JPWA
The Federation of Japan Pharmaceutical Wholesaler Associations

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医療用医薬品の流通改善に関する懇談会の新提言等の解説

(一社)日本医薬品卸売業連合会

I. 経緯

1983年3月に厚生省により「医療用医薬品流通近代化協議会」(以下、「流近協」という)が設置され、取引当事者間の文書契約促進のためモデル契約書の策定や、「医療用医薬品の流通近代化と薬価について」の取りまとめを行い、行政や取引当事者の取組を要請した。その後、公正取引委員会が「流通・取引慣行に関する独占禁止法上の指針」を公表し、各取引当事者による流通改善への取組が進められた。それらの取組により、値引補償の廃止、薬価差の縮小、モデル契約の推進等、一定の成果が見られたが、未妥結・仮納入や総価山買い、過度なリベート等が未解決の問題として残った。

2004年6月には流近協の取組を引き継ぐ形で厚生労働省医政局長の私的懇談会として「医療用医薬品の流通改善に関する懇談会」(以下、「流改懇」という)が設置され、その後の医薬分業の進展、卸売事業者の再編・統合、IT化の進展等を踏まえた流通慣行の現状分析と流通改善方策の検討を行った。

2007年9月には流改懇より「医療用医薬品の流通改善について(緊急提言)」(以下「緊急提言」という)が発出され、一次売差マイナス等の改善、長期にわたる未妥結・仮納入の改善、総価契約の改善の三点を取引当事者が留意すべき事項として取りまとめ、改善に向けた取組を要請した。

2012年度からは更なる課題解決に向けた取組として、流改懇の下にワーキングチームを設置し、取引当事者間での取引の現状及び問題点等について、より具体的な議論、調整を行い、改善に向けた取組を行ってきた。

2015年9月には、成長戦略に資する創薬に係るイノベーションの推進、後発医薬品の急速な伸長やいわゆる「未妥結減算制度」の導入など、医療用医薬品の流通を取り巻く環境が大きな転換期を迎えていることを踏まえ、緊急提言に加え、今後10年先を見据えた流通改善を促進するため、流改懇より「医療用医薬品の流通改善の促進について(提言)」(以下、「新提言」という)が発出され、商習慣の改善に向けた取組を取引当事者へ要請した。

II. 緊急提言・新提言の内容と課題当事者

2007 年に発出された緊急提言ならびに 2012 年に発出された新提言の内容をまとめ、またそれらに関係するであろう課題当事者を整理した。緊急提言における内容は「緊」、新提言における内容は「新」と記載する。

1. 市場変化や社会的要請に対応する流通のあり方の検討

	内容	課題当事者	参照
a	個々の医薬品毎に流通コストが賄える商習慣の醸成 (※1)	製薬企業、医薬品卸	新
b	通常の配送回数を超える急配業務を減らすための適正な在庫管理	医療機関・保険薬局、医薬品卸	新
c	個々の医薬品の価値及び費用負担の公平性を無視して利益のみを追求する価格交渉のアウトソーシング等、長期未妥結の原因となりえる行為の自粛	医療機関・保険薬局	新
d	基礎的医薬品の扱いについての議論(※2)	行政、製薬企業	新

(※1) 個々の医薬品に係わる流通コストを支払わない製薬企業のうち、限度を超えていると判断されるケースへの対応を行う。

(※2) 2016 年 4 月の薬価改正における基礎的医薬品の薬価維持ルールの導入により、実施に至った。

2. 一次売差マイナス、割戻し・アローアンスの拡大傾向の改善

	内容	課題当事者	参照
a	医療機関・保険薬局の信頼を得るための川上取引における透明性の一層の確保(※3)	製薬企業、医薬品卸	緊
b	一次売差マイナスの常態化解消を目的とした割戻し・アローアンスの一次仕切価への反映(※4)	製薬企業、医薬品卸	緊

(※3) 正味仕切価の早期把握のために、薬価内示後に割戻し・アローアンスの基準の早期提示および薬価公示後に一次仕切価の早期提示を行う(製薬企業、医薬品卸)。

(※4) 取引当事者により、市場環境の変化を踏まえた協議にもとづき仕切価水準の設定を行い、期末におけるアローアンスの見直しや仕切価修正的なアローアンスはあらかじめ仕切価や割戻しへ反映させる(製薬企業、医薬品卸)。

