AMT/NEWSLETTER

Life Science

January 31, 2025

Life Science Newsletter

January 2025

弁護士 近藤 純一 / 弁護士 淺井 茉里菜 / 弁護士 横田 瑛弓

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Ⅰ. 薬機法改正に関するとりまとめの公表

2025 年 1 月 10 日、厚生科学審議会医薬品医療機器制度部会において、薬機法[1]等制度改正に関するとりまとめが公表されました。今後、厚生労働省で検討が進められたのちに、通常国会に改正案が提出される見込みです。

とりまとめの内容については、以下のとおりです。

[1] 医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律(昭和35年法律第145号)

1. 医薬品等の品質確保及び安全対策の強化

変更点	概要
製造販売業者等による品質保証責任の明確化等	責任役員の変更命令を規定
	医薬品品質保証責任者の設置等
	医薬品の製造業者による製造管理・品質管理の強化
医薬品安全管理責任者の設置その他の製造販売後安全管理	医薬品安全管理責任者の設置、医薬品リスク管理計画の作成の義務化等
	リアルワールドデータの安全対策への利活用の明確化
	医薬品、医療機器等の製品データベースへの商品コード等の登録義務化
GMP 適合性調査の見直し	リスクに応じた適合性調査の実施等
	定期適合性調査に係る基準確認証制度の拡大
輸入確認制度の合理化	行政処分を受けた企業に対する輸入禁止の例外を規定
国家検定制度の合理化	書面審査のみで医薬品等の販売を可能にする
感染症定期報告制度の見直し	定期的な報告からリスクに応じた報告制度にする
体外診断用医薬品の特性を踏まえた性能評価等の見直し	情報収集、評価、報告を義務化、承認取消しの仕組みを導入
医薬品製造管理者等の要件の見直し	医薬品製造管理者要件及び体外診断用医薬品製造管理者要件の見直し
	生物由来製品の製造管理者要件の見直し
登録認証制度の安定的な運用に向けた制度の見直し	実地調査への PMDA[2]の立ち合い、登録認証機関の業務の休廃止に関する規定を整備

主な変更点

(1)責任役員の変更命令

責任役員による違法状態改善の懈怠や責任役員主導の違法行為に対応すべく、医薬品等[3]の製造販売業者又は製造業者を対象として、責任役員が原因で薬事に関する法令違反が生じた場合等、保健衛生上の危害の発生又は拡大を防止するために特に必要な場合には、当該責任役員の変更を命ずることができる旨を規定すべきとしました。

(2)医薬品品質保証責任者の設置等

医薬品の製造管理・品質管理上の不正事案を受け、医薬品製造販売業者による医薬品製造業者に対する効果的かつ適切な管理監督機能を確保するべく、医薬品製造販売業者の責務として、製造所における製造管理や品質管理が適正かつ円滑に行われていることの定期的な確認や情報収集を薬機法上に規定することに加えて、現時点では GQP 省令[4]で規定されている医薬品品質保証責任者の設置等を薬機法上規定すべきとしました。また、医薬品品質保証責任者については、(1)の変更命令の対象としても追加すべきとしました。

(3)医薬品の製造業者による製造管理・品質管理の強化

出荷優先や利益追求の姿勢を原因とする製造管理・品質管理上の不正事案に対応すべく、製造・品質過程について

[2] 独立行政法人医薬品医療機器総合機構

[3] 医薬品、医薬部外品、化粧品、医療機器、体外診断用医薬品又は再生医療等製品をいう。

[4] 医薬品、医薬部外品、化粧品及び再生医療等製品の品質管理の基準に関する省令（平成 16 年厚生労働省令第 136 号)

規制する GMP 省令[5]に現在規定されている基準について、より直接的な製造管理・品質管理上の遵守事項として薬機法上に規定して医薬品製造業者に義務付けるべきとしました。

(4)医薬品安全管理責任者の設置、医薬品リスク管理計画の作成の義務化等

現時点では、GVP 省令[6]で規定されている医薬品安全管理責任者の設置及び医薬品リスク管理計画の作成[7]を薬機法上規定すべきとしました。また、医薬品安全管理責任者については、(1)の変更命令の対象としても追加すべきとしました。

(5)リアルワールドデータ[8]の安全対策への利活用の明確化

リアルワールドデータの有用性に鑑み、リアルワールドデータのみによる再審査や使用成績評価申請が可能であることを明確化すべきとしました。

(6)体外診断用医薬品の特性を踏まえた性能評価等の見直し

ウィルス等を検出する体外用診断用医薬品については、承認後にウィルス等の変異によって性能が左右され得ることから、承認時のみならず市販後においても性能の担保を維持すべく、製造販売業者による情報収集、評価、報告規定を設け、性能が担保されてない場合承認を取り消す等、医薬品における再評価制度と同様の仕組みを導入すべきとしました。

