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## Moral reasoning perspectives of community pharmacists in situations of drug shortages

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## ABSTRACT

**Background:** Drug shortages affect health systems worldwide. Research in community pharmacy has focused on the nature, extent and impact of these shortages on patients and pharmacists. However, pharmacists' moral reasoning in situations of drug shortages has not been addressed.**Objective:** To explore the moral reasoning perspectives of Dutch community pharmacists in situations of drug shortages.**Method:** An electronic survey was developed around three drug shortage scenarios with a varying impact on patient outcomes: a Contraceptive, a Parkinson's and an Osteoporosis scenario. Pharmacists rated the likelihood of nine handling options and rated and ranked 13 considerations that may have played a role therein. The considerations represented three moral reasoning perspectives (MRPs): a business orientation (BO), a rules and regulations (RR), and a professional ethics (PE) MRP. Principle component analysis (PCA) was used to investigate construct validity of the MRPs. MRP rating and MRP ranking scores measured the relative importance of the different MRPs of pharmacists in the three shortages.**Results:** Results from 267 Pharmacists were obtained. They reported mostly similar handling in the three shortages, except for the likelihood to make agreements with prescribers or other pharmacists and regarding the decision to import a product. The PCA analysis confirmed the three MRPs that accounted for 29% of variance in the data. Both the MRP rating and especially the MRP ranking scores indicated that PE-MRP considerations were most influential on pharmacists' intended handling of the shortages. In the Contraceptive and the Osteoporosis scenarios, the relative importance of a BO-MRP was higher than in the Parkinson's scenario.**Conclusion:** Pharmacists predominantly reason with a PE-MRP when handling drug shortages. However, this perspective can be compromised when the drug shortage is perceived to have a lower impact on patient outcomes and when alternative drugs or therapy are expensive.

## Introduction

Drug shortages affect health systems worldwide and are increasing in number and duration in both developed and developing countries.<sup>1-7</sup> Worldwide different national stakeholders (governments, pharmacy associations, hospitals, health insurers, wholesalers, marketing authorization holders (MAH), etc.) aim to prevent and solve drug shortages. Mostly by informing health professionals about (potential) drug

shortages<sup>1,3,6,8,9</sup> and providing support materials and resources.<sup>3,6</sup> In The Netherlands, authorities and pharmacy practice detect different signals on potential drug shortages and authorities are informed later.<sup>7</sup> Authorities' role to assist pharmacists to solve drug shortage problems is limited. Hence, pharmacists have to deal with the problem when the patient is at the counter.

Regardless of their causes, drug shortages pose threats to the quality of pharmaceutical care and thus to patients' well-being and safety.<sup>3,10,11</sup>

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Health professionals' moral obligation to provide every citizen with access to appropriate healthcare is challenged,<sup>2,9-14</sup> which may result in professional and moral distress.<sup>13,15</sup>

Pharmacists are particularly challenged because they often must inform the patient that a certain drug is unavailable. Moreover, pharmacists are responsible for the provision of appropriate drug therapy, and this professional duty is placed under pressure when a drug is unavailable.<sup>16</sup> Pharmacists have to judge whether the quality of alternative drug treatments is sufficient and whether these treatments are effective and safe for a patient. Drug shortages also challenge pharmacists to address different stakeholders and health professionals who may not always support patient-level solutions necessitated by a drug shortage.<sup>4,9,17</sup> In several countries, legislation requires authorization from the prescribers for generic substitution even during circumstances when a drug is clearly unavailable. Therapeutic drug substitution may be even more cumbersome.<sup>18</sup> This places further stress and pressure on pharmacists as they are challenged to find solutions for their patients and concurrently have to make agreements with prescribers. Pharmacists can also be challenged with patients who refuse to take alternative medicines or who are noncompliant with these medicines.<sup>11,13</sup>

Pharmacists have reported that dealing with drug shortages has moral and economic implications.<sup>6,11,19</sup> Moral implications arise when pharmacists' decisions may lead to suboptimal health outcomes for patients.<sup>6,11,19</sup> For example, in case pharmacists have to dispense potentially less suitable alternative medicines or less appropriate dosage forms. These decisions also have economic implications as, importing alternative drugs is often more expensive, and pharmacists need extra time and personnel to find solutions for drug shortage problems. The resulting increased pharmacy operation costs<sup>3,9,11,13,20-22</sup> are generally not compensated and may even hamper pharmaceutical care for other patients.

