Outline of the Proposed Act Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, and Other Acts

Aim of the Proposed Amendments

The aim of these amendments is to implement the necessary measures to establish a mechanism for early approval under which—assuming that safety has been confirmed—conditional, time-limited marketing approval may be granted in emergencies once the efficacy of the pharmaceutical, medical device, or regenerative medicine product (hereinafter referred to as "pharmaceutical, etc.") has been estimated; as well as to create a mechanism for electronic prescriptions based on Online Confirmation System for Health Insurance Qualification and encourage its use.

Outline of the Proposed Amendments

1. Marketing Approval in Emergencies 【Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices】

The proposed amendments establish the following new mechanisms to enable early marketing approval in emergencies.

(1) Eligibility of pharmaceutical, etc. for which the early approval is applicable

○ Under the proposed amendments, a pharmaceutical, etc. that needs to be used urgently in order to prevent the spread of a disease or other health hazard that could seriously affect the lives and health of the people is eligible for early approval if there is no alternative means in existence.

(2) Operational standards

○ Under the proposed amendments, assuming that safety has been confirmed, approval may be granted once the efficacy of the pharmaceutical, etc. has been estimated.

(3) Conditions and term of approval

○ Under the proposed amendments, because approval is granted at the early stage at which efficacy has been estimated, the necessary conditions are attached to ensure the proper use of the pharmaceutical, etc. in question and restrictions are set in place that limit the duration of approval to a short term.

(4) Special measures to expedite review process

○ Under the proposed amendments, special measures are introduced for GMP inspections, national verifications as well as regulations on containers and packaging of the pharmaceutical, etc., in order to expedite review process for approval.

2. Creation of a mechanism for electronic prescriptions

【Medical Practitioners' Act, Dental Practitioners' Act, Act on Facilitating the Comprehensive Securement of Medical Care and Long-Term Care in Local Communities, and other Acts】

○ The proposed amendments would enable medical practitioners and others to issue electronic prescriptions; additionally, it would make things like registering and managing electronic prescriptions a part of the operations of the Health Insurance Claims Review & Reimbursement Services and the other organization, and would establish provisions on cost-sharing in connection with those management operations and on supervision by the Ministry of Health, Labour and Welfare.

Effective Date

The effective date for the amendments mentioned under 1., above, would be the date of promulgation; for the amendments mentioned in 2., above, it would be the date specified by Cabinet Order, which is to be February 1, 2023 at the latest.

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等の一部を改正する法律案の概要

改正の趣旨

緊急時において、安全性の確認を前提に、医薬品等の有効性が推定されたときに、条件や期限付の承認を与える迅速な薬事承認の仕組みを整備するとともに、オンライン資格確認を基盤とした電子処方箋の仕組みを創設し、その利活用を促すため、所要の措置を講ずる。

改正の概要

1．緊急時の薬事承認【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】

緊急時の迅速な薬事承認を可能とするため、以下の仕組みを新たに整備する。

① 適用対象となる医薬品等の条件

○ 国民の生命及び健康に重大な影響を与えるおそれがある疾病のまん延その他の健康被害の拡大を防止するために緊急に使用されることが必要な医薬品等について、他に代替手段が存在しない場合とする。

② 運用の基準

○ 安全性の確認を前提に、医薬品等の有効性が推定されたときに、薬事承認を与えることができることとする。

③ 承認の条件・期限

○ 有効性が推定された段階で承認を行うことから、承認に当たっては、当該承認の対象となる医薬品等の適正な使用の確保のために必要な条件及び短期間の期限を付すこととする。

④ 迅速化のための特例措置

○ 承認審査の迅速化のため、GMP調査、国家検定、容器包装等について特例を措置する。

2．電子処方箋の仕組みの創設【医師法、歯科医師法、地域における医療及び介護の総合的な確保の促進に関する法律等】

○ 医師等が電子処方箋を交付することができるようにするとともに、電子処方箋の記録、管理業務等を社会保険診療報酬支払基金等の業務に加え、当該管理業務等に係る費用負担や厚生労働省の監督規定を整備する。

施行期日

1については、公布の日。2については、令和５年２月１日までの間において政令で定める日。