2. 品質の確保された医療用医薬品等の供給

変更点	概要
医療用医薬品の製造販売業者における安定供給確保に向けた体制整備	安定供給体制管理責任者を設置し、安定供給のための必要な措置を遵守事項として規定
医療用医薬品の供給不安の迅速な把握、報告徴収及び協力要請等	医療用医薬品の供給不安の迅速な把握、報告徴収及び協力要請
	限定的な状況における医療用麻薬の業者間譲渡を緩和
安定供給確保医薬品の供給確保策	安定供給確保医薬品の指定、厚生労働大臣の要請の規定、報告義務の規定等
医薬品等の供給不足時の海外代替品へのアクセス改善	優先的な承認審査等を導入
製造方法等の中リスクの変更カテゴリの追加等	製造方法等の中リスクの変更カテゴリ、年次報告の追加
	日本薬局方不適合品目について個別承認の余地の規定等
	一部製造所について認定制から登録制に変更
医療用医薬品の需給データを活用したモニタリングの実施	厚生労働大臣による電子処方箋管理サービスデータの調査等を規定

主な変更点

(1)医療用医薬品の製造販売業者における安定供給確保に向けた体制整備

医療用医薬品の安定的な供給体制の確保観点から、製造販売業者に対し、法令上の安定供給確保のための取組を

[5] 医薬品及び医薬部外品の製造管理及び品質管理の基準に関する省令(平成 16 年厚生労働省令第 179 号)

[6] 製造販売後安全管理の基準に関する省令(平成 16 年厚生労働省令第 135 号)

[7] 「医薬品リスク管理計画の策定及び公表について」(薬生薬審発 0318 第 2 号、薬生安発 0318 第 1 号、令和 4 年 3 月 18 日)参照

[8] 実臨床の環境において収集された、患者の実際の健康状態や医療情報、治療経過等の安全性・有効性の評価に活用できる電子的データのこと。

行い、安定供給体制を管理する責任者の設置を義務付けるとともに、安定供給のための必要な措置(例えば、安定供給体制確保のための手順書の作成等)を遵守事項として規定すべきであるとしました。

(2)医療用医薬品の供給不安の迅速な把握、報告徴収及び協力要請

医療用医薬品の安定供給に関して、現状では通知によって定められ、又は事実上の指導によって行われている対応について、①製造販売業者に対する供給状況報告・供給不安報告の厚生労働大臣への届出の義務化、②供給不足のおそれがある場合に製造販売業者又は卸売販売業者に対して厚生労働大臣が製造・販売等の状況の報告を求めることができる旨の規定、③供給不足のおそれがある場合に製造販売業者、卸売販売業者、医療機関又は薬局等に対して厚生労働大臣が必要な協力の要請ができる旨の規定を設けるべきとしました。

(3)安定供給確保医薬品の供給確保策

医療上必要不可欠であって汎用され、安定的供給確保の取組が強く求められる医薬品について、厚生労働大臣が安定供給確保医薬品(仮称)として指定するとともに、生産の促進その他の安定的な供給の確保のために必要な措置の要請(安定確保医薬品 A・B 相当を想定)、需給状況の把握のための製造販売業者等に対する報告徴収(安定確保医薬品 A・B・C 相当を想定)等の規定を設けるべきとしました。

(4)医薬品等の供給不足時の海外代替品へのアクセス改善

日本において、既承認の医薬品等の供給不足が生じ、医療上著しい影響が生じる場合において、外国で流通している代替品によって対応することを可能とすべく、外国流通品の優先的な承認審査、一定期間の外国語表示による包装を容認する等の特例を行うことを可能とすべきとしました。

(5)製造方法等の中リスクの変更カテゴリ、年次報告の追加

現在は承認事項の一部変更に際し、軽微なものの届出を除いては厚生労働大臣の承認が必要とされているため、製品の変更・改良に時間を要することがあります。製品の改良について欧米に遅れることなく対応する必要性から、製造方法等に係る一部変更のうち、品質に与える影響が大きくない中リスク事項に係る変更について、一定期間(40 日程度を想定)内で承認する制度を設けるべきであるとしました。また、製造方法等に係る軽微変更のうち品質に与える影響が少ないものについては、変更内容を年に 1 回厚生労働大臣に報告する仕組みを設けるべきとしました。