Drug shortages require advanced levels of professionalism, such as a high level of pharmaceutical expertise, strong communication and collaboration skills<sup>11,19</sup> and advanced levels of moral reasoning. In situations that present moral dilemmas, moral reasoning entails reflection on whose and which values are at stake for any possible course of action and how professional decisions may influence patients' well-being.<sup>23-25</sup> Moral reasoning can be defined as deliberating about what a person ought, morally, to do, a species of practical reasoning.<sup>26</sup> Ethical reasoning is used in the same sense but is often more concerned with cognitive processes that persons follow in making a decision prior to behavior.<sup>27</sup> Ethical reasoning is therefore mostly used with respect to special fields of interest, e.g., business ethics, clinical ethics, etc. Throughout this paper the term moral reasoning is used, which can also be read as ethical reasoning. In the moral reasoning literature three developmental levels of moral reasoning perspectives (schemas) are recognized based on Kohlberg's cognitive moral development theory<sup>28</sup>: a pre-conventional level (reasoning focused on personal interest), a conventional level (reasoning focused on maintaining norms) and a post-conventional level (reasoning focused on universal principles, beyond personal interest and norms). Rest et al.<sup>29</sup> developed these three moral reasoning perspectives as a response to Kohlberg's claim of six sequential cognitive stages where one moves as on a staircase one stage at a time (Table 1). Rest et al. defined moral development more as a gradual shift from lower to more complex conceptions of how to organize society-wide co-operation. In their theory moral reasoning perspectives are more contextual and automatic and less reflective than Kohlberg's six stages, and are at any moment available to the individual.<sup>30</sup> An extensive comparison between the two models is described elsewhere.<sup>28,31,32</sup> In the view of Rest et al. moral reasoning perspectives (MRPs) are tacit beliefs and cognitions present in a person's long-term memory of which he or she is not explicitly aware.<sup>28,31-33</sup> These tacit beliefs and cognitions help individuals understand new information based on prior experiences.<sup>30</sup> Rest et al. developed thereto a moral reasoning test, the Defining Issues Test (DIT), that is able to activate a person's tacitly preferred perspective when a person reads written

**Table 1**Moral reasoning development theorized by Rest et al.<sup>32</sup> and Kohlberg.<sup>42,43</sup>

Rest's moral reasoning perspectives	Kohlberg's six stages of cognitive moral development
Post-conventional moral reasoning perspective (Universal principles, beyond personal interest and norms)	Stage 6. Morality of universal ethical principles Stage 5. Morality of contract and of democratically accepted law
Conventional moral reasoning perspective (Maintaining norms)	Stage 4. Authority maintaining morality
Pre-conventional moral reasoning perspective (Personal interest)	Stage 3. Being-good morality of maintaining good relations, approval of others Stage 2. Naive instrumental hedonism, and equal exchange Stage 1. Punishment and obedience orientation

statements that represent these MRPs.<sup>33</sup> People rate and rank their tacitly preferred MRP statements more highly when making decisions.<sup>31,33</sup>

Pharmacists' moral reasoning has been previously studied, both without the DIT<sup>34-36</sup> and with the DIT.<sup>28,32,37-40</sup> The results of these latter studies suggest that pharmacists score low on post-conventional moral reasoning compared to other health professionals.<sup>38</sup> However, a recent study suggested that an educational intervention aimed at improving moral reasoning competencies, positively affected the development of these competencies in pharmacists as measured with the DIT.<sup>41</sup>

To date, research on drug shortages in community pharmacy has focused on the nature, extent and impact of these shortages on patients and pharmacists and on causes of and solutions to the problem.<sup>3,6,7,9,11,13,14,17</sup> The aspect of moral reasoning during drug shortage situations has not been addressed. The aim of this study is to explore the moral reasoning perspectives of Dutch community pharmacists in situations of drug shortages.

## Method

An electronic survey was completed by Dutch community pharmacists. The survey explored respondents' intended actions and moral reasoning perspectives in three drug shortages.

### Respondents

In November 2019, approximately 2900 community pharmacists were registered in The Netherlands. They were invited and reminded once to participate in the study by completing a survey through the weekly digital membership newsletter of the Royal Dutch Pharmacists Association (KNMP) with a membership of approximately 95% of all community pharmacists. To increase the response rate we also sent digital invitations and reminders for the survey through two other professional channels: the Utrecht Pharmacy Practice Network for Education and Research (UPPER),<sup>44</sup> and the largest pharmacy chain BENU Apotheken. Through these three professional channels both community pharmacists and early-career pharmacists working in community pharmacy were reached. The survey was accessible from November 6 until December 9, 2019.

### Drug shortage scenario construction

The investigators first selected nine drug shortages which met the following criteria: the shortage affected all Dutch pharmacies in 2018-2019 and the shortage had a duration of at least 3 months. Subsequently an expert panel consisting of seven practicing community pharmacists selected three shortages that were expected to have a varying impact on patients outcomes: a contraceptive shortage

(Contraceptive scenario), a levodopa shortage (Parkinson's scenario) and an alendronic acid shortage (Osteoporosis scenario). See Table 2 for the perceived relevance of these three shortages.

