, it is not forcing physicians to do so.[132]

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126 See PCC, Section 234.

127 Contrary to certain other countries, neither the PCC nor the guidelines specifies for which period consent is valid. It should be possible to require in advance HCAs to consent in advance for all future disclosures, regardless of the type of upcoming interactions.

128 PCC, section 232 ("The pharmaceutical companies shall call the attention of the [HCAs] in the contracts with them to the fact that they are required to disclose the pecuniary benefits connected with the contractually agreed service pursuant to this Code. They shall also stipulate in this contract that the recipients of the pecuniary benefits agree to disclosure").

129 Long-term contracts which do not contain such a clause must however be renegotiated so that such clause be incorporated. See, e. g., scienceindustries, Recommendation n^{o} 1, (Fn. 114)

130 Scienceindustries, Recommendation No. 1, (Fn. 114).

131 According to scienceindustries' Recommendation No. 1, withdrawal of consent should only deploy effect for services not yet rendered, and not lead to the suppression of already published reports. However, in practice, many companies agree to remove the corresponding entry if an HCA withdraws consent after publication of the report.

132 See also note 32. The guideline of the Swiss Academies of arts and sciences (ASSM/SAMW) on Collaboration between the medical profession and industry does not address directly the issue of transparency through payment reports, but the latest version was adopted in November 2012, hence before the introduction of the PCC.

133 RS 235.1.

134 The Swiss Federal Act on Data Protection (FADP) protects both natural and legal persons (Article 3.b). It binds both federal authorities and private parties; cantonal authorities are not subjected to the FADP, but to the corresponding cantonal laws. In the European Union, legal persons do not receive the same degree of data protection as natural persons. See, e. g. recital 14 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 2. April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

It could be argued that consent can sometimes be bypassed. Indeed, the Federal Act on Data Protection (FADP),[133] which protects the privacy of both individuals and legal entities,[134] contains provisions permitting disclosure to be imposed over the objection of the data subject. However, whether such FADP exceptions would apply here remain uncertain.[135]

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In theory, a HCP or a HCO can choose to give partial consent, thus consenting to the disclosure of certain benefits, but not others. The EFPIA Disclosure Code FAQ (Frequently Asked Questions) recommends avoiding such practice of "cherry picking" as it is both misleading and contrary to the intent of the Code.[136] Indeed, cherry picking is likely to convey the wrong impression that the doctor at issue has only received limited benefits, concealing the fact that a larger benefit may be "hidden" in the aggregate category. As indicated by their methodological notes, most (but not all) companies forbid partial consent and require either full disclosure or full refusal (i.e. all payments are mentioned exclusively under the aggregated disclosure). A few companies have gone further and decided to only interact with consenting HCAs, thus announcing from the start that they will not enter into relationships with consent-withholding persons.[137]

According to scienceindustries total consent rates – i.e. the proportion of HCPs and HCOs who gave their consent for disclosure – amount to some 73% for HCPs and around 85% for HCOs in 2017.[138] Consent rates are lower when computed on the basis of pecuniary benefits' amount; HCAs who received substantial ToVs are less inclined to let them be disclosed.[139] While the current goal of scienceindustries is to achieve an 80% consent rate, the final goal is at 95%; a 100% consent rate is almost impossible to achieve given that consent withdrawal is tolerated.[140]

3. The Specific Topics to Be Disclosed

We now turn to the rules governing what is to be disclosed[141]. Disclosures are divided in three categories:

- *Individual* disclosures, stating the name and professional address of each HCP and each HCO, along with an amount for each type of interactions. There are three main types of interactions: i) donations and grants (but only in favor of HCOs[142]); ii) contribution to cost of events (further divided into three

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135 Under FADP, any processing (i. e. any form of treatment, including disclosure and storage; Articles 3.e and 3.f) of personal data (i. e. identified or identifiable data; Article 3.a FADP) requires a justification. When data subjects' consent is not available as justification, Article 13.1 FADP offers two alternatives: "an overriding private or public interest" or a legal basis in a Swiss law. Since no law exists on this matter, the question is whether an overriding private or public interest could justify "forced" disclosure. One could argue that disclosure of interactions between pharmaceutical companies and HCAs indeed serves a public health interest. However, how much public health benefits from greater transparency is debatable – although the Swiss Federal Supreme Court holds a broad conception of these overriding interests (cf. ATF 142 III 263 and ATF 138 II 346). Therefore, concluding that the public interest is indeed overriding is not self-evident (see as a point of comparison the judgments issued by the E. U. Court of Justice in C-92/09 of November 9. 2010 and in C-465/00 of May 20, 2003). In any case, the Swiss trade associations have chosen to stay on the safe side of the FADP and to always require consent as the justification for data processing.

136 EFPIA, EFPIA HCP/HCP Disclosure Code Frequently Asked Questions – FAQ, Question 3.02-2 (http://transparency.efpia.eu/countries/download/24/document_3/qa-jops-disclosure-code-22.12.2014-eng.docx).