3. ドラッグ・ラグやドラッグ・ロス解消に向けた創薬環境・規制環境の整備

変更点	概要
小児用医薬品のドラッグ・ロス解消に向けた開発計画策定の促進	小児用医薬品開発の計画策定を努力義務として規定等
希少・重篤な疾患に対する医薬品等に係る条件付き承認の見直し	探索的試験の段階で承認を与える等
リアルワールドデータの薬事申請への利活用の明確化	医薬品等の承認申請時の添付資料の規定を一般的なものに改める
再生医療等製品の特性を踏まえた授与等の例外的許容	規格外品について一定の場合に販売等を許容
医薬品の臨床試験の実施の基準に関する見直し	GCP 省令[9]の改正等の検討

[9] 医薬品の臨床試験の実施の基準に関する省令(平成 9 年厚生省令第 28 号)

主な変更点

(1)小児用医薬品のドラッグ・ロス解消に向けた開発計画策定の促進

小児用医薬品の開発は一般に進みにくく、環境整備に取り組んできた[10]ものの、未だ十分でないことに鑑み、成人用の医薬品の承認申請者に対して、小児用医薬品開発の計画策定を努力義務として課すべきとしました。

(2)希少・重篤な疾患に対する医薬品等に係る条件付き承認の見直し

現行の条件承認付き制度[11]は、一定程度の効果が確認された探索的試験の結果に基づく場合や、検証的試験の実施途中である場合の適用を想定しており、制度創設後の承認件数が少なくなっています。そこで、重篤かつ代替する適切な治療法がない場合など、医療上の必要性が高い製品について、承認の取消し規定を設けたうえで、探索的試験の段階で、臨床的有用性が合理的に予測可能である場合に承認を可能にすることができるように見直すべきとしました。

(3)リアルワールドデータの薬事申請への利活用の明確化

臨床試験の試験成績に関する資料その他の資料に限らず、リアルワールドデータを受け付ける観点から、医薬品等の承認申請時の添付資料に関する規定は、「医薬品等の品質、有効性及び安全性に関する資料」とする等、より一般的な規定に見直すべきであるとした。

(4)医薬品の臨床試験の実施の基準に関する見直し

医療上必要性の高い医薬品の承認前における患者アクセスのニーズに対応するため、現行の拡大治験の手続(症例報告、モニタリング、有害事象報告、治験薬概要書の取扱い等)を簡素化するとともに、すでに治験届が提出されている医薬品について患者一人を対象とする場合には特に簡略な手続により拡大治験を実施できる運用を可能とすべく、GCP 省令の改正等の検討を進めるべきとしました。

GCP 適合性調査については、リスクに応じた調査実施の合理化や、SMO[12]に対する治験依頼者の監督強化を図るほか、治験に携わる従事者の負担軽減を含め治験の更なる効率化を促進すべきとしました。

4. 薬局機能・薬剤師業務のあり方の見直し及び医薬品の適正使用の推進

変更点	概要
デジタル技術を活用した薬剤師等の遠隔管理による医薬品販売	薬剤師等の遠隔管理の下での医薬品の保管及び受け渡しを可能にする
調剤業務の一部外部委託の制度化	調剤業務の一部の委託の制度化等
薬局の機能等のあり方の見直し	健康サポート薬局の認定制度の創設等
薬局機能情報提供制度の見直し	薬局機能情報提供制度の報告先の変更等
医薬品の販売区分及び販売方法の見直し	処方箋なしでの医療用医薬品の販売の原則禁止
	要指導医薬品に係るオンライン服薬指導方法の追加等
	濫用等のおそれのある医薬品の販売方法の厳格化
	一般用医薬品の分類は現行制度を維持しつつ、販売方法を指針で明確化
処方箋等の保存期間の見直し	処方箋等の保存期間を 5 年間に延長

[10] 例えば、特定用途医薬品指定制度の創設、再審査期間の延長等の対応。

[11] 医療上の必要性の高い希少・重篤な疾患に対する医薬品について検証的試験の結果を待たずに探索的な試験までの結果に基づき、薬事承認を行う制度。

[12] Site Management Organization の略、治験施設支援機関のこと。

主な変更点

(1)デジタル技術を活用した薬剤師等の遠隔管理による医薬品販売

映像及び音声によるリアルタイムのコミュニケーションツールが普及していることから、薬剤師等が常駐しない店舗においても、別の一定の店舗の薬剤師等による遠隔での管理の下、一般用医薬品を保管し、薬剤師等が相談応需可能な環境下で購入者に受け渡すことを可能にすべきとしました。