### Survey development

An electronic survey was developed by the research team (MK, AF and MB); this survey was based on cognitive moral development literature,<sup>28,28,29,32,32</sup> (inter)national pharmacy practice literature,<sup>16,39,46–49</sup> and the context of Dutch pharmacy practices (see the survey in Appendix A). For each of the three drug shortage scenarios, the respondents had to use a four point scale (very likely, likely, unlikely, very unlikely) to rate the likelihood that they would use each of nine options of intended action to address the shortage. A four-point scale for rating the likelihood of the intended action options was chosen to force respondents to choose their intended action either negatively or positively, as all respondents have experienced the shortages in their pharmacy. The respondents then had to rate the extent to which 13 considerations played a role in handling the drug shortage problem using a five-point scale (very strong, strong, weakly, very weakly, no role). This five-point scale from very strong to no role was chosen because a consideration might not play a role in the intended actions. Finally, the respondents had to rank the four most relevant considerations. Participants also answered general questions about their gender, age, type of pharmacy and job profile.

### Measuring moral reasoning perspectives

The profession-specific moral reasoning measure developed for this study was based on earlier research.<sup>46,49</sup> In that research, based on Kohlberg's cognitive moral development theory and the DIT,<sup>28</sup> Rest's three MRPs have been adjusted to the community pharmacy practice context: (1) at the pre-conventional level, pharmacists' MRP is focused on maintaining a viable business and included personal interests (this MRP has been named business orientation and is labeled BO-MRP); (2) at the conventional level, pharmacists' MRP is centered around adhering to rules and regulations (this MRP has been named rules and regulations and is labeled RR-MRP); and (3) at the post-conventional level, pharmacists' MRP is guided by professional ethics (this MRP has been named professional ethics and is labeled PE-MRP).<sup>16,49</sup> In this study, the research team (MK, AF and MB) designed the to be rated and ranked considerations for these MRPs in the context of the three drug shortages and the professional values of Dutch pharmacy practice.<sup>47,48</sup> The team used the three drug shortage scenarios to develop four different considerations for each MRP. Some considerations were used in more than one scenario.

### Validation of the survey

The survey was validated by using an intensive process to reach consensus between the research team (MK, AF and MB) and an expert panel of five experienced pharmacists over the course of three meetings.

**Table 2**  
The three drug shortages used in the study.

Drug shortage scenario	Duration	Average number of users per pharmacy <sup>a</sup>	Perceived relevance of the shortage (impact on patient outcomes)
1 – <b>Contraceptive</b> (Ethinylestradiol/Levonorgestrel 0.03/0.15 mg [oral] tablet)	May 2018–November 2019	50, <sup>045</sup>	Medium; although alternative treatments were available, women had to switch to oral contraceptives with a different composition of active ingredients
2 – <b>Parkinson's medicine</b> (Levodopa/Carbidopa 125 mg tablet)	January 2018–Present (Irregular supply persists)	19 <sup>b</sup>	High; switching to alternative treatment required a pharmacotherapeutic substitution with a potentially reduced ability to control Parkinson's symptoms
3 – <b>Osteoporosis medicine</b> (Alendronic acid 70 mg tablet)	February 2019–Present (Irregular supply persists)	61 <sup>b</sup>	Low; fewer practical alternatives were available (e.g., daily alendronic acid, 10 mg instead of 70 mg once a week) and temporary discontinuation of bisphosphonates did not jeopardize patients' health

<sup>a</sup> 1.996 community pharmacies in the Netherlands per January 1, 2018, published by the Foundation for Pharmaceutical Statistics in The Hague in its Annual Report "SFK Data en feiten 2019"

<sup>b</sup> National Health Care Institute. The drug information system. <https://GIPdatabank.nl>.

All five pharmacists were active in the special interest group on pharmacy ethics of the Royal Dutch Pharmacists Association. Four of the five experts were also practicing senior community pharmacists. First, the accuracy, readability and content of the drug shortage scenarios, options of intended action and considerations were assessed. Further, every consideration was judged on its representation of the MRP, which for the PE-considerations contains the professional values.<sup>47</sup> If no consensus was reached, a consideration was reformulated or discarded. The top four considerations for each MRP and scenario were chosen for use in the survey. The entire survey was tested by seven community pharmacists to make final adjustments.

### Data analysis

SPSS 25 was used for all data analysis.

### Control considerations

One of the 13 considerations per drug shortage scenario was a control consideration (i.e., a meaningless consideration, labeled 'M'), which was formulated to correct for respondents providing potentially unreliable answers.<sup>32</sup> If respondents ranked such a control consideration more than one time, their surveys were excluded from analysis.

### Validation of moral reasoning perspectives

First, a principal component analysis (PCA) was performed to check the rating scores for construct validity, searching for a confirmation of the three MRPs in three distinguishing components. The rating scores were thus checked for factorability with the Kaiser-Meyer-Olkin's measure (KMO, ideal value < 0.6). Subsequently, correlations between variables were tested with Bartlett's test of sphericity (index  $p < 0.05$ ). Varimax rotation was used to extract the components to increase interpretability of the data. The components were further examined by their percentage of variance explained, their eigenvalues (eligible value > 1) and their component statement loadings (eligible value  $\geq 0.35$ , or a difference of >0.2 between the correlation values if a statement loaded highly on more than one component).<sup>49,50</sup>

### Measuring moral reasoning perspectives: the MRP rating and ranking score

In order to measure the relative influence of the three moral reasoning perspectives (BO, RR and PE), rating and ranking scores were calculated for each MRP.