137 For example, GSK writes that "[it] will not work with HCPs where consent is not given. Where consent is given but subsequently withdrawn [GSK] will not then work with that HCP on activities covered by individual disclosure for a period of one year" (http://www.gsk.com/en-gb/responsibility/our-behaviour/engaging-with-healthcare-professionals/europe/switzerland/#tab-5901).

138 Scienceindustries, Annual Report of the Code Secretariat 2017, p. 3, at. https://en.scienceindustries.ch/_file/22230/kodex-sekretariat-jahresbericht-2017-e-def.pdf.

139 Information provided by scienceindustries.

140 Id.

141 The template for disclosure is reproduced in Annex I below.

142 HCPs are not allowed to receive grants (except for research) nor donations. Ipsen's PCC Note (p. 9) provides a good description of what donations and grants include: "A Grant or a Donation is a payment made to a third party *without consideration or any kind of return in exchange* of such payment for an educational, scientific or a charitable purpose:

- An Educational Grant is funding provided to an HCO to support a bona fide, independent educational program, such as medical science or public health policy. The primary purpose of the support is the provision of legitimate educational program.

- A Scientific Grant can take the form of funding to third party entities for the purpose of the advancement of medical or scientific knowledge.

- A donation is a charitable contribution to a third-party entity (charities) with charitable and philanthropic intent,

subcategories: a) sponsorship agreements,[143] b) registration fees and c) travel and accommodation); iii) consultancy fees and related expenses.

− *Aggregate* disclosures – divided according to the same three types and subtypes – group together the ToVs awarded to all persons (separately for HCPs and HCOs) *whose consent could not be obtained.* The number of persons (once again separately for HCPs and for HCOs) who objected to the disclosure is indicated for each categories.[144] Moreover, the report must indicate, separately for HCPs and for HCOs, the percentage of undisclosed recipients over the total number of recipients (individualized and aggregate).[145]

− *Aggregate disclosure for research & development (R&D)* states the total amount which was paid to HCAs (HCPs and HCOs together) for R&D activities, disclosing neither the identity of the recipients nor the number of recipients. R&D is defined to include both clinical and non-clinical studies; non-interventional studies, which are prospective in nature, also fall within the scope of R&D. R&D expenses that are not related to a ToV to an HCA, for example in-house drug development, remain fully outside the scope of the PCC.

The table below summarizes the different types of pecuniary benefits (ToVs) to be disclosed:[146]

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without any expressed or implied benefit other than general goodwill.

Locally sponsored external studies are disclosed under the Grant category" (our emphasis).

143 Sponsorship would include for example rental of a trade stand at a fair, payments for advertising space; payments for organizing satellite symposia; payments for speakers delivering the conferences at the event. The list is based on the German FSA Q&A. Pfizer's PCC Note (p. 4) also provides a good description.

144 For example, in the case of Eli Lilly, the PCC report indicates that nine HCPs who received travel and accommodation benefits for a total of CHF 7'827 in 2015 refused that their identity be disclosed.

145 PCC, section 275.2 and EFPIA Code section 3.02. In our example of Eli Lilly, this percentage of consent-withholding individuals is stated at 33%, meaning that 9 individuals out of 27 HCPs who received travel and accommodation benefits refused consent.

146 See the EFPIA standardised template (EFPIA Disclosure Code Schedule 2). Our table is inspired by the table drawn by the entity maintaining the Belgian national disclosure platform, available at https://www.betransparent.be/en/faq-en/.

Categories	Pecuniary benefits published	Type of data
Healthcare organisations (HCOs)	– Donations and grants (but not samples, nor items of small value[147]) – Contribution to costs of events, divided into: – sponsorship agreements with HCOs/third parties appointed by HCOs to manage an event. – registration fees – travel & accommodation (but not meals and drinks) – Fee for service and consultancy[148], divided into: – fees – associated expenses agreed in the corresponding contract, including travel and accommodation	Individual data if consent has been obtained; aggregate if not.
Healthcare professionals (HCPs)	– Contribution to costs of events, divided into: – registration fees, – travel & accommodation (but not meals and drinks)[149] – Fee for service and consultancy, divided into: – fees – associated expenses agreed in the corresponding contract, including travel and accommodation	Individual data if consent has been obtained; aggregate if not.
Research and development (R&D)	– Pecuniary benefits paid to HCOs and HCPs (jointly) in relation with the planning or conduct of: – non-clinical studies – clinical studies – non-interventional studies	Aggregate data (no details)

Footnotes of the table: [147], [148], [149]

147 As a reminder, rebates on drug purchases, free drug samples, items of small value, as well as free meals and drinks offered to HCPs are not to be reported at all, even if they could be understood to fall within the category “donations”. See subsection I. F. 1 above.

148 According to the German FSA Q&A (p. 24–25), service and consultancy can include: “speaker’s fee; speaker training; medical literature; data analyses and evaluations; production of training materials; general consultancy work”. See also Finland Q&A, p. 5. Pfizer’s PCC Note (p. 4) gives the following examples: “Speaker engagements; Advisory Boards; Study-related engagements; Preceptorships; Post-marketing surveillance studies; Medical writing; Data analysis; Development of education materials; General consulting/advising; Speaker training if linked to a speaker engagement”.