3. 後発医薬品の使用促進を踏まえた流通のあり方の検討

	内容	課題当事者	参照
a	2017 年度央までに流通の混乱を避けるための措置の策定(※5)	行政	新
b	現行の規格揃えルールの見直しの検討(医療現場において使用頻度の少ない非汎用規格について他メーカーと規格を補完できる規格揃えを認める等)	行政	新
c	更なる一般名処方の推進	行政、医療機関	新
d	汎用医薬品リストの作成と共有化	医療機関・保険薬局	新
e	効率的な在庫管理・配送を行う供給体制の構築	医薬品卸、製薬企業	新
f	変動情報を含んだ新バーコード表示必須化に向けた工程表の作成	行政、製薬企業、医薬品卸、医療機関・保険薬局	新
g	金額ベースの割戻し・アローアンス体系の検討	製薬企業、医薬品卸	新
h	医療費削減効果の明確化	行政、医療機関・保険薬局	新

(※5) 2017 年央までの後発品数量シェア目標は 70%に設定されており(現在は 2020 年度までにさらに 80%の目標値が追加されている)、同一成分複数銘柄の存在による後発医薬品流通量の増加および在庫管理コストの急激な高騰が見込まれる。

4. 医薬品の価値に基づく単品単価交渉の更なる促進

	内容	課題当事者	参照
a	単品単価取引等の適切な価格形成やコスト負担に対する流通当事者の取組への評価の在り方についての検討	医薬品卸、製薬企業、医療機関・保険薬局	新
b	持続可能な公的医療保険制度における単品単価取引の重要性・趣旨の理解、および共通認識を持った価格交渉の推進	医薬品卸、医療機関・保険薬局	緊/新
c	単品単価明細のついた取引基本契約書・覚書の締結の更なる促進	医薬品卸、医療機関・保険薬局	緊/新
d	薬価調査・改定の頻度変更には賛成しかねることへのご理解(※6)	行政	新

(※6) 全ての流通当事者が納得できる適正な市場実勢価格を形成するために十分な交渉期間の確保が必要であることからも、流改懇として薬価調査・改定の頻度変更は行うべきではないと考えている。

5.　長期未妥結・仮納入の改善

	内容	課題当事者	参照
a	妥結率と単品単価取引の状況を踏まえた未妥結減算制度の在り方についての検討(※7) ・ 行政による未妥結減算制度の導入が市場取引及び価格形成に与えた影響の評価	行政、医療機関・保険薬局、医薬品卸	新
b	購入量、配送コスト、支払い条件、包装単位の大小、信用状況等を条件とした経済合理性のある価格交渉の実施	医薬品卸、医療機関・保険薬局、製薬企業	緊/新
c	医療機関・保険薬局に対する価格提示の早期化	医薬品卸	緊
d	遡及値引きの廃止	医薬品卸、医療機関・保険薬局	緊
e	会計期間に対応した時期における妥結の推進	医薬品卸、医療機関・保険薬局	緊

(※7) 未妥結減算制度が導入されたことにより妥結率は大幅改善しているが、早期に妥結させることのみを今以上に強制的に進めると、実勢価格を適切に把握できなくなるばかりか、部分妥結や総価取引を助長し、流通改善に逆行することになり得るため、妥結率と単品単価取引をセットで慎重に検討する必要がある。また未妥結減算制度はあくまで経過的なものであり、将来的には廃止されるべきと流改懇では考えている。

III. 今後の進め方

我が国の強靭な流通体制を将来にわたり持続可能なものとし、安定的に医薬品供給を行っていくために、公的医療保険制度の担い手である課題当事者間で連携し、流改懇ならびにそのワーキングチームを通じた上記の内容の課題への真摯な取組と、中医協等における議論が行われるべきである。

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Explanation of New Proposal of the Council for the Improvement of Commercial Transaction Practices of Ethical Drugs (Ryukaikon)