**MRP rating score:** For this score the meaningless considerations were excluded, leaving 12 considerations per scenario, of which four represented the BO-MRP, four the RR-MRP and another four the PE-MRP. Each consideration in a scenario was given a numerical weight from four (the consideration played a very strong role) to zero (the consideration played no role). Hence, for each MRP in a scenario a respondent could have a maximum MRP rating score of (4 times 4) 16 points if all four considerations of one MRP (BO, RR or PE-MRP) played a very strong role in handling the drug shortage, and a minimum MRP rating

score of 0 points if none of these four considerations played any role. For each respondent the BO-MRP, the RR-MRP and the PE-MRP rating score were expressed as a percentage of the maximum score. Finally, these three MRP score percentages were normalized to 100% to present their relative percentages.

**MRP ranking score:** A numerical weight from four (first ranked) to one (fourth ranked) was given to each ranked consideration.<sup>51</sup> Ranked meaningless considerations were assigned a weight of zero points. Per MRP per scenario the weights were added up. A respondent could receive a maximum score per MRP per scenario of 10 points (if four considerations of one MRP were ranked) and a minimum of 0 points (if no considerations of one MRP were ranked). The three MRP ranking scores per scenario were calculated per respondent by dividing the summed weights by the maximum score. Additionally the number of times each consideration was ranked, was counted.

#### Ethics approval

The Institutional Review Board Utrecht of the division Pharmacoeconomics & Clinical Pharmacology, Utrecht University formally approved the research.

#### Results

Two hundred sixty-seven respondents (94% community pharmacists and 6% early-career pharmacists practicing in community pharmacy) completed the survey. Of these respondents, 63% were women, 39% worked in a (small)chain pharmacy, 79% were primary responsible pharmacist at their pharmacy, and the median age was 42 years (IQR = 32–52 years). Reference of these characteristics to national data were included in [Appendix B](#). No respondents ranked more than one meaningless consideration (although seven respondents ranked one), so no surveys were excluded.

#### Handling of the drug shortage

According to the survey results, pharmacists rated the likelihood of six of the nine intended actions in the three shortages almost equally ([Table 3](#)). More pharmacists were likely to make alternative drug agreements with prescribers in the Contraceptive and Osteoporosis scenarios (80% and 70%, respectively) than in the Parkinson's scenario (55%). Slightly fewer pharmacists were likely to make agreements with other pharmacists in the Parkinson's and Osteoporosis scenarios (39% and 41%, respectively) than in the Contraceptive scenario (50%). Finally, most pharmacists (80%) were unlikely to import osteoporosis medicine, but they were likely to import contraceptive and Parkinson's medicine (61% and 75% of pharmacists, respectively).

#### Moral reasoning perspective considerations

The principle component analysis (PCA) confirmed that the BO-, RR- and PE-considerations represented the respective MRPs. The PCA was performed using the rating data of all 267 respondents. The analysis confirmed the construct validity of the data: the KMO index was 0.75, and Bartlett's test was statistically significant ( $p < 0.000$ ). The scree plot did not indicate relevant increments beyond five components. Therefore, the PCA-varimax rotation was performed with three, four and five components. The three components explained 29% of the variance in the data and had eigenvalues larger than two. When four components were used for the rotation, the explained variance increased by 5%, and when five components were used, the explained variance increased by an additional 4%. However, interpreting the considerations that correlated when using four or five components did not provide new moral reasoning perspectives. Therefore, we set the number of components to three.

[Table 4](#) presents the correlation loadings of the three PCA components for each scenario's considerations and indicates that the majority

**Table 3**

Self-reported likelihood of handling three drug shortage scenarios by Dutch community pharmacists (N = 267).