149 Travel and accommodation would include notably “airfares, train tickets, taxis, tolls, parking fees and hotel accommodation”. German FSA Q&A, p. 23. If transport was organized collectively (e. g., a chartered bus for a group of doctors), the German FSA recommends disclosure in the aggregate. On the other hand, Ipsen’s PCC Note (p. 11)

In practice, there is considerable overlap between, or doubt over, these categories. For a given payment, several categories may be considered and thus call for a more precise analysis of the fact pattern. For example, payments made to HCPs participating in an advisory board tasked with counseling on the design of an oncoming clinical trial should be ascribed to the R&D category (and reported in the aggregate), while if the advisory board is to comment past clinical trial results, the payments should be individually assigned to the individuals as fees for service and consultancy. Similarly, if a physician receives funding to conduct a non-interventional study meant to increase general knowledge (without being directly useful to the pharmaceutical companies in order to obtain or maintain marketing approval), the corresponding payment should be listed under fees for service and consultancy. However, if the company plans to acquire the results and use them, for example to support an official reimbursement procedure, then the payment belongs to the aggregate R&D categories. Foreign (national) Q&A guidance documents abound with classification issues and tips on how to resolve them. Yet the practice among national code authorities is not homogenous. [150] National associations[151] are allowed to impose higher standards.[152] To our knowledge, this is not the case of the PCC in Switzerland.

The PCC does not say whether individual companies are at liberty to disclose additional topics if they so wish. The EFPIA Code is similarly silent.[153] Our own analysis of PCC reports revealed that additional information is provided, albeit rarely.

4. Contributions to the Continuing Training of HCAs

Certain PCC reports contain an additional category comprising contributions made for the training (i.e. continuing education) of HCAs. This choice is based on the Code Secretariat's Recommendation No. 2 titled "Organisation of events: disclosure of pecuniary benefits". It must be read jointly with section 333 of the Pharma Code which allows pharmaceutical companies to waive the participant's financial contribution to an event held in Switzerland and lasting less than one day. According to the recommendation, "[i]f the attendance fee for events lasting up to one day does not cover all the costs and this results in a specific, pecuniary reduction in the attendance fee financed by a company, the amount of any such reduction only needs to be shown in summary form for reasons of practicality and under an additional heading entitled 'Contributions to the continuing training of HCP/HCO'. The same provision applies to the amount of the attendance fee at such events, which is deducted or refunded by a company for the benefit of an HCP or

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HCO".[154] In other words, the provision allows PCC companies to disclose in aggregate form their expenses for one-day or half-day events. For example, if an afternoon conference has costed CHF 100'000, while all attendance fees paid by HCPs amounted to CHF 75'000, the difference of CHF 25'000 can be disclosed as "Contributions to the continuing training of HCP/HCO".

This recommendation is purely optional, but these ToVs must in any case be disclosed. Indeed, companies not including the "Contributions to the continuing training of HCP/HCO" section in their PCC report have to disclose such ToVs elsewhere in their PCC reports; they often do so under the "Contribution to the costs of Events – Registration Fees" sub-section, either in an individualized format if the HCA's consent has been obtained, or in aggregate if consent has not been obtained.[155]

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states that the cost of the mass transport is attributed to each beneficiary HCP.

150 See, e. g., German FSA Q&A, p. 14.

151 For example, the Q&A guidance from the German trade association indicates that companies are free to include additional information with accompanying explanations in their methodological notes.

152 See Section 4.02 of the EFPIA Code.

153 For example, the German association clearly signals to its member companies that they are free to publish information going beyond the requirement of the German Code and they should explain their choices in their methodological notes. German FSA Q&A, p. 4.

154 PCC Recommendation No. 2, p. 2.

155 Information provided by scienceindustries.

5. Procedural Safeguards

Some pharmaceutical companies specify in their methodological notes that HCAs can preview their actual data before they are disclosed.[156] Thus, both HCPs and HCAs can check whether the information about to be published is correct and complete. This gives them a second chance to object, even though they initially agreed to the disclosure by contract. This also gives them the opportunity to point out possible errors or missing elements.

The level of precision in the description of the procedure varies greatly. Some companies (e.g. Roche) set forth a detailed procedure explaining how and when the information is communicated, how and when HCOs can respond, and what happens when HCOs object to the entries. Other companies do not describe any procedure, creating uncertainty as to how complaints are addressed.

II. An Overview of Other Initiatives

As mentioned in the introduction, the Swiss PCC is modelled on the EFPIA Code. It is therefore helpful to portray this European initiative (see subsection II.A below). Furthermore, the various transparency initiatives worldwide were generally inspired by U.S. schemes.[157] Indeed, the United States now have the most far-ranging disclosure regime, which we outline in subsection II.B. Finally, at the Swiss federal level, it was initially contemplated to introduce binding transparency obligations, mostly resting on physicians; this proposal and how it came to be discarded are presented in subsection II.C.