(2)調剤業務の一部外部委託の制度化

薬局薬剤師が対人業務に注力できるよう、薬局の所在地の都道府県知事等の許可により、調剤業務の一部の委託を可能とすべきとしました。

(3)処方箋なしでの医療用医薬品の販売の原則禁止

医療用医薬品については、現行の処方箋医薬品に限らず、処方箋に基づく販売が原則としたうえで、一定の条件を満たすやむを得ない場合に限り薬局において処方箋なしでの販売を認めるべきであるとしました。ただし、漢方薬・生薬についてはその特性[13]に鑑み、別途適切な対応がなされるべきであるとしました。

なお、厚生労働省はこれまでも医療用医薬品については処方箋に基づく薬剤交付を原則とし、「必要な受診勧奨」の努力義務化や一般人への広告禁止等を通知[14]で定めていましたが、2025 年 1 月 17 日、処方箋なしで販売できる医療用医薬品(非処方箋医薬品)の販売を行う、いわゆる零売薬局 3 社が、当該通知が違憲であるとして国を提訴しています。

(4)要指導医薬品に係るオンライン服薬指導方法の追加等

要指導医薬品について、オンライン服薬指導を可能としつつ、医薬品の適正使用のために必要事項等の確認について対面での実施が適切であると判断される品目については、対面指導を必要とし、オンライン服薬指導による情報提供等のみにより販売可能な対象から除外すべきとしました。

Ⅱ．2025 年度薬価改定

中央社会保険医療協議会総会は、2025 年 1 月 15 日、2025 年度の薬価改定を承認しました。過去 2 回の薬価改定では、全医薬品一律で平均乖離率の 0.625 倍(乖離率 4.375%超)を超える品目について薬価改定を行いましたが、今回の薬価改定では、改訂対象範囲をカテゴリごとに設定しました。画期性の高い新薬や後発医薬品は改訂対象範囲を狭く、一方で長期収載品は広くしメリハリの効いた設定としました。また、中間年改定としては初めて、新薬創出等加算の累積控除が実施されます。

カテゴリごとの改定対象範囲は以下のとおりです。

[13]「医薬品の販売制度に関する検討会 とりまとめ」(令和 6 年 1 月 12 日 医薬品の販売制度に関する検討会)https://www.mhlw.go.jp/content/11121000/001199663.pdf

[14]「処方箋医薬品以外の医療用医薬品の販売方法等の再周知について」(薬生発 0805 第 23 号 令和 4 年 8 月 5 日)

	新薬創出等加算対象品 (650 品目)	新薬創出等加算対象品以外の新薬 (1830 品目)	長期収載品 (1710 品目)	後発品 (8859 品目)	その他品目 (4390 品目)
改定対象範囲	平均乖離率 1 倍超 (乖離率 5.2%超)	平均乖離率 0.75 倍超 (乖離率 3.9%超)	平均乖離率 0.5 倍超 (乖離率 2.6%超)	平均乖離率 1 倍超 (乖離率 5.2%超)	平均乖離率 1 倍超 (乖離率 5.2%超)
改定対象品目数 (割合)	60 品目 (9%)	1000 品目 (55%)	1500 品目 (88%)	5860 品目 (66%)	900 品目 (20%)

1. Release of Summary Report on the Amendments to the Pharmaceuticals Act

On January 10, 2025, the Pharmaceuticals and Medical Devices System Subcommittee of the Health Science Council released a summary report on the amendments to the Pharmaceuticals Act[15] and regulatory revisions. After further review by the Ministry of Health, Labour and Welfare, a draft amendment to the Pharmaceuticals Act is expected to be submitted to the ordinary session of the Diet.

The details of the summary report are as follows:

1.1 Reinforcement of Quality Assurance and Safety Measures for Pharmaceuticals, etc.

Amendments	Outline
Clarification of responsibility to ensure quality by marketing authorization holders, etc.	Inclusion of provisions regarding an order to change responsible officers
	Appointment of Quality Assurance Manager of pharmaceuticals, etc.
	Reinforcement of manufacturing control and quality control by manufacturers of pharmaceuticals
Appointment of Safety Assurance Manager and other post-marketing safety controls	Appointment of a Safety Control Manager, and mandatory preparation of pharmaceutical risk control plans, etc.
	Clarification of the use of Real World Data for safety measures
	Mandatory registration of product codes, etc. in product databases for pharmaceuticals and medical devices, etc.
Revision of GMP compliance inspections	Implementation of risk-based compliance inspections
	Expansion of the standard confirmation certificate system for periodic compliance inspections
Streamlining of import verification system	Inclusion of provisions concerning exceptions to import bans for companies that have been subject to administrative penalties
Streamlining of National Certification System	Permission of the sale of pharmaceuticals, etc. only by documentary examination
Revision of the periodic reporting system for infectious diseases	Change from periodic reporting to a risk-based reporting system