Intended action option	Scenario	Very unlikely/ Unlikely	Likely/ Very Likely
1. I explain to the patient that I cannot dispense the medicine due to its shortage	Contraceptive	26.2%	73.8%
	Parkinson's	24.3%	75.7%
2. I refer the patient to the prescriber for possible alternative (pharmaceutical) treatments	Contraceptive	59.9%	40.1%
	Parkinson's	61.0%	39.0%
3. I propose a possible alternative pharmaceutical treatment to the prescriber	Osteoporosis	73.4%	26.6%
	Contraceptive	10.5%	89.5%
4. I discuss possible alternative (pharmaceutical) treatments with the patient	Parkinson's	9.4%	90.6%
	Osteoporosis	6.7%	93.3%
5. I import the medicine of which there is a shortage	Contraceptive	9.4%	90.6%
	Parkinson's	14.2%	85.8%
6. I have made agreements in advance with the prescribers in my area related to alternatives for this drug shortage	Osteoporosis	8.6%	91.4%
	Contraceptive	39.0%	61.0%
7. I have made agreements in advance with pharmacists in my area related to alternatives for this drug shortage	Parkinson's	25.1%	74.9%
	Osteoporosis	79.8%	20.2%
8. I advise the patient to check whether another pharmacy has this medicine in stock	Contraceptive	19.9%	80.1%
	Parkinson's	44.6%	55.4%
9. I check other pharmacies in my area on behalf of the patient to see if they still have this medicine in stock	Osteoporosis	29.6%	70.4%
	Contraceptive	50.2%	49.8%
	Parkinson's	61.0%	39.0%
	Osteoporosis	59.2%	40.8%
	Contraceptive	87.6%	12.4%
	Parkinson's	85.8%	14.2%
	Osteoporosis	88.8%	11.2%
	Contraceptive	31.1%	68.9%
	Parkinson's	17.2%	82.8%
	Osteoporosis	32.6%	67.4%

of the considerations with eligible correlations represent the same MRPs, either BO-MRP, RR-MRP or PE-MRP. Only one eligible consideration (O2) loaded on more than one component (i.e., loaded on two MRPs), and only two eligible considerations (C5 and O13) correlated with considerations of another MRP.

#### MRP rating and ranking score

The MRP rating score percentages in [Table 5](#) suggest that all three moral reasoning perspectives play a role in pharmacists' reasoning when handling the three drug shortages. The BO-MRP rating score percentage is the lowest in each drug shortage scenario (28.9%, 23.2% and 24.4% for the Contraceptive, Parkinson's the Osteoporosis scenarios, respectively), and the PE-MRP rating score percentage is the highest (39.0%, 44.4% and 45.3%, respectively). The MRP ranking score percentages demonstrate that the PE-MRP is even more dominant in all three scenarios (60.2%, 72.1% and 68.6%, for Contraceptive, Parkinson's and Osteoporosis scenarios, respectively). The difference between the BO-MRP and the PE-MRP is larger in the Parkinson's scenario than in other two scenarios. The same trend was found when the MRP rating and ranking scores were corrected for the considerations that matched the criteria of eligibility and when the considerations that loaded with another MRP (O2 and C5) were given the scores for that MRP (see the Methods section for the criteria of eligibility and [Table 4](#) for the eligible considerations used for this correction. See [Table 6](#) in [Appendix C](#) for the scores based on these corrections.)

#### Discussion

This study indicates that professional ethics (PE-MRP) is the dominant moral reasoning perspective for Dutch community pharmacists in the three presented drug shortages. The business orientation perspective is the least important perspective but was more important in