A. The European EFPIA Disclosure Code

The European EFPIA Code of June 2013 and the Swiss PCC of September 2014 are very similar, since scienceindustries, as one of several member associations of EFPIA, was obliged to transpose the former. Nonetheless, the Swiss association has made some minor changes, which we highlight below.

First, the personal scope of application of the EFPIA Code is somewhat broader, as it includes nurses as members of the healthcare professional (HCP) group, regardless of whether they have the competence to administer drugs. As we explained above, the Swiss PCC does not, since current Swiss law does not entitle them to use – under their own responsibility – prescription drugs.[158] Going over disclosure on the internet, we have nonetheless noticed a few PCC reports identifying nurses.[159]

Second, the EFPIA Code calls for sanctions (“enforcement”), even though it does not promulgate them directly. According to this Code, sanctions “should be proportionate […], have a deterrent effect and take account of repeated offences”;[160] additionally, “a combination of publication and fines will generally be considered to be the most effective sanction”.[161] The EFPIA Code leaves the selection of sanctions up to member associations.[162] Following its usual approach, scienceindustries has made the deliberate choice to forgo sanctions and to bet on spontaneous compliance.[163] Thus, a company which does

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156 See, for example, Roche Methodological Note, p. 4.

157 We report on the Federal scheme that was voted in 2010, with the first disclosure taking place in 2014. Before that date, eight States had introduced their own transparency obligations. See, e. g. Joseph S. Ross et al., Pharmaceutical company payments to physicians, Early experiences with disclosures laws in Vermont and Minnesota, 297(11) JAMA p. 1216–1223 (2007).

158 See subsection I. C.1.

159 We identified them thanks to the fact that some companies mentioned the title (e. g. Prof., Dr.) of the beneficiary and by searching information on the people lacking a title.

160 EFPIA Disclosure Code, section 4.04.

161 EFPIA Disclosure Code, section 4.04.

162 Schedule 3, Section 4 and 5 of the EFPIA Code explain however how complaints should be received, addressed and followed upon. It states that “in cases of serious/repeated breach, the company name(s) should be published together with details of the case.”

163 Scienceindustries has explained in some details why it believes that (private) sanctions to enforce its Codes are not appropriate. See scienceindustries, Annual Report of the Code Secretariat 2015 (“The implementation of the code follows the principle of amicable settlement of conflicts assisted in case of need by mediation by the Code Secretariat. Unlike other foreign codes in the pharmaceutical industry the Swiss Code has deliberately refrained from imposing penalties. In dealing with notifications of conduct in breach of the Code, the Code Secretariat plays an essentially intermediary role similar to that of a Justice of the Peace. Its neutral assessment as to whether a breach of the Code has or has not occurred in a particular case is practically always respected by the parties involved in the

not disclose ToVs in a full and timely manner, despite its undertaking to do so, cannot be fined or otherwise punished. Indeed, it will not even be publicly named.[164] The PCC assumes that violations will be rare and can be resolved through dialogue. Indeed, the Code Secretariat is entrusted with verifying companies' compliance (e.g. through sample checks or third-party denunciations) and negotiating remedial steps.[165] In theory, if no solution can be found through "mediation",[166] the PCC allows the Code Secretariat to "refer the matter to the appropriate State authority for a judgment".[167] However, in practice, since no authority in Switzerland may exercise jurisdiction over such a dispute (no law regulates pharmaceutical disclosures), such threat is entirely futile.

A final point worth highlighting – even though it is not a difference between the Swiss and the EFPIA Codes – is the treatment of meals and drinks offered to HCPs. Under the EFPIA Disclosure Code,[168] as well as under the PCC,[169] such benefits to HCPs do not need to be disclosed at all. The underlying reasoning is, on the one hand that the administrative burden for disclosing such small transactions is disproportionate, and on the other hand, that a threshold for meals and drinks in each country suffices to curb potential abuses.[170] Hence, the Code requires each national association to set its own ceiling limit per meal.[171] There is no overall cap per year, per HCP or per event. Under the PCC, as mentioned above, the bar is set high, since the maximum payment is CHF 150.– per HCP and per meal occurrence. In other countries, the limit is markedly lower, e.g. 60€ for Italia,[172] Germany[173] and France;[174] 40€ for a lunch and 80€ for a dinner in Belgium[175]; £ 75 for UK.[176]

B. The U.S . Sunshine Act

When the U.S. Congress finally voted the "Obamacare" Act in 2010, it seized this opportunity to impose broad transparency obligations. Section 6002 of the "Patient Protection and Affordable Care Act" (ACA[177]) is titled "Transparency Reports and Reporting of Physician Ownership of Investment Interests"[178] and is commonly called "the Sunshine Act". Under its provisions, pharmaceutical companies must publicly disclose

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case. In comparison with the implementation of similar foreign codes, the statistics concerning the PC always show slightly higher case numbers. However, these are a sign of the universally respected quality of this procedure, i. e. the ease of access and the rapid and transparent decisions taken. As indicated once again in our Annual Report, this always enables conduct in breach of the code to be eliminated rapidly and almost always by joint agreement.").