[15] Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Act No. 145 of 1960)

Revision of performance evaluation, etc. based on the characteristics of in-vitro diagnostics	Mandatory information collection, evaluation, and reporting, and introduction of a mechanism for rescindment of marketing authorizations
Revision of the requirements for manufacturing supervisors of pharmaceuticals, etc.	Revision of the requirements for manufacturing supervisors of pharmaceuticals and manufacturing supervisors for in-vitro diagnostics
	Revision of the requirements for manufacturing supervisors of biological products
Revision of the system for stable operation of the registered certification system	Inclusion of provisions for the PMDA[16] to be present during on-site inspections and for the suspension or discontinuation of the service of registered certification bodies

Major Amendments

(1) Order to change responsible officers

In order to address failure of responsible officers to remedy illegal conditions or illegal acts initiated by responsible officers, it was decided that there should be provisions under the Pharmaceuticals Act to permit the issuance of an order to change the responsible officers of marketing authorization holders or manufacturers of pharmaceuticals, etc.[17], when it is particularly necessary to prevent the occurrence or spread of health hazards, including the violation of laws and regulations on pharmaceutical affairs by any responsible officer.

(2) Appointment of Quality Assurance Manager, etc.

In order to ensure effective and appropriate management and supervision of pharmaceutical manufacturers by marketing authorization holders of pharmaceuticals in view of the occurrence of misconduct in the manufacturing and quality control of pharmaceuticals, it was decided that the following should be expressly stipulated in the Pharmaceuticals Act: (i) marketing authorization holders of pharmaceuticals are liable to regularly confirm and collect information to ensure proper and smooth manufacturing and quality control at manufacturing facilities; and (ii) the appointment of Quality Assurance Manager of pharmaceuticals as currently required under the GQP Ordinance[18]. It was also decided that Quality Assurance Manager of marketing authorization holders should be added to the list of responsible officers subject to such orders to change as mentioned in (1) above.

(3) Reinforcement of manufacturing and quality control by manufacturers of pharmaceuticals

In order to address manufacturing and quality control-related misconduct caused by prioritization of shipments and profit-seeking, it was decided that the standards currently set forth

[16] Pharmaceuticals and Medical Devices Agency

[17] This refers to pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices, in-vitro diagnostics, or regenerative medicine products.

[18] Ministerial Ordinance on Standards for Quality Assurance for Drugs, Quasi-drugs, Cosmetics and Medical Devices (Ordinance of the Ministry of Health, Labour and Welfare No. 136 of 2004)

in the GMP Ordinance[19], which regulates manufacturing and quality processes, should be incorporated into the Pharmaceuticals Act as direct manufacturing and quality control compliance requirements that are required to be met by manufacturers of pharmaceuticals.

(4) Appointment of Safety Control Manager and mandatory preparation of pharmaceutical risk control plans, etc.

The appointment of a Safety Control Manager and the preparation of pharmaceutical risk control plans[20] are currently set forth in the GVP Ordinance[21], but it was decided that it should be prescribed in the Pharmaceuticals Act. It was also decided that Safety Control Manager should be added to the list of responsible officers subject to such orders to change as mentioned in (1) above.

(5) Clarification of the use of Real World Data[22] for safety measures

Given the usefulness of Real World Data, it was decided that it should be clarified that reexaminations and post-marketing surveillance applications can be made based solely on Real World Data.

(6) Revision of performance evaluation, etc. based on the characteristics of in-vitro diagnostics

Since the performance of in-vitro diagnostics that detect viruses can be affected by the mutation of viruses, etc. after marketing authorization, it was decided that (i) information collection, evaluation, and reporting by the marketing authorization holders should be required under law to maintain performance assurance not only at the time of marketing authorization, but also at the post-marketing stage, and (ii) a system similar to the reevaluation system for pharmaceuticals should be established to allow for possible rescindment of marketing authorizations if performance is not assured.

1.2 Supply of Quality-Assured Ethical drugs, etc.

Amendments	Outline
Establishment of a system to ensure stable supply by marketing authorization holders of ethical drugs	Appointment of Stable Supply System Manager and inclusion of provisions regarding necessary measures for stable supply as compliance items
Prompt identification, collection of reports, and request for cooperation	Prompt identification, collection of reports, and request for cooperation concerning limited supplies of

[19] Ministerial Order on Standards for Manufacturing Control and Quality Control for Drugs and Quasi-Drugs (Ordinance of the Ministry of Health, Labour and Welfare No. 179 of 2004)