**Table 4**  
PCA component correlations of considerations in the three drug shortage scenarios.

Consideration <sup>a</sup>	PCA components			MRP <sup>b</sup>	
	1	2	3		
P8	That the patient may go to another pharmacy if I do not solve this problem	<u>0.722</u> <sup>c</sup>	0.019	0.019	BO
O11	That the extra time I spend searching for an alternative will not be reimbursed	<u>0.716</u>	0.039	-0.055	BO
O1	That the patient may go to another pharmacy if I do not solve this problem	<u>0.715</u>	0.074	0.050	BO
P13	That the extra time I spend searching for an alternative is not reimbursed	<u>0.682</u>	0.053	-0.054	BO
O6	Whether the patient has read about the medicine on the Internet	<u>0.640</u>	0.092	0.049	M <sup>d</sup>
O9	That when I receive a prescription, I always want to deliver the medicine because I am paid per prescription-line	<u>0.610</u>	0.166	-0.069	BO
O2	That I receive a complaint from the Community Pharmacists Disputes Committee	<u>0.591</u>	<u>0.366</u>	0.112	RR
P12	That the neurologist recognizes my pharmaceutical expertise with Parkinson's	<u>0.522</u>	0.086	0.235	BO
P6	That the treating neurologist is a good friend of mine	<u>0.454</u>	-0.154	0.122	M
P3	That this patient is a regular customer who takes many medications	<u>0.440</u>	0.106	0.119	BO
C8	Whether the patient's neighbor comes to the pharmacy where I work	<u>0.423</u>	0.001	0.064	M
C6	The number of patients for whom I may have to import a foreign oral contraceptive	<u>0.382</u>	0.267	0.010	BO
C11	Whether pharmacists in the vicinity of my pharmacy import this oral contraceptive	<u>0.375</u>	0.176	-0.026	BO
C13	The relative price of imported ethinylestradiol/levonorgestrel	0.298	0.234	-0.169	BO
O3	That weekly administration is preferable to daily administration for ease of use	0.217	0.155	0.183	PE
O5	Whether not using alendronic acid for a few weeks is a problem	0.155	-0.021	0.062	PE
P11	Whether the Health and Youth Care Inspectorate consents to the import of levodopa/carbidopa 125 mg tablets	-0.007	<u>0.799</u>	-0.024	RR
O8	Whether the Health and Youth Care Inspectorate consents to the import of alendronic acid 70 mg	0.112	<u>0.731</u>	0.025	RR
C4	Whether the Health and Youth Care Inspectorate consents to the import of this oral contraceptive	0.012	<u>0.710</u>	0.030	RR
C7	That I do not deviate from professional guidelines	-0.049	<u>0.506</u>	0.170	RR
O7	That I have a valid prescription if I were to substitute	0.195	<u>0.494</u>	0.127	RR
P2	That I adhere to the contract with the health insurer	0.295	0.432	0.048	RR
O13	Whether the health insurer will reimburse the/an alternative	0.268	0.418	-0.078	BO
C5	Whether the patient is willing to pay the extra cost of an imported oral contraceptive	0.129	<u>0.409</u>	-0.103	BO
O4	That I do not deviate from the Fracture Prevention Guideline of The Dutch College of General Practitioners	0.070	0.401	0.242	RR
C9	Whether I run the risk of a complaint from a disciplinary court for healthcare	0.399	0.400	0.142	RR
P4	That in the case of Parkinson's medication I never deviate from the KNMP Drug Substitution Guideline	0.111	0.347	0.332	RR
C1	That I adhere to the advice regarding this shortage on the Farmanco website	-0.046	0.344	0.095	RR
C12	The expected duration for which the patient cannot use ethinylestradiol/levonorgestrel 0.03/0.150 mg tablets	0.174	0.193	-0.015	PE
P5	That Parkinson's can worsen when the patient receives alternative treatment	0.043	0.053	<u>0.615</u>	PE
O12	That the patient worries that he will break a bone again	0.197	0.037	<u>0.582</u>	PE
P7	That I can trust the quality of imported levodopa/carbidopa 125 mg tablets	-0.002	0.147	<u>0.564</u>	PE
P9	Whether I can do something for this patient with my pharmaceutical expertise	0.055	-0.152	<u>0.535</u>	PE
C3	That every patient has equal access to this oral contraceptive	-0.003	0.143	<u>0.533</u>	PE
C10	Whether I can answer the care question of this patient with my pharmaceutical expertise	-0.037	-0.018	<u>0.464</u>	PE
O10	Whether there is evidence that alternative bisphosphonates are equally effective	0.118	0.168	<u>0.461</u>	PE
C2	That the patient may suffer from menstrual pain without contraception	0.041	-0.111	<u>0.383</u>	PE
P10	That I adhere to the advice/prescription of the treating prescriber	0.024	0.283	0.318	RR
P1	That every patient has equal access to levodopa/carbidopa 125 mg	0.004	0.187	0.244	PE

<sup>a</sup> Considerations: C (1–13) = Considerations of Contraception drug shortage scenario; P (1–13) = Considerations of Parkinson's drug shortage scenario; O (1–13) = Considerations of osteoporosis drug shortage scenario.

<sup>b</sup> Moral reasoning perspectives (MRPs): BO = Business orientation MRP; RR = Rules and regulations MRP; PE = Professional ethics MRP.

<sup>c</sup> Underlined component correlations are eligible values (i.e. values are  $\geq 0.35$  or the difference between the correlations is  $> 0.2$  if a statement loaded highly on more than one component).

<sup>d</sup> M = Meaningless consideration.

pharmacists' reasoning in the Contraceptive and Osteoporosis scenarios than in the Parkinson's scenario. This result is also reflected in how pharmacists handle the three drug shortages. Pharmacists prefer to take responsibility for solving a drug shortage problem (by, for example, proposing alternatives to prescribers and patients or by importing drugs) instead of leaving the patient or physician to solve the drug shortage problem.

That pharmacists in this study reasoned mostly through PE-MRP considerations is in line with a recent study in which pharmacists received an educational intervention aimed at improving moral reasoning competencies<sup>41</sup> but contrasts with earlier studies in which community pharmacists predominantly had very low post-conventional MRP scores<sup>23,38,52</sup> and studies that suggested that pharmacists were more influenced by a rules and regulation or legal perspective.<sup>35,36,53</sup> This difference in moral reasoning perspective may be rooted in (national) pharmacists' professional guidance (e.g., education, policy) and in the professional culture in each country (e.g., the role of community pharmacists).<sup>49,54–58</sup> In The Netherlands professional ethics entails that pharmacists are professionally autonomous in providing the best pharmaceutical care for the patient. They are responsible for dispensing medicines and have a role which is comparable with clinical pharmacists in many other countries.<sup>59,60</sup> Also, their professional relationship with

primary care physicians is often stronger than in other countries.<sup>61,62</sup> In Australia pharmacists seem to be influenced in their PE-MRP reasoning by the principle of patient rights, as a study regarding the validation of the Professional Ethics in Pharmacy (PEP) test among Australian pharmacists showed.<sup>46</sup> In The Netherlands, where the applicability of the PEP test was studied among Dutch pharmacists, pharmacists' PE-MRP was not influenced by these patient rights considerations.<sup>49</sup>