164 This is explicitly stipulated in PCC section 517. Compare with section 2.8 of the IFPMA Code of Practice ("The information to be disclosed includes the identity of the company in breach"). Scienceindustries does publish a short annual report, but it does not contain information about the specific companies found not to be in compliance; the PCC does not foresee such possibility. This annual public report is provided for by the EFPIA Code, Schedule 3, section 1 and PCC, section 518. Additionally, the Code Secretariat may publish summaries of its "decisions on implementation […] and of experience with practical implementation which is of general interest" (PCC, section 517).

165 See PCC, section 513 through to 515. The provisions of the PCC regarding sanctions are essentially a copy-paste of those found in the PC, section 6.

166 PCC, section 515.2.

167 PCC, section 551.

168 EFPIA Disclosure Code, section 1.02.

169 PCC, section 233.5.

170 EFPIA Disclosure Code: Your Questions Answered, p. 6.

171 EFPIA HCP Code, section 10.05.

172 Farmindustria, Codice Deontologico, article 3.16.

173 FSA-Kodex zur Zusammenarbeit der pharmazeutischen Industrie mit Ärzten, Apothekern und weiteren Angehörigen der Fachkreise, section 9.2. This code goes even further by defining what kinds of drinks and pastries are allowed in particular events.

174 LEEM, Dispositions déontologiques professionnelles, section 1.2.1.c.

175 Pharma.be, Lignes directrices concernant la valeur des repas qui sont offerts à des professionnels du secteur de la santé dans le cadre de manifestations scientifiques.

176 ABPI, Code of practice for the pharmaceutical industry, clause 22.2.

177 The Patient Protection and Affordable Care Act (ACA) was signed into law in March 2010.

178 ACA, Title VI – Transparency and Program Integrity, Subtitle A – Physician Ownership and Other Transparency, Section 6002; this section has introduced a new Section 1128G to the Social Security Act, which has been codified as 42 U. S. C. 1320a-7h.

all transfers of value to physicians. The first publication took place in September 2014.[179] The scope of the U.S. law is broad – particularly compared to the Swiss PCC. In this section, we highlight the differences between the two systems.

First, all manufacturing companies (whether based in the United States or not) which have products benefitting from public reimbursement (e.g. through Medicare or Medicaid) are bound by these transparency obligations. In practice, this entails the inclusion of practically all pharmaceutical companies selling on the U.S. market. In addition, group purchasing organizations (i.e. entities that specialize in the negotiation and purchasing of medical products) bear the same obligations.[180] There are over 1'600 reporting entities.[181]

Second, all products which are eligible for reimbursement are covered. This includes prescription drugs,[182] medical devices, biological products and other medical supplies. However, it is not imperative that a transfer of value be connected to a certain product for disclosure to be mandatory. It is enough that the company is selling at least once such product. Drugs under development are included, unless the company has not (yet) *any* approved drug on the mar-

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ket.[183] Whenever a payment can be tied back to a given product, that product must be specifically disclosed in the corresponding report.[184]

Third, disclosure encompasses a wide scope of benefits, including royalties, investment interests and charitable contributions.[185] Trinkets valued over USD 10 (or USD 100 in aggregate per year) are included,[186] as are meals and drinks, unless offered on an indistinctive basis. Amounts paid for R&D services must be disclosed on an individual basis;[187] for research on drugs not yet approved, disclosure may be delayed until the 4th anniversary following the payment or until FDA approval (the earlier of the two). Free samples to be distributed to patients are exempt from disclosure, as are rebates on purchases.

Fourth, the consent of recipients, chiefly physicians[188] and teaching hospitals,[189] is *not* required.[190] There is therefore no aggregate disclosure, except in the rare case where it was not possible to identify the recipients accurately.

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179 Since 2015, annual publication takes place in June. However, the database is updated regularly throughout the year to reflect corrections.

180 See Section 1128G (e)(1).

181 See Marisa A. Trasatti/Caroline Willsey, The Physician Payment Sunshine Act, Navigating the Act for Health Care Provider and Medical Device/Big Pharma Clients, In-House Defense Quarterly, p. 27, 2016.

182 As in Switzerland, are not covered by the U. S. regime drugs which do not require a prescription.

183 Mark J. Ratain, Forecasting unanticipated consequences of 'The Sunshine Act': Mostly cloudy, 32(22) Journal of Clinical Oncology p. 2293 (2014).

184 Section 1128G (a)(1)(A)(vii).

185 When a physician asks that a charitable contribution be made to a given organization, the disclosure must ascribe the payment to the physician.

186 The amount is to be adapted yearly based on the U. S. consumer price index for all urban consumers; it is now USD 10.22. See Section 1128G (e)(10)(B)(i).

187 This disclosure has been particularly criticized because, often, the physician who is listed under this category does not keep, nor even receives, all the funds mentioned. See, e. g. Faith A. Coleman, The promise and peril of the Open Payments Act.