[20] See "Formulation and Publication of the Pharmaceuticals Risk Control Plan" (Pharmaceuticals and Medical Devices Agency Notification No. 0318-2, Pharmaceuticals and Medical Devices Safety Notification No. 0318-2, March 18, 2022)

[21] Ministerial Ordinance on Standards for Good Vigilance Practice (Ordinance of the Ministry of Health, Labour and Welfare No. 135 of 2004)

[22] Electronic data collected in a real clinical setting that can be used to evaluate the safety and efficacy of a patient's actual health status, medical information, and course of treatment.

concerning limited supplies of ethical drugs	ethical drugs
	Relaxation of rules on inter-dealer transfers of medical narcotics in limited circumstances
Measures to ensure stable supply of Pharmaceuticals Requiring Secured Stable Supply	Designation of Pharmaceuticals Requiring Secured Stable Supply, inclusion of provisions for requests by the Minister of Health, Labour and Welfare, and inclusion of provisions concerning mandatory reporting, etc.
Improved access to overseas alternatives in the event of supply shortages of pharmaceuticals, etc.	Introduction of priority marketing authorization review, etc.
Addition of medium-risk to categories for change in manufacturing methods, etc.	Addition of medium-risk to categories for change in manufacturing methods, etc. and addition of annual reports
	Inclusion of provisions for the possibility of individual marketing authorizations for products that do not conform to the Japanese Pharmacopoeia
	Change from a certification system to a registration system for certain manufacturing facilities
Monitoring using prescription drug supply and demand data	Inclusion of provisions regarding the investigation of electronic prescription management service data by the Minister of Health, Labour and Welfare

Major Amendments

(1) Establishment of a system to ensure stable supply by marketing authorization holders of ethical drugs

From the perspective of ensuring a stable supply system for ethical drugs, it was decided that (i) provisions requiring marketing authorization holders to take measures to ensure a stable supply in accordance with laws and regulations (ii)appointment of a Stable Supply System Manager, and (iii) compliance with necessary measures for a stable supply (e.g., preparation of standard operating procedures to ensure a stable supply system) should be included in the Pharmaceuticals Act.

(2) Prompt identification, collection of reports, and request for cooperation concerning limited supplies of ethical drugs

With regard to the stable supply of ethical drugs, it was decided that the following measures, which are currently regulated by notification or by de facto guidances, should be implemented: (i) making it mandatory for marketing authorization holders to notify supply status reports and limited supply reports to the Minister of Health, Labour and Welfare; (ii) including a provision that the Minister of Health, Labour and Welfare may request marketing authorization holders or wholesale distributors to submit reports on the status of manufacture and sales when there is a risk of supply shortage; and (iii) including a provision that the Minister of Health, Labour and Welfare may request necessary cooperation from marketing authorization holders, wholesale distributors, medical institutions, or pharmacies, etc. if there is a risk of supply shortage.

(3) Measures to ensure stable supply of Pharmaceuticals Requiring Secured Stable Supply

It was decided that the Minister of Health, Labour and Welfare may designate pharmaceuticals that are essential for medical care and widely used, and for which efforts to ensure stable supply are strongly required as "Pharmaceuticals Requiring Secured Stable Supply" (tentative name). In addition, provisions to allow for the request of necessary measures to ensure a stable supply, including the promotion of production (which is expected to be adopted for those equivalent to Pharmaceuticals Requiring Secured Stable Supply A and B as currently designated by the Stakeholders Council for Pharmaceuticals Requiring Secured Stable Supply), and the collection of reports from marketing authorization holders to ascertain the supply-demand situation (which expected to be adopted for those equivalent to Pharmaceuticals Requiring Secured Stable Supply A, B, and C as currently designated by the Stakeholders Council for Pharmaceuticals Requiring Secured Stable Supply) should be included in the Pharmaceuticals Act.

(4) Improved access to overseas alternatives in the event of supply shortages of pharmaceuticals, etc.

In order to enable the use of alternatives distributed in foreign countries in the event of a supply shortage of any approved pharmaceuticals, etc. in Japan that would have a significant impact on medical care, it was decided that there should be an exception allowing preferential marketing authorization screening of products distributed in foreign countries and allowing packaging with foreign-language labels for a certain period of time.

(5) Addition of medium-risk to categories for change in manufacturing methods, etc. and addition of annual reports

Since partial changes to authorized items currently require authorization from the Minister of Health, Labour and Welfare, except for minor changes that only require notifications, product modification and improvement may take considerable time. In view of the need to improve products without falling behind the European Union and the United States, it was decided that a system for approving partial changes in manufacturing methods and other medium-risk items that do not have a significant impact on the quality of a product within a certain period of time (estimated to be around 40 days) should be established. In addition, it was also decided that a system to report the details of minor changes in manufacturing methods, etc. that have little impact on quality to the Minister of Health, Labour and Welfare once a year should be established.