September 7, 2016

I. Backgrounds

The Council for the Modernization of the Commercial Transaction Practices of Ethical Drugs (Ryukinkyo) was established in March 1983 by the Ministry of Health and Welfare and was asked to formulate a model contract for promoting written contracts between transacting parties, to compile a report on "The Modernization of the Commercial Transaction Practices of Ethical Drugs and *Yakka* (NHI Drug Prices)," and to request that efforts be made by the government and transacting parties. Later, the Japan Fair Trade Commission published the Guidelines concerning Distribution Systems and Business Practices under the Antimonopoly Act, and promoted efforts by the transacting parties to improve commercial transaction practices. These efforts achieved certain results, such as the abolition of price reduction guarantees, reductions in *yakka* variances, and the promotion of model contracts, but several unsolved problems remained, including deliveries without price agreements, bundled purchases, and excessive rebates.

In June 2004, the Council for the Improvement of Commercial Transaction Practices of Ethical Drugs (Ryukaikon) was established as a private council by the head of the Ministry of Health, Labour and Welfare's Health Policy Bureau as a continuation of efforts made by the Ryukinkyo. The council analyzed the present state of commercial transaction practices and examined policies to improve such, given the progress of the separation of dispensing and prescribing functions, the restructuring and consolidation of wholesalers, and developments in IT.

In September 2007, an Urgent Proposal regarding the Improvement of Commercial Transaction Practices of Ethical Drugs (hereafter, the "Urgent Proposal") was issued by the Ryukaikon. It compiled three issues that transacting parties needed to be aware of and asked that efforts be made to achieve improvements in those areas, specifically of the expansionary trend in negative margins between the customer purchase price (CPP) and the wholesaler purchase price (WPP), rebates, and allowances; continual delivery without price agreements; and bundled transactions.

In 2012, the Ryukaikon established the working group to work on further efforts aimed at solving the problems. The group members engaged in detailed deliberations, made adjustments, and worked toward improvements in the current status and problems involving transactions between transacting parties.

In September 2015, the environment surrounding the commercial transaction practices of ethical drugs was about to enter a major transition period with the promotion of innovations related to drug creation that contributes to growth strategies, the rapid growth of generic drugs, and the scheme of medical reimbursement fee cuts for low rates on price agreements. Given this, in addition to its Urgent Proposal, the Ryukaikon issued a Proposal regarding the Improvement of Commercial Transaction Practices of Ethical Drugs (hereafter, the "New Proposal") to promote improvements in the commercial transaction practices of ethical drugs over the next 10 years, in which it asked transacting parties to make efforts aimed at improving commercial practices.

II. Content of the Urgent Proposal and New Proposal and the Relevant Parties

This section presents content from the Urgent Proposal issued in 2007 and the New Proposal issued in 2012, and identifies the parties that have a relevant role in each. Items from the Urgent Proposal are marked "U" while those from the New Proposal are marked "N."

1. Examination of the Concept of Commercial Transaction Practices That Meet Market Changes and Social Needs

	Description	Relevant Parties	Note
a	Create commercial practices in which the transaction practice costs of each individual drug[1] are covered	Drug manufacturers, *Oroshi* (pharmaceutical wholesalers)	N
b	Engage in appropriate inventory management to reduce emergency delivery services that exceed the number of ordinary deliveries	Medical institutions, Pharmacies, *Oroshi*	N
c	Voluntarily regulate behavior that might lead to continual delivery without price agreements, such as outsourcing price negotiations in pursuit of profits while ignoring the value of individual drugs and the fairness of cost burden	Medical institutions, Pharmacies	N
d	Discuss basic drug handling[2]	Government, Drug manufacturers	N

1: Those drug manufacturers that do not pay distribution costs related to individual drugs shall take response measures in cases in which it is deemed that the limit has been exceeded.

2: Implementation was achieved by introducing *yakka* (NHI price) maintenance rules for basic drugs in the NHI price revisions in April 2016.

2. Improvement of the Expansionary Trends in Negative Margins Between CPP and WPP, Rebates, and Allowances

	Description	Relevant Parties	Note
a	Ensure further transparency in upstream transactions to earn the trust of medical institutions and health insurance pharmacies[3]	Drug manufacturers, *Oroshi*	U
b	Reflect rebates and allowances in the wholesaler purchase price (WPP)[4] to offset the normalization of negative margins between CPP minus WPP	Drug manufacturers, *Oroshi*	U

3: To ascertain the net WPP early, engage in the early disclosure of rebate and allowance standards after *yakka* (NHI price) is disclosed internally and engage in the early disclosure of the WPP after *yakka* is disclosed publicly (drug manufacturers, *oroshi*).