188 "All other health professionals, including those with prescriptive authority such as Doctors of Pharmacy (PharmDs), Physician Assistants (Pas) and Nurse Practitioners (NPs), are omitted from this legislation". Quinn Grundy et al., Interactions between non-physician clinicians and industry: A systematic review, 10(11) PLOS e1001561 (2013). As of mid-2015, over 600'000 physicians had received reported benefits. See Trasatti & Willsey, (Fn. 181), p. 25. See also CMS Report to Congress 2017.

189 There are over 1200 teaching hospitals subject to these requirements.

190 In some cases, recipients may review their corresponding entry, before it is submitted, if they so wish; they may then ask for changes when justified. However, manufacturers are not obliged to offer a pre-submission review. Once the entry is submitted, recipients may object to the content and ask for corrections; they must follow a formal process for so doing; if they do nothing, the payment is published as such. A very low proportion of the reports (25'000 out of more 11 million records) are contested. "In the cases when a dispute cannot be resolved, the most recent submitted and attested data by the applicable manufacturer will be published, but will be marked as disputed". CMS Fact Sheet on Reporting requirements for applicable manufacturers, at https://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Applicable-Manufacturer-fact-sheet.pdf. Daniel T. Oberlin & Chris M. Gonzales have reported how technically difficult it is for physicians to register and report mistakes in the reported data: Letter to the Editor, 91(5) Mayo Clinical Proceedings, May 2016, p. 685–686.

Fifth, disclosure occurs on a centralized platform called 'Open Payments' maintained by CMS (U.S. Centers for Medicare & Medicaid Services).[191] Pharmaceutical companies send their data to CMS, which then aggregates them and makes them available in a variety of formats. The database is remarkably user-friendly, making it easy to access the information using various search approaches. For example, a user can query the database to learn how much a given physician has received from all pharmaceutical companies. As much as feasible, CMS tries to provide information on the nature of payments received.

Sixth, failure to comply with the Sunshine Act is punished through pecuniary sanctions, which can reach USD 1,15 million.[192] However, no penalty has yet been imposed, as CMS has prioritized outreach and dialogue.[193]

The objectives underlying the enactment of the Sunshine Act deserved to be highlighted. As explained by the U.S. Department of Health and Human Services:[194]

> "payments […] to physicians and teaching hospitals can also introduce conflicts of interest that may influence, research, education and clinical decision-making in ways that compromise clinical integrity and patient care, and may lead to increased health care costs. We recognize that disclosure alone is not sufficient to differentiate beneficial financial relationships from those that create conflict of interests or are otherwise improper. […] However, transparency will shed light on the nature and extent of relationships, and will hopefully discourage the development of inappropriate relationships and help prevent the increased and potentially unnecessary health care costs that can arise from such conflicts."

One understands that transparency is viewed as a tool among others to ensure integrity and to possibly achieve lower costs. However, the ambition remains modest, as it is made clear that reaching the objectives ultimately depends on the reactions of the actors on the market, starting with patients (e.g. would they abandon physicians with too "deep" relationships with the industry). Recent numbers have shown

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that the numbers of payments and the number of paid physicians have increased – not decreased – following introduction of the rules.[195]

Both the scope of and the level of compliance with the U.S. Sunshine Act have been the subject of criticism. In addition, the estimated costs appear to be staggering: they amount to "approximately $ 269 million in the first year [following implementation] and $ 180 million annually thereafter"[196], while both monetary and nonmonetary benefits are not quantified[197].

C. The Future Revised Swiss TherapeuticProducts Act

The Swiss Therapeutic Products Act (TPA), first enacted in December 2000, was revised in March 2016. The revised version entered into force on January 1, 2019, given the need to revise most ordinances. However, the provisions on transparency will enter into force later, probably in 2020.[198]

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191 See Section 1128G (c)(1)(C).

192 There are separate provisions for negligent failure to report and knowing failure to report. See Section 1128G. (b) Penalties for noncompliance. The two can be combined. See CMS Fact Sheet (Fn. 190).

193 See CMS, Open Payments Program Report to Congress, 2016 (covering payments made during 2014). When will CMS actually begin to impose penalties is an open question. See CenterWatch, Mixed experience with the Sunshine Act (2016), at https://www.centerwatch.com/news-online/2016/08/01/mixed-experience-sunshine-act/; Mark Gardner, Is 2016 The Year That CMS Starts Fining Sunshine Act Violators? In Consulting, Industry Reposts (2016), at https://www.namsa.com/industry-reposts/2016-year-cms-starts-fining-sunshine-act-violators/.

194 Final Rule of the Department of Health and Human Services, Centers for Medicare and Medicaid Services, Transparency Reports and Reporting of Physician Ownership or Investment Interests, Federal Register 78 (22), p. 9459. February 2013.

195 Payments went from $ 2.68 billion in 2014 to $ 2.8 billion in 2016, while listed physicians went from 625'000 in 2014 to 631'000 in 2016. See Tracy Staton, Pharma shells out $2B-plus to doctors – again – with Allergan and Celgene in the lead, Fierce Pharma, July 5, 2017.