1.3 Improvement of Drug Discovery and Regulatory Environments to Eliminate Drug Lag and Drug Loss

Amendments	Outline
Promotion of development planning for the elimination of drug losses in pediatric pharmaceuticals	Inclusion of provisions under which a preparation of pediatric pharmaceutical development plan will be a duty of effort, etc.
Revision of conditional marketing authorization of pharmaceuticals, etc. for rare and serious diseases	Grant of marketing authorization at the exploratory trial stage, etc.

Clarification of the use of Real World Data for pharmaceutical applications	Revision to generalize the provisions concerning attachments to the application for marketing authorization of pharmaceuticals, etc.
Exceptional permission to provide based on the characteristics of regenerative medicine products	Permission of sales, etc. of non-compliant products in certain cases
Revision of standards for good clinical practices for pharmaceuticals	Consideration of revision of GCP Ordinance[23], etc.

Major Amendments

(1) Promotion of development planning for the elimination of drug losses in pediatric pharmaceuticals

Recognizing that pediatric pharmaceutical development is generally slow and that improvements that have already been made[24] are still insufficient, it was decided that applicants seeking marketing authorization for adult pharmaceuticals should be required to make an effort to develop a pediatric pharmaceutical development plan.

(2) Revision of conditional marketing authorization of pharmaceuticals, etc. for rare and serious diseases

The current conditional marketing authorization system[25] is intended to be applied to cases which rely on the results of exploratory trials that have confirmed a certain level of efficacy or are in the process of conducting verification tests. The number of marketing authorization under this system has been low since the system was established. Therefore, it was decided that a revision to the system should be implemented to allow for marketing authorization of products with high medical needs, such as in cases of serious illness and lack of appropriate alternative treatments if the clinical benefit of the product is reasonably foreseeable at the stage of exploratory trials. It was also decided that a provision for rescindment of marketing authorization should be included in the Pharmaceuticals Act.

(3) Clarification of the use of Real World Data for pharmaceutical applications

For the purpose of accepting Real World Data, in addition to materials acquired in clinical trial results and other materials, it was decided that the provisions regarding attachments to applications for marketing authorization of pharmaceuticals, etc. should be revised to more general wordings, such as "materials regarding the quality, efficacy and safety of pharmaceuticals, etc.".

[23] Ministerial Ordinance on Good Clinical Practice for Drugs (Ordinance of the Ministry of Health and Welfare Ordinance No. 28 of 1997)

[24] For example, the establishment of a system for designation of pharmaceuticals for specific uses, and extension of the reexamination period.

[25] A system whereby regulatory marketing authorization is granted based on the results of exploratory trials without waiting for the results of verification tests for pharmaceuticals intended for rare and serious diseases with high medical needs.

(4) Revision of standards for good clinical practices for pharmaceuticals

In order to meet the need for patient access to medically necessary pharmaceuticals prior to their marketing authorization, it was decided that amendments be made to the GCP Ordinance to simplify the current procedures for expanded clinical trials (case reporting, monitoring, adverse event reporting, handling of investigational medicinal product dossiers, etc.), and, in reference to the single patient IND in the U.S., to introduce a simplified procedure for expanded clinical trials targeting a single patient if a clinical trial notification has already been submitted for the relevant pharmaceutical .

Regarding GCP compliance inspections, it was decided that the implementation of risk-based inspections should be streamlined, the supervision of sponsors over a SMO [26] should be strengthened, and further efficiency in clinical trials, including reducing the burden on those involved in the trials, should be promoted.

1.4 Revision of Pharmacy Functions and Pharmacist Services and Promotion of Proper Use of Pharmaceuticals

Amendments	Outline
Sales of pharmaceuticals through remote management by pharmacists and others using digital technology	Enable storage and delivery of pharmaceuticals under remote control of pharmacists, etc.
Institutionalization of partial outsourcing of dispensing operations	Institutionalization of partial outsourcing of dispensing operations, etc.
Revision of pharmacy functions, etc.	Establishment of a certification system for health support pharmacies, etc.
Revision of the system for providing information on pharmacy functions	Changes to the reporting parties of the pharmacy functional information provision system, etc.
Revision of sales categories and sales methods of pharmaceuticals	General prohibition on the sale of ethical drugs without a prescription
	Addition of online medication guidance method for pharmaceuticals requiring instructions, etc.
	More stringent sales methods for pharmaceuticals that have the potential for abuse, etc.
	Clarification of sales method in guidelines while maintaining the current system for categorizing OTC pharmaceuticals
Revision of retention periods for prescriptions, etc.	Extension of the retention period for prescriptions, etc. to 5 years

[26] Abbreviation for Site Management Organization, a clinical trial site support organization.