4: The transacting parties set the WPP based on the mutual agreement of both parties given changes in the market environment, and end-of-term revisions to allowances and WPP corrective allowances are first reflected in the WPP and rebates (drug manufacturers, *oroshi*).

3. Examination of the Concept of Commercial Transaction Practices to Promote the Use of Generic Drugs

	Description	Relevant Parties	Note
a	Formulate measures to avoid confusion in commercial distribution practices by the middle of FY2017[5]	Government	N
b	Consider revising current formulation rules (e.g., recognize formulation settings that can supplement with other makers on non-general purpose formulations that are only infrequently used in medical settings)	Government	N
c	Further promote generic name prescriptions	Government, Medical institutions	N
d	Create and share lists of general purpose drugs	Medical institutions, Pharmacies	N
e.	Create supply systems for achieving efficient inventory management and delivery	*Oroshi*, Drug manufacturers	N
f	Create procedure tables aimed at new barcode labeling requirements that include information on changes by pharmaceutical unit/package	Government, Drug manufacturers, *Oroshi*, Medical institutions, Pharmacies	N
g	Investigate the system of monetary-based rebates and allowances	Drug manufacturers, *Oroshi*	N
h	Clarify the effects of healthcare cost cuts	Government, Medical institutions, Pharmacies	N

5: The target share of generic drugs by the middle of 2017 is set at 70% (the target is now higher, at 80% by FY 2020), and due to the presence of multiple brands with the same ingredients, there is expected to be an increase in the distribution volumes of generic drugs and a dramatic increase in inventory management costs.

4. Further Promote Unit Price-based Negotiations Based on Drug Values

	Description	Relevant Parties	Note
a	Examine the concept to evaluate the efforts of transaction parties with regard to appropriate price setting, such as unit price-based transactions, and cost burdens	*Oroshi*, Drug manufacturers, Medical institutions, pharmacies	N
b	Understand the importance and overview of unit price-based transactions in a sustainable public health insurance system and promote price negotiations based on that common understanding	*Oroshi*, Medical institutions, Pharmacies	U/N
c	Further promote the conclusion of basic trade agreements and memorandum of agreement with details about unit prices	*Oroshi*, Medical institutions, Pharmacies	U/N
d	Promote understanding that there must not be changes in the frequency of *yakka* surveys and revisions[6]	Government	N

6: Since there must be adequate time for negotiating the establishment of appropriate CPP that will satisfy all transaction parties Ryukaikon does not feel that changes in the frequency of *yakka* surveys and revisions must be made.

5. Resolution of Continual Delivery without Price Agreements

	Description	Relevant Parties	Note
a	Examine the concept of the scheme of medical reimbursement fee cuts for low rates on price agreements based on price agreement rates and the status of unit price-based transactions[7] • Evaluate the impacts of the government's introduction of the scheme of medical reimbursement fee cuts for low rates on price agreements on market transactions and price setting	Government, Medical institutions, Pharmacies, *Oroshi*	N
b	Conduct price negotiations that are economically rational, based on conditions such as purchase volume, delivery cost, payment terms, package unit size, and creditworthiness	*Oroshi*, Medical institutions, Pharmacies, Drug manufacturers	U/N
c	Present prices earlier to medical institutions and health insurance pharmacies	*Oroshi*	U
d	Eliminate retroactive discounts	*Oroshi*, Medical institutions, Pharmacies	U
e.	Promote settlements at times that align with accounting periods	*Oroshi*, Medical institutions, Pharmacies	U

7: Price agreement rates have been vastly improved with the introduction of the scheme of medical reimbursement fee cuts for low rates on price agreements, but if the importance is placed only on the conclusion of agreements at an early stage, it may become impossible to appropriately ascertain

the customer purchase price, could extend partial price agreements or bundled transactions, or result in backsliding on improvements in the commercial transaction practices of ethical drugs. Thus, price agreement rates and unit price-based transactions must be carefully examined as a set. Also, the Ryukaikon expects that the scheme of medical reimbursement fee cuts for low rates on price agreements is provisional and it will have to be abolished in the future.