The PE considerations that were ranked by a large number of pharmacists as being the most influential in handling the shortages suggest that during drug shortages, pharmacists base their moral reflections especially on their professional values. For example, the professional value "commitment to the patient's well-being" is reflected in the frequently ranked PE-consideration P5 ("That Parkinson's can get worse when the patient receives alternative treatment"), which was ranked by 235 out of 267 pharmacists. Similarly, pharmacists base their moral reasoning on the professional values "pharmaceutical expertise" and "responsibility to society". These values are respectively reflected by the often-ranked PE considerations O5 ("Whether not using alendronic acid for a few weeks is a problem"), which was ranked by 192 pharmacists, and P1 ("That every patient has equal access to the medicine"), which was ranked by 174 pharmacists.

When dealing with the Parkinson's scenario, pharmacists ranked PE-

Table 5

MRP rating and MRP ranking score percentages of Dutch community pharmacists (N = 267) for three moral reasoning perspectives in three drug shortage scenarios.

Considerations <sup>b</sup>	MRPs <sup>a</sup> in the Contraceptive scenario			MRPs <sup>a</sup> in the Parkinson's scenario			MRPs <sup>a</sup> in the Osteoporosis scenario		
	BO	RR	PE	BO	RR	PE	BO	RR	PE
	C5, C6, C11, C13	C1, C4, C7, C9	C2, C3, C10, C12	P3, P8, P12, P13	P2, P4, P10, P11	P1, P5, P7, P9	O1, O9, O11, O13	O2, O4, O7, O8	O3, O5, O10, O12
MRP rating score <sup>c</sup> percentage	28.9%	32.1%	39.0%	23.2%	32.4%	44.4%	24.4%	30.3%	45.3%
MRP ranking score <sup>d,e</sup> percentage	15.3%	24.4%	60.2%	6.5%	21.3%	72.1%	14.1%	16.9%	68.6%

<sup>a</sup> Moral reasoning perspectives (MRPs): BO = Business orientation MRP; RR = Rules and regulations MRP; PE = Professional ethics MRP.

<sup>b</sup> Considerations: C (1–13) = Considerations of Contraception drug shortage scenario; P (1–13) = Considerations of Parkinson's drug shortage scenario; O (1–13) = Considerations of Osteoporosis drug shortage scenario.

<sup>c</sup> The MRP rating score percentage for each MRP is based on the rating data for four considerations that represent each perspective.

<sup>d</sup> The MRP ranking score percentage for each MRP is based on the ranking data and only for the ranked considerations of each perspective.

<sup>e</sup> The MRP ranking score percentages for the three MRPs in each drug shortage scenario do not add up to 100% because seven respondents ranked one meaningless consideration (0 points); for these participants, the three MRP ranking scores for each scenario do not reach a total of 10 points.

considerations more frequently than in the other drug shortage scenarios. This difference is not surprising as we purposely selected three drug shortages with potentially different impacts (i.e., perceived relevance) on patients' health outcomes (Table 2). We envisaged that pharmacists' intended actions and moral reasoning may be dependent on the scenario. A patient with Parkinson's disease is more likely to experience serious health complications from switching drugs, which may explain why professional ethics considerations were most prominent and why more pharmacists intended to import a drug that was not originally authorized for the Dutch market in this scenario than in the other two.

Further, when the pharmacists reason from a BO-MRP in these drug shortage scenarios, it was mainly because they perceived the following considerations to be of importance in the handling of these shortages: (1) a patient's willingness to pay the extra cost for the imported medicine (BO-consideration C5: "Whether the patient is willing to pay the extra costs of an imported oral contraceptive," which was ranked by 101 pharmacists) or (2) whether the health insurer would reimburse an alternative (BO-consideration O13: "Whether the health insurer will reimburse the/an alternative," which was ranked by 119 pharmacists). The former consideration was ranked in the Contraceptive scenario, the latter, in the Osteoporosis scenario. In the Netherlands, contraceptives are not reimbursed for women who are above 20 years. Although more pharmacists were inclined to import the contraceptive (Table 3, intended action option 5), pharmacists may have reasoned that this would only make sense when women are willing to pay the extra costs. At the time of the contraceptive shortage, the relative price of the imported contraceptive was higher than the listed price in the Netherlands. Pharmacies would incur an economic burden as the higher price of the imported medicine would not be reimbursed.<sup>20</sup> The large number of contraceptive users may also have influenced the reasoning of some pharmacists. The frequently ranked BO-consideration C5 can be better understood in this context. For the osteoporosis medicine (Table 3, intended action option 5), alternatives were available in the Netherlands, so importing was not necessary for most of the patients. However, these alternatives were either less practical (e.g., daily doses of 10 mg alendronic acid instead of 70 mg once a week) or more expensive (e.g., combining alendronic acid with vitamin D). Besides, from a pharmacotherapeutic perspective, a patient may experience no negative health effects from temporary ceasing to take a bisphosphonate such as alendronic acid. Nevertheless, the pharmacist would have to explain these options to the patient. If the pharmacist and the patient decide together that importing the 70 mg alendronic acid is the most appropriate decision, the pharmacist or the patient may be impacted economically. In the Netherlands, every patient is compulsorily insured for their (pharmaceutical) health care. The insurer would either have to pay for the imported drugs, which would generally be more expensive,