Major Amendments

(1) Sales of pharmaceuticals through remote management by pharmacists and others using digital technology

With the widespread use of real-time communication tools using video and audio, it was decided that OTC pharmaceuticals should be allowed to be kept at stores which can be controlled by a pharmacist remotely, and be delivered to purchasers in an environment where pharmacists are available to provide consultation and service, even if the pharmacist is not physically stationed at the store.

(2) Institutionalization of partial outsourcing of dispensing operations

In order to allow pharmacy pharmacists to focus on interpersonal services, it was decided that partial outsourcing of dispensing services should be allowed with the marketing authorization of the prefectural governors where the pharmacy is located.

(3) General prohibition on the sale of ethical drugs[27] without a prescription

It was decided that ethical drugs should, in principle, be sold on a prescription basis, and that sales without a prescription in pharmacies should only be permitted in unavoidable cases that meet certain conditions. However, it was also decided that appropriate measures should be taken separately for Chinese herbal medicines and herbal medicines in view of their characteristics[28].

The Ministry of Health, Labour and Welfare has taken the position that ethical drugs should in principle only be supplied on a prescription basis, and had issued a notice[29] that efforts should be made to "recommend necessary medical consultation" and that advertising to the general public should be prohibited. However, on January 17, 2025, three pharmacies that sold ethical drugs (other than Prescription Drugs) without prescriptions filed a lawsuit against the national government claiming that the notice is unconstitutional.

(4) Addition of online medication guidance method for Pharmaceuticals Requiring Guidance

It was decided that online medication instructions should be available for Pharmaceuticals Requiring Guidance, but face-to-face guidance should still be required for products where physical confirmation of necessary information is considered necessary for their appropriate use. These types of products should be excluded from the list of products that can be sold only by providing information via online medication instructions.

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[27] Ethical drugs are drugs supplied for the purpose of use by or on the prescription or instruction of a doctor or dentist. While certain ethical drugs are designated as Prescription Drugs and cannot be sold without prescriptions, the law has been silent on whether a prescription is necessary for the sale of ethical drugs that are not designated as Prescription Drugs.

[28] Summary Report of the Study Group on the Marketing System of Pharmaceuticals" (January 12, 2024, Study Group on the Marketing System of Pharmaceuticals)
https://www.mhlw.go.jp/content/11121000/001199663.pdf

[29] "Re-acknowledgment of Sales Methods, etc. of Ethical drugs Other Than Prescription Drugs" (Pharmaceuticals and Medical Devices Agency Notification No. 0805-23, August 5, 2022)

2. NHI Price Revision for FY2025

On January 15, 2025, the General Assembly of the Central Social Insurance Medical Council (*Chuikyo*) approved the NHI price revision policy for FY2025. In the past two NHI price revisions, the NHI price for all pharmaceuticals was revised uniformly for items that exceeded 0.625x in the average deviation (deviation rate: over 4.375%). This time, the scope of revision was set for each category; the scope of revision for highly innovative new drugs and generics has been narrowed, while the scope for long-listed drugs has been widened. In addition, for the first time in an interim year revision, the deduction of the cumulative new drug creation additions will be implemented.

The scope of revision for each category is as follows:

	Products eligible for new drug creation and other additions (650 items)	New drugs other than products eligible for new drug creation and other additions (1,830 items)	Long-listed drugs (1,710 items)	Generics (8,859 items)	Other Items (4,390 items)
Scope of revision	Average deviation rate: above 1x (Deviation rate: above 5.2%)	Average deviation rate: above 0.75x (Deviation rate: above 3.9%)	Average deviation rate: above 0.5x (Deviation rate: above 2.6%)	Average deviation rate: above 1x (Deviation rate: above 5.2%)	Average deviation rate: above 1x (Deviation rate: above 5.2%)
Number of items subject to revision (percentage)	60 (9%)	1,000 (55%)	1,500 (88%)	5,860 (66%)	900 (20%)

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■ 本ニュースレターの執筆者は、以下のとおりです。

弁護士 近藤 純一（junichi.kondo_grp@amt-law.com）

弁護士 淺井 茉里菜（marina.asai@amt-law.com）

弁護士 横田 瑛弓（emi.yokota@amt-law.com）

Authors:

Junichi Kondo (junichi.kondo_grp@amt-law.com)

Marina Asai (marina.asai@amt-law.com)

Emi Yokota (emi.yokota@amt-law.com)

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