III. Next Steps

To make Japan's strong distribution system sustainable and capable of ensuring a stable drug supply into the future, it is important that partnerships be developed between the relevant parties responsible for delivering the services of the public health insurance system. Deliberate efforts to address issues on the topics outlined above must be made through Ryukaikon and its working group, and these issues must be deliberated by the Central Social Insurance Medical Council (Chuikyo).

医療用医薬品の流通取引に関する英単語について ＜参考英訳表＞

English Descriptions about Commercial Transaction of Ethical Drugs in Japan
- Reference English Translation Sheet -

#	日本語	English	Remarks
1	医療用医薬品	ethical drug	Medicine/medical drug that must be prescribed or whose use can only be permitted by a medical doctor
2	規格 (スペック)	specification	Specifications as defined by various authorities, vary by country; e.g. JP, USP, EP
3	規格 (剤形)	formulation	Formulations as designed by a pharmaceutical company; e.g. 2mg/l I.V.
4	特許品	patented drug	Medicine/medical drug which is discovered, developed, and marketed by a pharmaceutical company
5	後発品	generic drug	Medicine/medical drug intended to be interchangeable with an innovator product. In Japan, each generic drug has its own brand name assigned to it by the pharmaceutical company that has received marketing approval (MA) regardless of the generic name/active pharmaceutical ingredient (API)
6	長期収載品	long-listed drug	Medicine/medical drug that goes off-patent and for which there exists a generic drug
7	厚生労働省	Ministry of Health, Labour and Welfare (MHLW)	Government agency which establishes, implements, and revises medical/nursing-care reimbursement fee allocation policies, including the reimbursement of medicines through the Central Social Insurance Medical Council (Chuikyo)
8	中央社会保険医療協議会（中医協）	Central Social Insurance Medical Council (Chuikyo)	An advisory panel to the minister of Health, Labour and Welfare (MHLW), consisting of representatives from the MHLW, the pharmaceutical industry, associations of medical institutions and health insurance pharmacies, and the Oroshi association (JPWA). One of Chuikyo's role is to discuss and determine a medical fee division
9	保険医療機関	health insurance medical institution	Hospital or clinic that can prescribe or dispense medicines
10	保険薬局	health insurance pharmacy	Pharmacy where a pharmacist receives prescriptions and dispenses medicines
11	医薬品卸	Oroshi	Pharmaceutical wholesalers. They play a role in supporting revisions to the reimbursement price of ethical drugs (Yakka) and handle deliveries of medicines to and returns from medical institutions and health insurance pharmacies, as well as inventory/credit management, price negotiations, and demand-information gathering with these institutions.
12	国民皆保険制度	National Health Insurance System	Public health insurance system that covers all Japanese citizens
13	薬価	Yakka / NHI Price	Reimbursement price for ethical drugs / National Health Insurance Price
14	薬価基準制度	Yakka Scheme / NHI Price Scheme	Scheme for listing ethical drugs on the NHI drug price list and revising NHI prices on the basis of the Yakka Survey
15	薬価改定	Yakka Revision / NHI Price Revision	Revision of NHI prices, implemented every two years
16	薬価調査	Yakka Survey / NHI Price Survey	Only method for revision of each NHI drug price on the basis of reports from Oroshi, medical institutions and health insurance pharmacies about actual ex-wholesaler prices of each ethical drug
17	銘柄別収載	listing by brand	Approach for listing ethical drugs on the NHI drug price list, introduced in 1978
18	銘柄別薬価	drug pricing by brand name	Pricing system of the NHI price scheme, introduced in 1978
19	診療報酬	medical fee	Remuneration for medical treatment in terms of drug prices and dispensing, revised every two years
20	経済財政運営と改革の基本方針(骨太の方針)	Basic Policy on Economic and Fiscal Management and Reform (Honebuto Policy)	A set of policy guidelines used by the Liberal Democratic Party, starting in 2001 and was not used to describe the policies of the Democratic Party of Japan, which was in power from 2010 to 2012. The Honebuto Policy 2015 approved by the Cabinet of Japan on June 30, 2015, aims to increase generic drugs' quantitative share of off-patent prescription drugs to greater than 70% by mid-2017 and to greater than 80% as soon as possible between FY2018