196 Final Rule of the Affordable Care Act, Federal Register/Vol. 28, No. 27, pp. 9458ff., p. 9458, available at: https://www.cms.gov/OpenPayments/Downloads/Affordable-Care-Act-Section-6002-Final-Rule.pdf .

197 Id.

198 Following the final vote on the revised TPA, the Federal Interior Department has been working on the revision of the corresponding ordinances. The proposed new versions were submitted for consultation in June 2017. The consultation was extended to October 2017. See the web page of the Federal Administration on planned consultation: https://www.admin.ch/ch/f/gg/pc/pendent.html .

The revised TPA will introduce a new Section 2a on integrity and transparency. The new Article 55[199] is closely mirrored on the actual Article 33, which it would replace. As previously, it forbids the offering and the receiving of undue pecuniary benefits. Section 2 of Article 55 lists the items which do not fall under the prohibition; for example, gifts of modest value which are related to the practice of medicine or of pharmacy are allowed; similarly, financial grants to fund research are normally allowed.

Article 56[200] will introduce new transparency obligations, both for HCPs and for pharmaceutical companies. Under this provision, anyone offering or accepting discounts or rebates in connection with the purchasing of any medicine must indicate so in the corresponding accounting documents. Upon request, this person must reveal the rebates and discounts to the public authorities. The Federal Council can waive the requirement for low-risk products[201] – and has done so for class E medicines (i.e. medicines that can be sold in any store) .[202] Moreover, these rebates and discounts, when in relation with drugs reimbursed by social insurance, should ultimately benefit patients.[203]

In the initial draft of the Federal Council, the provision (then Article 57c) had a broader scope, as it would have mandated public disclosure by HCAs. Indeed, section 2 would have required anyone prescribing, dispensing, using or buying therapeutic products, including any organization employing the former persons, to inform their clients in an appropriate manner of any relationship with pharmaceutical companies. More specifically, the information publicly disclosed would have included ownership interests in companies manufacturing or offering therapeutic products, positions occupied within bodies of such companies as well as ownership interests of pharmaceutical companies in medical offices, pharmacies or purchasing organizations.[204]

This transparency obligation at article 57c was discarded during parliamentary debates. Based on the discussion held within its Parliamentary Commission on Social Security and Public Health, the National Council proposed multiple changes to the various provisions of this section, among them the deletion of Article 57c section 2. Before Parliament, the debate focused chiefly on the scope of the anti-corruption provision; few arguments were voiced to justify the deletion of the disclosure obligation, except that the latter was viewed as onerous and unpractical.[205]

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By a vote of 143 (against a disclosure obligation) to 45 (in favour of the disclosure obligation), all the proposed changes to Articles 57a to 57c (including the said deletion) were accepted on May 7, 2014.

Later, on December 10, 2014, the Council of States endorsed the changes first decided by the National Council (by a vote of 28 for the version of the National Council against 13 defending the version of the Federal Council). The discussion was similarly sparse. Federal Councillor Alain Berset repeated the reasons

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199 See note 48 already citing future article 55 TPA. See for details Felix Kesselring, Neue Regeln für Rabatte, Kickbacks und Sponsoring. Die revidierten Bestimmungen im Heilmittel- und Krankenversicherungsgesetz im Überblick, LSR 3/2018, 159–173.

200 According to future article 56 titled “Obligation de transparence”: “[1] Quiconque octroie ou accepte des rabais ou ristournes lors de l’achat de produits thérapeutiques doit les indiquer dans les pièces justificatives et les comptes ainsi que dans les livres de comptes et, sur demande, les signaler aux autorités compétentes. [2] Le Conseil fédéral règle les modalités. [3] Pour les produits thérapeutiques présentant un risque minime, le Conseil fédéral peut prévoir des exceptions à l’obligation visée à l’al. 1.”

201 The future ordinance does not reinforce the mechanism of the new Article 56, which will force HCAs to keep track, through accounting books, of all received pecuniary documents. The new (at this stage draft) ordinance implementing Articles 4, 55 and 56 of the future TPA – the OITPTh – will not bring forth significant change. This draft text was under consultation between June 21 and 20 October 20, 2017. It does clarify the range of permissible interactions but does not extend transparency (article 10); only the possibility of denouncing infringements to the Federal Office of Public Health is introduced (Article 11). The Federal Council followed the minimal viewpoint of the Parliament, renouncing further initiative.

202 Article 10 al. 2 OITPTh.

203 See articles 76a and 76b of the proposed revision of the Swiss Ordinance on sickness insurance (OAMal).

204 Likewise, the Federal Council would have been authorized to introduce exceptions to these broad disclosure obligations (article 57c section 3 of the Federal Council’s draft).