or patients would have to pay for the imported drug themselves. Of course a BO-MRP does not imply that the pharmacist who reasons from that perspective lacks patient-centeredness completely. When pharmacists rank considerations about 'patients' ability or willingness to pay for the alternative medicine' as very influential in handling a drug shortage, they might reason from the perspective that the patient cannot afford a drug, but might also reason from the perspective of their own business interests because this can imply that they won't get paid.

Lastly, pharmacists' reasoning with respect to rules and regulations mainly concerned their adherence to drug shortage advice issued by the Royal Dutch Pharmacists Association, KNMP (RR-consideration C1: "That I adhere to the advice regarding this shortage on the Farmanco website," which was ranked by 133 pharmacists). This consideration can be explained by the Dutch drug shortage problem, which has increased substantially over the last 10 years. Between 2008 and 2018, new cases of drug shortages (mainly temporary shortages) increased from 190 medicines to 769, and the number of shortages nearly doubled to 1500 shortages in 2019.<sup>63</sup> Pharmacists are professionally supported by their professional organization, which runs a website to provide advice on the expected duration of shortages and potential solutions. This information may save time and help pharmacists choose the optimal solution for an individual patient.

Overall, pharmacists' moral reasoning perspectives regarding the three drug shortages suggest that Dutch pharmacists are particularly challenged in their PE-MRP when an alternative treatment is either expensive and not covered by the health insurer or when they perceive the drug shortage's impact on a patient's health outcome as low to medium (Table 2). In these cases, a business orientation reasoning may become more prominent.

### Strengths and limitations

Because three methods to recruit community pharmacists to complete this study were used, it is expected that all community pharmacists (N ≈ 2900) in the Netherlands could have received at least one invitation. However, we are aware that many pharmacists receive large amounts of emails and newsletters every day and probably a significant proportion of the invited pharmacists might not have actually read the invitation. We achieved a response of 10%, which is reasonable for this type of study. The respondents were representative of all pharmacists working in Dutch community pharmacy except for the percentage of primary responsible pharmacists. Their relatively higher percentage may be due to two reasons: their end responsibility for drug shortage problems and thereto related decisions, and a lower number of locum pharmacists since 2017. Furthermore, it might be that pharmacists with a more strongly developed sense of professional ethics may have been more likely to respond.

Another strength of this study is that we used three scenarios that were very likely to be familiar to all respondents. Moreover, handling options and moral considerations were formulated with the aid of a panel of practicing pharmacists who share the same professional values, practice and language as the participants.<sup>49</sup> The validity of the survey was confirmed by the PCA. The three scenarios were also intentionally chosen for the perceived differences in their potential impact (i.e., perceived relevance) on patients' health outcomes. However, with these three drug shortages we have not captured all drug shortages and thereto related potential handling options. We therefore cannot generalize pharmacists' MRPs to all sorts of drug shortages.

Insights into moral reasoning can help individual pharmacists to reflect on their motives for handling drug shortages and can also be used for pre- and postgraduate education on professional ethics development. Since drug shortages are still increasing and likely to remain present in the coming years,<sup>6</sup> pharmacists must prepare themselves and develop their professional ethics MRP to professionally act in situations of drug shortages. This ability may improve patient care and protect pharmacists from moral distress. In order to develop pharmacists' professional ethics MRP more attention should be given to the reflection on and handling of moral dilemmas both in pre- and postgraduate education. The technique of moral case deliberation may be suitable for this.<sup>64,65</sup>

## Conclusion

We conclude that pharmacists do consider responsible pharmaceutical care for patients in drug shortage situations. However, this professional ethics moral reasoning perspective can be overruled by a business orientation perspective when the drug shortage may be perceived to have a lower impact on patient outcomes and when alternative drugs or therapy are expensive.

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## CRedit authorship contribution statement

**M. Kruijtbosch:** Writing - original draft, Conceptualization, Methodology, Investigation, Formal analysis, Validation, Visualization, Data curation, Writing - review & editing, Project administration, Funding. **A. Floor-Schreuderling:** Conceptualization, Methodology, Validation, Writing - review & editing, Project administration, Funding. **E. van Leeuwen:** Conceptualization, Writing - review & editing. **W. Göttgens-Jansen:** Conceptualization. **M.L. Bouvy:** Conceptualization, Methodology, Validation, Writing - review & editing, Supervision, Project administration, Funding.

## Declaration of competing interest

None.

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## Appendix A. Supplementary data

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