21	流通改善	Improvement of Commercial Transaction Practice of Ethical Drugs	
22	医療用医薬品の流通改善に関する懇談会	Council for the Improvement of Commercial Transaction Practice of Ethical Drugs (Ryukaikon)	Council under the Chuikyo, consisting of representatives from the MHLW, pharmaceutical industry, associations of medical institutions and health insurance pharmacies, and the Oroshi association (JPWA)
23	緊急提言	Urgent Proposal	Proposal issued by Ryukaikon in September 2007
24	新提言	New Proposal	Proposal issued by Ryukaikon in September 2015
25	仕切価	wholesaler purchase price (WPP)	The price at which Oroshi purchase medicines from pharmaceutical companies, excluding any rebates or allowances paid by the pharmaceutical company. Ex-manufacturer drug price, not deducting any rebates or allowances paid by the pharmaceutical company. Similar to the average wholesale
26	割戻し/リベート	rebate	An amount paid by pharmaceutical companies to Oroshi for their distribution activities and credit management.
27	アローアンス	allowance	An amount paid by pharmaceutical companies to Oroshi for information delivery to and gathering from medical institutions and health insurance
28	正味仕切価格・最終原価	net wholesaler purchase price (net WPP)	The price at which Oroshi purchase medicines from pharmaceutical companies, including any rebates or allowances paid by the pharmaceutical
29	市場実勢価	customer purchase price (CPP)	Actual ex-wholesaler drug price
30	単品単価取引	unit price-based transaction	Actual ex-wholesaler drug price for each medicine
31	総価取引	bundled transaction	Transactions without unit pricing; interferes with the Yakka Survey and accurate Yakka Revisions
32	総価取引の改善	resolution of bundled transactions	Promotion of single-product, single-price transactions to improve the accuracy of the Yakka Survey
33	未妥結・仮納入	delivery without price agreement	Delivery of medicines without price agreement between Oroshi and medical institutions / insurance pharmacies
34	長期未妥結・仮納入の改善	resolution of continual delivery without price agreements	Promotion of the delivery of medicines after a price agreement has been reached between the Oroshi and the medical institution / health insurance pharmacy
35	一次売差マイナス	negative margin between CPP and WPP	It is basically covered by rebates and allowances
36	一次売差マイナスの改善	improvement of the expansionary trend in negative margins between CPP and WPP	
37	新薬創出・適応外薬解消等促進加算制度	NHI price maintenance scheme for the acceleration of innovative new drug development and the elimination of drug lag	Special pricing scheme introduced on a trial basis, based on the variation rate between the NHI price and the CPP
38	未妥結減算制度	The scheme of medical reimbursement fee cuts for low rate on price agreement	Scheme, in which if the rate is below 50% of all transactions between a wholesaler and a medical institution/insurance pharmacy during April-September in the year of NHI Price Revision, medical institution / insurance pharmacy has to pay penalty to the government
39	新バーコード表示	New barcode labelling on pharmaceutical products	Barcode labeling on original package units and sales package units denoting information on changes, such as the serial number or code and shelf life
40	変動情報	information on changes by pharmaceutical unit / package	Information on original package units and sales package units denoting information on changes such as serial number or code and shelf life
41	あり方	concept	Not "format"
42	取引基本契約書	basic trade agreement	A document outlining basic information about exchanges between an Oroshi and a medical institution / insurance pharmacy. In most cases, these do not contain detailed transaction terms and conditions.
43	覚書	memorandum of agreement	A document containing detailed transaction terms governing an exchange between an Oroshi and a medical institution / insurance pharmacy to facilitate their entry into a basic trade agreement
44	不動在庫	obsolete inventory	Excess inventory that does not turn over for a long period
45	頻回配送・急配/急配業務/緊急配送	frequent delivery / emergency delivery	Delivery that occurs outside of a regular delivery, generally at no charge
46	元梱包装単位	original package unit	Original package unit of drugs (e.g., a box holding several cartons, each containing individually packaged products)
47	販売包装単位	sales package unit	Minimum sales package unit of drugs

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