205 Member of the National Council Marina Carobbio Guscetti said: “Für das BAG, das als zuständige Behörde mit dem Vollzug dieser neuen Bestimmungen betraut ist, kann dies zu einem erheblichen zusätzlichen Kontrollaufwand führen. Dieser Aufwand kann indessen stark vermindert werden, wenn das BAG nicht von sich aus flächendeckende Kontrollen einrichten muss, sondern dann eingreift, wenn es Hinweise auf Verstösse gegen die Vorschriften erhält.” (BO 2014 N 697) (https://www.parlament.ch/fr/ratsbetrieb/amtliches-bulletin/amtliches-bulletin-die-videos?TranscriptId=173733).

underlying the Federal Council's proposal in favour of greater transparency.[206] Against such disclosure, Felix Gutzwiller, State Council member of the liberal-radical group, explained:

> "Ich möchte Sie bitten, bei Artikel 57c Absatz 2 der Mehrheit zu folgen. Es ist vernünftig vorzusehen, dass der Bundesrat die Einzelheiten regelt. Wenn Sie den Entwurf des Bundesrates ansehen, stellen Sie fest, dass er einen Detaillierungsgrad aufweist, den wir nicht in diesem Gesetz haben wollen; die Details können in der Verordnung aufgenommen werden.
>
> Zudem stellt sich wirklich die Frage nach einer praxistauglichen Umsetzung. Wie Sie sehen, soll jemand, der Heilmittel abgibt, seine Kundschaft über seine Beteiligungen usw. informieren. Man kann sich kaum vorstellen – das habe ich auch in der Kommission erwähnt –, dass ein Kardiologieprofessor aus Genf, der vielleicht zwei Novartis-Aktien hat und da und dort mitwirkt, dass in seiner Praxis anschreiben muss. Das sind alles Dinge, die nicht praktikabel sind.
>
> Ich denke, dass Transparenz sehr wichtig ist. Wir haben bei den vorhergehenden Artikeln entsprechende Beschlüsse gefasst. Deshalb kann man hier dem Bundesrat vertrauen, dass er die Einzelheiten adäquat regelt."[207]

The respective positions were not further discussed. The remaining parliamentary sessions focused on different topics. Thus, the idea to mandate transparency at the level of physicians was essentially abandoned.

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III. Annex: EFPIA Disclosure Code Schedule 2 (Disclosure Template)

SCHEDULE 2 - TEMPLATE

Date of publication: .....

	Full Name (Art. 1.01)	HCPs: City of Principal Practice HCOs: city where registered (Art. 3)	Country of Principal Practice (Schedule 1)	Principal Practice Address (Art. 3)	Unique country identifier OPTIONAL (Art. 3)	Donations and Grants to HCOs (Art. 3.01.1.a)	Contribution to costs of Events (Art. 3.01.1.b & 3.01.2.a)		Fee for service and consultancy (Art. 3.01.1.c & 3.01.2.c)			TOTAL OPTIONAL
							Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accommodation	Fees	Related expenses agreed in the fee for service or consultancy contract, including travel & accommodation relevant to the contract	
HCPs	*INDIVIDUAL NAMED DISCLOSURE - one line per HCP (i.e. all transfers of value during a year for an individual HCP will be summed up. Itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)*											
	Dr A					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount	
	Dr B					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount	
	etc.					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount	
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons											
	Aggregate amount attributable to transfers of value to such Recipients - *Art. 3.02*					N/A	N/A	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs	Optional
	Number of Recipients in aggregate disclosure - *Art. 3.02*					N/A	N/A	number	number	number	number	Optional
	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art. 3.02					N/A	N/A	%	%	%	%	N/A
HCOs	*INDIVIDUAL NAMED DISCLOSURE - one line per HCO (i.e. all transfers of value during a year for an individual HCO will be summed up. Itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)*											
	HCO 1					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Optional
	HCO 2					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Optional
	etc.					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Optional
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons											
	Aggregate amount attributable to transfers of value to such Recipients - *Art. 3.02*					Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Optional
	Number of Recipients in aggregate disclosure - *Art. 3.02*					number	number	number	number	number	number	Optional
	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art. 3.02					%	%	%	%	%	%	N/A

	AGGREGATE DISCLOSURE		
R&D	Transfers of Value re Research & Development as defined - *Article 3.04 and Schedule 1*	*TOTAL AMOUNT*	*OPTIONAL*

206 He stated: "Nous souhaitons que les patients soient informés de façon transparente sur les participations ou les engagements importants – évidemment il ne s'agit pas de mentionner la propriété d'une action ou de quelque chose de semblable – des professionnels de la santé. En effet, ces participations ou ces engagements pourraient être de nature à influencer le jugement. Cela peut être fait de manière relativement simple, par exemple au moyen d'une liste publiée sur Internet. On peut imaginer qu'il n'est pas sans intérêt pour les patients de savoir que la personne qui leur prescrit des médicaments a peut-être des participations importantes dans le cabinet médical, dans la pharmacie, ou des participations croisées, mais toujours d'une certaine importance. En termes de transparence, on ne voit pas très bien pour quelle raison on souhaiterait cacher ces choses. La question qui se pose est celle de savoir si nous aurons une base légale suffisante pour mettre en œuvre ce qui figure dans le projet du Conseil fédéral. En vertu de la proposition de la majorité, c'est un peu délicat. Nous devrons analyser cela de près, mais il s'agit véritablement d'autre chose."

207 BO 2014 E 1274.